Analyzing the Legal Impact of *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.* on Obviousness and Selection Patents One Year Later

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The Supreme Court decision in *Sanofi-Aventis v. Apotex*, 2008 SCC 61 ("*Sanofi*") came out about a year ago on November 9, 2008, so this is a good time to evaluate what its effect has been so far.

The tests for anticipation and obviousness set out in the decision are now well known and inevitably cited by lower courts dealing with anticipation, obviousness or selection patents. *Sanofi* has effectively superceded the *Beloit*[1] decision, invariably cited previously by Canadian courts in anticipation or obviousness cases.

At the hearing, the judges seemed particularly interested in whether the law of obviousness should be revisited, I thought. By contrast, they seemed in general unsympathetic to arguments that the selection patent doctrine should be changed or dispensed with because it permitted impermissible evergreening. The appellant Apotex, having only an hour, never addressed obviousness in oral submissions, although obviousness was of course dealt with in their factum.

I brought up obviousness in my ten minute oral argument[2] on behalf of an intervener Canadian Generic Pharmaceutical Association ("CGPA"). Various judges seemed interested, and Justice Rothstein seemed struck by the fact that if the lower courts were correct in saying "obvious to try" was not the law of Canada, then there was a clear

[1] *Beloit Canada Ltd. v. Valmet Oy*, [1986] F.C.J. No. 87, 8 C.P.R. (3d) 289 (F.C.A.) ("*Beloit*")
[2] All I was allowed!

discrepancy between Canada's law and that of the UK and the US, as exemplified by the *KSR*[3] decision (which the UK courts had said was similar in spirit to their own law).

In its submissions, Apotex and CGPA[4] sought to put to rest the line of cases cited by Justice Shore below as to the test for obviousness. This line of jurisprudence, originating with *Fox on Patents*, was to the effect that if the notional skilled worker must do any testing, then the invention cannot be obvious. Furthermore, Justice Shore cited the various cases that said that the "worth a try" test in the UK cases is not part of Canadian law.

CGPA also attacked the *Beloit* test as outmoded. Justice Hugessen's famous words, "It [the test for obviousness] is a very difficult test to satisfy", CGPA submitted, direct the court to adopt a subjective mindset pre-disposed toward the patentee, rather than an objective test that balances the concerns of the patentee and the public.

The Supreme Court indeed held that the lower court's application of the test for obviousness was "too restrictive and rigid," and that an "obvious to try" approach was appropriate in some cases. However, the court also provided language that went the other way, for example, that it must be more or less self-evident or that what is being tested ought to work, and that to be obvious something must be "very plain".

The court also re-visited the test for anticipation, arguably making it easier to meet.

Although *Sanofi* is applied in all the cases discussed below, it is difficult to say whether it has changed the balance in patent cases as a practical matter.

Most of the cases decided since *Sanofi* clearly would have gone the same way if the *Sanofi* decision had never come down. Possibly, one could argue one or two might have

[3] *KSR International Co. v. Teleflex Inc. et al*., (2007) 127 S.Ct. 1727 at 1739, 1742 ("*KSR*")
[4] The portion of CGPA factum in the Supreme Court dealing with obviousness is set out as Appendix "A".

come out differently without *Sanofi*, but there is no case so far as I know where the court expressly says so.

It is perhaps arguable that Madam Justice Snyder's decision invalidating the ramipril patent, which turned heavily on the obvious to try doctrine, might have gone the other way at least with respect to obviousness, without *Sanofi*. Her decision in the somewhat similar perindopril case, decided before *Sanofi*, did go the other way (the patent was not invalid as obvious). But there were other grounds of attack, in particular, lack of sound prediction, and there were some important factual distinctions as to obviousness between the cases, as Justice Snider herself pointed out in her ramipril reasons.

Court decisions are always dependant on their facts, so attempting to determine the effect of a particular decision on subsequent cases is of course speculative.

Summaries and some comments on *Sanofi*, three subsequent Federal Court of Appeal decisions, and various lower court decisions, are set out below.

The *Sanofi* decision

The appeal arose out of a proceeding under the *Patented Medicines (Notice of Compliance) Regulations* ("*PMNOC Regulations*") involving patent 1,336,777 (the "777 patent"). (Because a decision under the *PMNOC Regulations* is not determinative, there is an Apotex impeachment action now under way with respect to the same patent.[5])

The 777 patent claims a dextro-rotary isomer, also known as clopidogrel, which has beneficial properties over the known racemate and the other isomer, namely, better efficacy and lower toxicity. A racemate is a substance containing equal amounts of two optical isomers known as enantiomers i.e. a racemate is an equal mixture of two molecules which are identical except one is a mirror image of the other. The 777 patent

[5] Federal Court action no. T-644-09. Sanofi-Synthelabo sues for infringement of the 777 patent in T-933-09.

also claims the bisulfate salt of clopidogrel.

A prohibition order had been granted by Justice Shore, and then upheld in the Federal Court of Appeal.

Essentially, Apotex argued that there was double patenting over Canadian patent 1,194,875 (the "875 patent"), which claimed the racemate, disclosed the racemate could exist in the form of two enantiomers, and also claimed the enantiomers. However, the 875 patent did not teach how the isolate the enantiomers, or which was better.

Apotex also argued that the 777 patent was obvious because the separation of the two enantiomers involved non-inventive techniques, well-known in the art as of the relevant date in 1986. Although a person skilled in the art would not know ahead of time which separation technique would work, he or she would carry out the known techniques until one did work, as matter of common practice, so there was no inventive step.

Anticipation: The SCC in unanimous reasons written by Justice Rothstein held that the application judge below "overstated the stringency of the test for anticipation." (paragraph 23). Citing the decision of the UK House of Lords in *Synthon* (paragraph 24 – 25), the Court set out two requirements to the test for anticipation: (1) the prior patent must disclose subject matter which if performed earlier would infringe the patent, and (2) there must be enabling disclosure.

For the purposes of determining if there was enabling disclosure, some trial and error is permitted; the question is whether the skilled addressee would be able to work the invention (see paragraphs 26 – 30, discussion of "Disclosure" at paragraphs 31 – 32, "Enablement" at paragraphs 33 – 37, including a list of four non-exhaustive factors to be considered in determining if there has been enabling disclosure, at paragraph 37).

Applying the law to the facts, the Court held that the prior art 875 patent did not disclose the invention because a skilled person reading the 875 patent would not arrive at the

invention in the 777 patent (paragraph 39), and would not have known of the beneficial properties of clopidogrel i.e that it was less toxic (paragraph 40 - 41), although Justice Rothstein acknowledged that a person of skill would expect that one enantiomner would be superior in efficacy to the other.

Although the first step in establishing anticipation, prior disclosure of the invention, had not been established, the Court nevertheless made some observations about the facts with respect to the second requirement, enablement, for guidance in the future. Although some trial and error is permitted, the investigation done by the inventor to find clopidogrel was beyond the permitted amount; it "required extensive investigation over a period of months." (paragraph 42 – 48).

Obviousness: The application judge below, Justice Shore, had rejected the "worth a try approach" as not permitted under the test for obviousness in the *Beloit* case (paragraph 52). However, the Court said the judge applied the test for obviousness in too restrictive and rigid a manner (paragraph 61 – 63, 82), citing both US and American case law as to obviousness. In particular, the Court quoted the 2007 *KSR* decision of the US Supreme Court, which calls for flexibility in assessing obviousness, and held that if there are a finite number of identified predictable options, and person of skill has reason to pursue the options within his or her grasp, the result may be uninventive. In such a case, the fact that a combination was "obvious to try" might establish that it was obvious. (paragraph 58). Justice Rothstein noted a similar approach to the "obvious to try test" had been adopted in the UK and that "the convergence of United Kingdom and United States law on this issue suggests that the restrictiveness with which the *Beloit* test has been interpreted in Canada should be re-examined." (paragraph 60).

However the "obvious to try" approach must be approached cautiously. It is only one factor. It is not a mandatory test. Mere possibility that you will find something is not enough. It must be "more or less self-evident that what is being tested ought to work." Mere possibility that something might turn up is not enough. The answer must be "very plain." (paragraphs 64 – 66) Factors to be used in applying the "obvious to try" test

include the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research, the effort involved in pursuing them and the expectation of success (paragraphs 59, 64).

Four steps are to be used in analyzing obviousness, taken from *Windsurfer*, the standard UK case (paragraph 67). In areas such as pharmaceuticals, where advances are often won by experiment, the obvious to try approach may be appropriate (paragraph 68). Other "Obvious to Try Considerations" are set out at paragraphs 69 – 71.

The invention was not obvious. The prior art 875 patent did not teach the advantages of clopidogrel. Although there were known methods of testing the enantiomers, it was not self-evident to try them. The investigation was "prolonged and arduous". Nothing in the 875 patent provided a motivation to pursue the 777 invention. Sanofi spent months investigating the racemate up to the point of clinical trials (paragraphs 72 – 91). The invention was not "obvious to try" because it was not self-evident what the properties of the enantiomer would be, and the investigation took a long time (paragraph 92).

Double patenting: Although the Court noted that evergreening is "a significant concern" (paragraph 97), it largely upheld the selection patent doctrine. Selection patents encourage improvements in that the inventor selects "bits of the subject matter of the original genus patent because that bit does something different and better than what was claimed in the genus patent." (paragraph 100) The 875 patent claimed 250,000 possible compounds, and said they all work. It was later found that in fact they did not all did work as promised. "That information is valuable." (paragraph 104). The SCC agreed with Apotex that the emphasis must be on the claims, not the disclosure in evaluating double patenting (paragraph 108), but found that the relevant claims of the 875 genus patent and the 777 patent were not "conterminous", i.e. did not claim the same invention, and were "patentably distinct." The inventions were different (paragraph 110) because the genus patent claimed a vast range of possible compounds, whereas the 777 patent claimed only the dextro-rotatory isomer, clopidogrel, and disclosed that it had beneficial properties (paragraph 111 – 115).

How has *Sanofi* been interpreted by the lower Courts in pharma cases?

I Federal Court of Appeal

The Federal Court of Appeal has considered *Sanofi* in at least three decisions, upholding the lower court in all three.

In the perindopril case, the FCA upheld Justice Snyder's decision that the patent was valid and infringed. The FCA also decided two appeals from PMNOC cases. Prohibition was granted in one (sildenafil) but not the other (clarithromyxcin crystal form).

Although Justice Snider's decision on perindopril was decided before *Sanofi*, the FCA commented that her reasons were consistent with the principles in *Sanofi*.

The sildenafil case is of interest because the appeal turned largely on the argument, which the FCA rejected, that *Sanofi* had changed the law of obviousness such that Justice Mosley's lower court decision of granting prohibition should be overturned.

In the clarithromycin appeal, the FCA upheld Justice Hughes' decision, the first lower court decision applying *Sanofi*, which had appeared just a day or two before the lower court hearing. Justice Hughes had dismissed the application, finding the allegation of anticipation and obviousness was justified. The Federal Court affirmed on anticipation, rejected argument the patent was a selection patent, and did not go on to consider obviousness.

The three cases are summarized below.

The perindopril case: *Apotex v. ADIR, Servier,* 2008 FC 825, aff'd 2009 FCA 222

The Court of Appeal dismissed Apotex's appeal of Justice Snider's decision at a trial in which she found Canadian Patent No. 1,341,196 valid and infringed.

Claim 1 claimed a class of compounds described in the disclosure as useful in reducing the activity of enzymes responsible for hypertension or cardiac insufficiency. Claims 2, 3 and 5 were dependant, each claiming a restricted class of the compounds in claim 1. Claim 5 claimed perindopril, an ACE inhibitor, and its pharmaceutically acceptable salts.

The obviousness analysis is set out at paragraphs 67-90 of the FCA decision. The panel noted:

> The question of obviousness is largely a factual inquiry. The trial judge applied the framework articulated in *Janssen-Ortho*. Subsequently, the Supreme Court of Canada issued its decision in *Sanofi*. The *Janssen-Ortho* framework is not inconsistent with that described in *Sanofi*. Therefore, the trial judge's factual determinations are equally relevant to the *Sanofi* analysis.

Apotex argued Justice Snider erred in directing the obviousness inquiry to the claims of the 196 Patent and as a result rejected what the disclosure taught. If she had construed the entire specification she would have concluded that the invention is a class of compounds described in the General Formula I. The Court of Appeal relied in part of the *Sanofi* decision in rejecting this; the question of obviousness should be determined by reference to the claim.

> Justice Rothstein stated [in *Sanofi*], at paragraph 67, that the second step is the need to "identify the inventive concept of the claim in question or if that cannot readily be done, construe it."

The Court found that it was open to Justice Snider to conclude that it was not obvious to a skilled person to design an ACE inhibitor with a perhydroindole carboxylic acid moiety at the C-terminus or a linear alkyl group at the N-terminus. The Court noted that Justice

Snider's determinations were consistent with the framework of obviousness set out in *Sanofi*.

The Federal Court of Appeal also rejected arguments that Justice Snider erred as to first inventorship, lack of utility, sound prediction, and certain corrections to the claims made by the patentee.

The sildenafil case: *Pfizer v. Apotex*, 2007 FC 971, aff'd 2009 FCA 8

This was a case under the PMNOC Regulations concerning sildenafil, better known as VIAGRA. The best way to summarize the Apotex allegation of obviousness is perhaps to quote the UK Court of Appeal, holding the equivalent patent invalid as obvious, including its narrower claims to sildenafil: "Anybody who read Rajfer and Murray would have realized that PDE inhibitors were likely to be effective in treatment of [erectile disfunction]. There was nothing inventive in trying them out for that purpose. The work to identify those that worked was routine, and in any event, it was conceded that the screening process did not involve invention."[6]

Justice Mosley, prior to the SCC decision in *Sanofi*, concluded as follows on the obviousness issue: "Keeping in mind the strict nature of the obviousness test, … what emerges is a picture of a field of rapidly advancing science which led to the discovery but did not directly point to it….At best there was speculation, which in hindsight proved to be correct, that PDE5 inhibitors might treat impotence. … the <u>most that could be said is that at the priority date is that it would be 'worth a try'"</u> (paragraphs 123, 125, 126). [Emphasis added].

At the appeal, Apotex argued that the *Sanofi* decision "brought a fundamental change to the jurisprudential approach to obviousness in Canada by incorporating the 'worth a try' test into Canadian law." Justice Mosley should therefore be overturned.

[6] *Lilly Icos Ltd v. Pfizer*, [2002] E.W.J. No. 77, paragraph 52.

The Federal Court of Appeal agreed that the appropriate test to apply in Canada is the "obvious to try" test (paragraph 28). However, for a solution to be "obvious to try" it must be very plain or the invention must be more or less self-evident (paragraphs 27 and 29). The possibility that something might work or is worthwhile to pursue does not meet the "obvious to try" test (paragraph 45).

> The test recognized [in *Sanofi*] 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 Federal Court of Appeal found that Justice Mosley's decision may not have used the words "obvious to try", but his analysis was in line with *Sanofi*. Justice Mosley did not err when he looked for evidence that the invention was more or less self-evident and rejected any argument that the invention was obvious based on mere possibilities or speculation (paragraphs 30, 36 and 37).

The Court of Appeal also noted that the obviousness test applied by Justice Laddie in the UK decision is broader than the test adopted by the Supreme Court of Canada in *Sanofi*. The test applied by Justice Laddie will be met when the prior art indicates that something may work and it is an avenue of experimentation worth pursuing. This is not the case in Canada where the obviousness test will only be met when there is evidence that the solution was more or less self-evident.

The clarithromycin crystal case: *Abbot v. Sandoz*, 2008 FC 1359, aff'd 2009 FCA 94.

The FCA dismissed Abbott's appeal of Justice Hughes' decision dismissing a prohibition application. Sandoz alleged that claim 5 of Canadian Patent No. 2,386,527 (the "527 patent") was invalid for anticipation and obviousness.

The only claim in issue, claim 5, claimed the use of clarithromycin Form I, for the treatment of bacterial infections in a host mammal." Applying the *Sanofi* decision, and

the UK *Synthon* test, Justice Hughes held the allegation justified that claim 5 was anticipated by the US 602 patent which disclosed the recrystallization of clarithromycin to Form I. The 602 patent was also enabling because it describes clarithromycin, its use, and how to make it in a crystalline form that is Form I (although no one at the time had identified or named Form I, but this was irrelevant).

Abbott argued on appeal that that this was a selection patent case, relying on *Sanofi*. Justice Hughes erred, argued Abbott, in finding that claim 5 was anticipated because the 602 patent failed to disclose the special advantages (i.e. improved bioavailability and significant formulation advantages) of Form I over Form II. Justice Hughes should have considered these special advantages to be essential elements of claim 5.

The Federal Court of Appeal rejected this. Claim 5 properly construed includes the use of Form I in mixture with other forms of clarithromycin such as Forms 0 and II. Given that claim 5 covers the use of clarithromycin where a very small amount of the clarithromycin is Form I, the increased solubility of Form I was not an essential element.

The FCA found it unnecessary to consider obviousness and non-infringement, and dismissed the appeal

2 Federal Court decisions applying *Sanofi*

There were at least seven lower court cases where the decision considered or applied *Sanofi*, turning on such issues as anticipation, obviousness or double patenting, or a selection patent argument.

Three decisions arise from patent actions: the ramipril case mentioned above, where the patent was held invalid as obvious by Justice Snider, the amlodipine decision of Justice Hughes where a selection patent was held invalid on various grounds, and the recent

cefaclor case, where Madam Justice Gauthier held various process patents to be valid and infringed.

a. Trial decisions

The amlodipine besylate case: *Ratiopharm v. Pfizer* (T-1712-07), 2009 FC 711

Justice Hughes found that claim 11 of Canadian Patent No. 1,321,393 (the "393 Patent") was invalid on various grounds. Claim 11 claimed the besylate salt of amlodipine. Amlodipine was already known.

The prior art disclosed pharmaceutically acceptable salt forms of amlodipine, and named several, although not besylate. Besylate was known as a potentially useful salt in developing pharmaceuticals.

At paragraphs 158-173, Justice Hughes found that the selection of the besylate salt of amlodipine was obvious. The inventors tried a number of salts including the besylate salt through a well known process called a salt screen. A few of the salts screened, including the besylate, were good enough, so they stopped testing. Justice Hughes found that a person skilled in the art would have every reason to test the besylate salt.

Justice Hughes dealt with the argument that the patent was selection patent, and therefore valid at paragraphs 174-180. He said that "an attempt to create a special category for 'selection' patents is really nothing more than a way of approaching an issue of obviousness" [paragraph 175]. However, if such a category exists, Justice Hughes found that the 393 patent is not a valid selection patent. The evidence and the patent fail to support the claim that the besylate salt of amlodipine is sufficiently superior to the other salts such as the tosylate or mesylate salts so as to make it "unique" or "outstanding" or "particularly suitable".

The patent was also held invalid for lack of utility, insufficiency, and failure of the patentee to make proper disclosure to the patent office under s. 53(1) of the *Patent Act*.

The ramipril case: *Sanofi-Aventis v., Apotex, Novopharm*, 2009 FC 676

Justice Snider dismissed Sanofi's infringement actions and found that certain claims of Canadian Patent No. 1,341,206 (the "206 patent") are invalid for lack of sound prediction of utility. In the alternative, Justice Snider found that these claims are invalid for obviousness.

Claims 1, 2, 3, 6 and 12 of the 206 patent claim carboxyalkyl dipeptides compounds such as ramipril. In general, the compounds of the claims in issue are very similar in structure to enalapril except that the proline group of enalapril is replaced with a spirocyclic or bicyclic ring structure. Claim 12 claims several stereoisomers of a carboxyalkyl dipeptide compound containing a 5,5 bicyclic ring and five chiral centres. When all the chiral centres are in the S-configuration, the compound is ramipril (see paras 79-118 and 138 for claim construction). Justice Snider found that the 206 patent promised that the claimed compounds would have utility in both ACE inhibition and reduction of high blood pressure (i.e. use as antihypertensive agents) (see paragraphs 119-137 for Justice Snider's analysis on the promise of the patent).

Justice Snider dealt with lack of sound prediction at paragraphs 142-259 of her decision. The 206 Patent was invalid because there was no evidence in the 206 patent or otherwise for a person skilled in the art to soundly predict at the Canadian filing date that the claimed compounds could be used as ACE inhibitors and antihypertensive agents. Also the patent failed to disclose facts and reasoning to soundly predict the utility of the invention.

In the alternative, Justice Snider dealt with obviousness at paragraphs 260 – 320. Applying the test in *Sanofi*, she noted that

> As I see it, the term "general knowledge" is not so much the "forest of art" or list of documents, publications and patent applications. Rather, it is the knowledge that emerges from this prior art and whether such knowledge would have been generally known. When the art referred to by the parties is examined, it is clear that there are some general themes that emerge that would come to the attention of our person skilled in the art. All of the art referred to by the Defendants and their experts is in the field of ACE inhibition, unlike *Perindopril*, above, where some of the art was in relation to non-ACE research and development. The skilled person, in this case, in assessing the information described by the parties, would not be asked to extend his research beyond the ACE inhibition field.

A person skilled in the art would have been highly motivated to come up with a new ACE inhibitor and in particular motivation to develop novel analogues of enalapril. The disclosure by Merck at a conference and in subsequent publications established that enalapril was the new standard in ACE research and that an all S-configuration on the enalapril backbone is preferred. There were several publications in relation to the drug captopril that would teach a skilled person that the proline ring of enalapril could be replaced with other structures and still maintain activity.

Prior art made it obvious to try substituting a 5,5-bicyclic ring for the proline ring:

> From this point, it is more likely than not that the skilled person would be motivated to try various fused-ring structures. I acknowledge that having to try every size and shape of fused rings would be extremely difficult for the skilled person. The syntheses involved are, as I have learned in this trial, not simple. However, in my view, some of the prior art would have led the skilled person quickly to try a 5,5 bicyclic ring structure.

She concluded that it would have been more or less self evident that a 5,5-bicyclic ring substituted for the proline moiety of the enalapril molecule would have worked:

> [315] Having reviewed all of the evidence presented on the question of obviousness, I am persuaded that the 5,5 bicyclic ring substituted for the

> proline ring on the enalapril backbone would have been obvious to try. This is not a case where "the prior art would have alerted the person skilled in the art to the possibility that something might be worth trying" (*Sildenafil*, above, at para. 29). On these particular facts, I am satisfied that the invention of ramipril, as embodied in Claim 12, was "more or less self evident".
>
> [316] This is not to say that the skilled person would not also have tried synthesizing and testing a 6,5 bicyclic ring moiety or other configurations on an enalapril backbone. I do not know. But, even if that is the case, the existence of more than one possibility does not automatically exclude the possible obviousness of any given option.
>
> [317] The final question that would be asked of our notional skilled person is whether it was obvious that the 5,5 bicyclic ring on an enalapril backbone "ought to work". I think that the answer to that question is a qualified "yes". If Dr. Bartlett is correct that, on the basis of his "space" theory, one could soundly predict that a 5,5 bicyclic ring on an enalapril backbone would work, then a skilled person would expect that compound to have activity. If the theory is applicable and available to the Schering scientists, I see no reason why it was not available to the person skilled in the art.

Justice Snyder also noted "[t]he effort, nature and amount of effort required to achieve the invention would not be insignificant. However, ...there were known methods of synthesis available to the skilled person to make, separate and test the targeted compounds."

The cefaclor case: *Eli Lilly v. Apotex*, 2009 FC 991.

Several patents were at issue claiming processes used to make a key intermediate in making cefaclor, a known antibiotic. There were known ways of making cefaclor; the patents related to a less expensive process. Apotex argued it did not infringe, because the processes had been carried out outside Canada. After an extensive analysis of the Sacharrine doctrine, the court rejected this argument, and held at least one claim of all the patents to be infringed.

Apotex argued the patents were invalid on various grounds including obviousness. The issue was whether it was obvious to use various known chemical reactions on certain compounds in order to achieve certain results.

A prior art article, the Rydon taught the use of a hexane solvent to carry out the reaction, but the patents claim the use of an aromatic or halogenated hydrocarbon solvent. Justice Gauthier found the Rydon Article teaches away from the claimed solvent and therefore it is not self-evident that an aromatic or halogenated hydrocarbon solvent could be used to carry out the reaction. In addition, Justice Gauthier found that practicing the method described in Rydon with the benefit of technology disclosed in the prior art (i.e. ^{31}P NMR) would not make the invention obvious.

Arguments that the patents were invalid for lack of utility, lack of sound prediction/inoperability, deficiency of specification and ambiguity were also rejected.

b. Prohibition decisions under the *PMNOC Regulations*

Besides these three trial decisions, there are at least six decisions under the *PMNOC Regulations* that apply or turn in some way on the *Sanofi* decision.

In three of those, the escitalopram cases (all dealt with in one decision), the clarithromycin XL case and the oxycodone case, allegations of obviousness were held unjustified, and prohibition was granted.

In two other cases, raloxefene and cefepime, both decided by Justice Hughes, the court dismissed the prohibition application finding the allegation justified that the patent was invalid as obvious.

The escitalopram cases: *Lundbeck v. Genpharm, Lundbeck v. Apotex* and *Lundbeck v. Cobalt,* 2009 FC 146

Justice Harrington granted a prohibition order in each of three proceedings, heard before him separately, but one after the other, and dealt with in common reasons. Like *Sanofi*, the case was about an enantiomer.

Justice Harrington held the patent at issue was not a selection patent, however, he held, if it was a selection patent, he would have held the allegation justified that it was invalid. This implies the validity of a selection patent is governed by different, perhaps tougher, rules than other patents.

Escitalopram is the S-enantiomer of the racemate citalopram, a known compound. The three respondents alleged that Canadian Patent No. 1,339,452 (the "'452 patent") claimed a selection from a prior genus patent, but was an invalid selection patent because no unexpected or unknown benefit over the genus is disclosed in the 452 patent.

The court held the patent was not a selection patent because it did not meet the two part test for anticipation in *Sanofi*. In particular, there was no prior disclosure. If the subject matter of the prior patent were performed, the racemate would be produced, not an enantiomer. A claim for the racemate is not a claim for the enantiomer.

Justice Harrington said, however, that if he is wrong and the 452 patent is indeed a selection patent, it is invalid because there was no indication that escitalopram had any other desirable or surprising traits over the genus. Escitalopram was at most twice as potent as citalopram, which is not sufficiently unexpected to serve as the basis of a selection patent.

With respect to obviousness, Justice Harrington applied the four part test in *Sanofi*. The differences between the prior art and the inventive concept were not obvious. There was considerable time and effort spent by Lundbeck on isolating the enantiomers of citalopram [paragraphs 91-101]. Even if it were obvious to try to resolve escitalopram, it was not self –evident that what was being tried ought to work.

The 452 Patent was not anticipated because the prior art disclosing the racemate did not disclose the enantiomer.

The oxycodone case: *Purdue v. Pharmascience*, 2009 FC 726, and the clarithromycin XL case: *Abbott v. Sandoz*, 2009 FC 648

Two cases (oxycodone, and clarithromycin XL), decided by Justices Harrington and Heneghan respectively, involve patents on using known slow release excipients to produce sustained release formulations having certain pharmacokinetic profiles in bio-studies. In both, prohibition orders were granted, on the basis that it was not self-evident that was being tried ought to work, and investigation by the skilled person would have been arduous. If there is routine testing of a trial and error nature to be done, using various amounts of a sustained release agent, although a person of skill cannot predict the outcome of each particular bio-study, should the invention be obvious? Both courts said no.

The cefepime case: *Bristol-Myers v. Apotex*, 2009 FC 137

Justice Hughes dismissed the prohibition application regarding the drug cefepime and Canadian Patent No. 1,298,288 (the "288 Patent"). Justice Hughes found the allegations justified that claims 2 and 3 of the 288 Patent were invalid for obviousness and double patenting.

The 288 Patent claimed several crystalline addition salts of cefepime, purportedly more temperature stable compared to the known form of cefepime.

Two pieces of prior art, a U.S. patent and a Greek patent, disclosed the crystalline dihydrochloride salt and its temperature stability which taught everything that is essential in claims 2 and 3 except to identify that the hydration of the crystalline dihydrochloride as a monohydrate. [paragraph 157].

Applying the test in *Sanofi*, Justice Hughes held it would have been obvious that the monohydrate form of the crystalline dihydrochloride acid addition salt had temperature stability. The 288 patent only discloses one stability test. No other comparison is made to other hydrated forms of the same salt or different salts [paragraphs 159 and 163]. It would be more or less self-evident that if a test of the members of the class were done, one would be better than another.

Justice Hughes rejected with Bristol-Myers' argument that the facts were similar to the case in *Sanofi*, and in effect the patent should be saved because it was a selection patent. In *Sanofi*, he noted, the patent went into great detail on how to separate the enantiomer and provided data showing the superiority of the enantiomer [paragraph 170]. In contrast, the 288 Patent had only one piece of data reflecting a measurement and did not say that the superiority of the monohydrate is unexpected, nor was evidence put forward that this would be unexpected [paragraph 171].

Claims 2 and 3 were not invalid for anticipation in light of the 055 Patent, because the court attached little weight to Apotex's evidence of testing certain examples in the prior art.

The raloxifene "impurities" case: *Eli Lilly v. Novopharm*, 2009 FC 301[7]

Justice Hughes dismissed Eli Lilly's application to prohibit Novopharm from selling raloxifene tablets until the expiry of Canadian Patent No. 2,158,399 (the "399 patent"). The allegation was justified that the 399 patent was invalid for anticipation and obviousness.

Raloxifene was disclosed in a prior art US patent. The 399 patent purported to improve on the prior art by teaching a way to make raloxifene without undesirable impurities.

[7] See also *Eli Lilly v. Apotex*, 2009 FC 320, also decided by Justice Hughes, dismissing a prohibition case with respect to the same patent.

Justice Hughes found that the 399 patent was anticipated by the prior US patent. Certain examples in the old patent disclose a purified crystal form of raloxifene hydrochloride. Novopharm's experiments replicated the examples and produced material with a x-ray powder diffraction ("XRPD") similar to the XRPD in claim 1 of the 399 Patent.

Justice Hughes also found that the 399 Patent was obvious. He found no difference between the inventive concept and what is disclosed in the old patent and a prior art article, the Jones article. The identification of unwanted impurities, and the purification of materials were all known to a person skilled in the art.

Appendix A
Excerpt from CGPA factum in SCC in *Sanofi*

Obviousness

25. It is submitted that the decisions below expose the unduly restrictive nature of the test for obviousness as sometimes applied in Canada.

26. Both courts below cited the well-known test for obviousness in the *Beloit* case.[8] The application judge also seemed to apply a restrictive rule that if the evidence shows the invention was merely "worth a try" to the notional skilled uninventive technician, the factfinder is thereby precluded from finding the invention obvious, regardless of the nature of the claims at issue or the circumstances. The application judge particularly emphasized judicial language rejecting the "English 'worth a try' test" as inapplicable in Canada.[9]

27. Similarly, the application judge restricted his assessment of whether there had been inventive ingenuity by finding that if the evidence shows the notional skilled uninventive technician required "testing" to arrive at the invention, excluding simple verification of known information, inventive ingenuity is automatically established.[10]

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[8] *Beloit Canada Ltd. v. Valmet Oy*, [1986] F.C.J. No. 87, 8 C.P.R. (3d) 289 (F.C.A.) ("*Beloit*"), Apotex' B. of A., Vol 1, Tab 12, cited as to obviousness at FC Reasons, AR, Vol 1, Tab 2, paragraphs 75, 78, and at FCA Reasons, AR, Vol 1, Tab 4, paragraph 22.
[9] FC Reasons, AR, Vol 1, Tab 2, paragraphs 78, 79, citing *Farbwerke Hoechst AG v. Halocarbon (Ontario) Ltd.*, [1979] 2 S.C.R. 929, 27 N.R. 582, 42 C.P.R. (2d) 145, Apotex' B of A, Vol 2, Tab 27, and *A.B. Hassle v. Genpharm*, [2004] F.C.J. No. 2079, 2003 FC 1443 ("*Genpharm*"), CGPA' B of A, Tab 1, apparently referring to paragraphs 112, 113 of that decision. See also *Pfizer Canada Inc. v. Apotex Inc.*, 2007 FC 971 at paragraphs 106, 126, CGPA' B of A, Tab 15. The FCA Reasons, AR, Vol 1, Tab 4, however, applied *Janssen-Ortho Inc. v. Novopharm Limited*, 2006 FC 1234 (later aff'd 2007 FCA 217), Sanofi B of A, Vol 1, Tab 9, which does not appear to preclude testing by the notional skilled technician, nor exclude the "worth a try" approach.
[10] FC Reasons, AR, Vol 1, Tab 2, paragraph 78, citing *Bayer Aktiengesellschaft v. Apotex Inc.*, [1995] O.J. No. 141, 60 C.P.R.(3d) 58 (Ont. Gen. Div.) ("*Bayer*"), aff'd [1998] O.J. No. 3849, 113 O.A.C. 1, 82 C.P.R. (3d) 526 (C.A.), Apotex' B. of A., Vol 1, Tab 9.

28. It is submitted that in bringing this rigid approach to its assessment of the evidence relating to obviousness, the courts below erred.

29. Testing does not automatically equate with invention. There is no inflexible rule in Canada that if the notional skilled technician would have had to do testing to arrive at the invention, an obviousness challenge must fail.

> There is no inventiveness in following an obvious and well-charted route using known techniques and processes involving known compositions unless the inventor encounters difficulties that could not have been reasonably expected by a person versed in the art or overcome by the application of ordinary skill.[11]

30. The restrictive notion that experimentation always equates to invention cited in some Canadian cases appears to derive from a single passage in Dr. Harold Fox's text,

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[11] *Apotex Inc. and Novopharm Ltd. v. Wellcome Foundation Ltd.*, (1998) 79 C.P.R. (3d) 193 at paragraph 243 (F.C.T.D.), varied but not on the issue of obviousness, [2001] 1 F.C. 495 (C.A.), aff'd [2002] 4 S.C.R. 153, CGPA' B of A, Tab 3. See also *Aventis Pharma Inc. v. Apotex Inc*, 2005 FC 1504 at paragraph 96, CGPA' B of A, Tab 5. Most recently, the Federal Court of Appeal, describing "principal factors" to be applied in considering obviousness, stated: "if commonplace thought and techniques can come up with a solution, there may be a reduced possibility that the solution required inventive ingenuity." (*Janssen-Ortho v. Novopharm*, 2007 FCA 217 at paragraph 25, heading 5, Sanofi' B of A, Vol 1, Tab 9). Testing may be uninventive in the context of the pharmaceutical industry in which a substantial amount of testing is routinely undertaken by skilled formulators (*Apotex v. Hoffmann-LaRoche*, (1987) 15 C.P.R. (3d) 217, Apotex' B. of A., Vol 1, Tab 5). Experimentation to create a formulation following known methods is not inventive (*Apotex Inc. v. Syntex Pharmaceuticals International Ltd*., (1999) 1 C.P.R. (4th) 22, 166 F.T.R. 161, CGPA' B of A, Tab 4). In *Burns & Russell Canada v. Day & Campbell Ltd*., [1965] 48 C.P.R. 207 (Ex. Ct.), CGPA' B of A, Tab 6, the court stated: "The courts have supplied a standard for this hypothetical person in determining whether or not an invention exists by saying that it is or is not 'beyond the skill of the calling' or 'beyond the skill of the routineer.'" Because the skilled person would turn to alternative formulation methods in an earlier patent and determine whether each or any of those methods would solve, or at least possibly solve the problem, the patent was invalid for anticipation, *although not obviousness*, a result which appears to highlight the unduly restrictive nature of the cited *Beloit* test for obviousness (*SmithKline Beecham Pharma Inc. v. Apotex Inc.*, 2001 FCT 770 at paragraphs 40, 45 - 51, aff'd 21 C.P.R.(4th) 129, CGPA' B of A, Tab 20).

The Canadian Law and Practice Relating To Letters Patent for Inventions, 4th ed., 1969, p. 70 - 71, which the application judge emphasized by underlining:[12]

> In order that a thing shall be "obvious", it must be something that would directly occur to someone who was searching for something novel, a new manufacture, or whatever it might be, without the necessity of his having to do any experimenting or serious thought, or research, whether the research be in the laboratory or amongst literature.

31. The four cases cited as authority for this statement by Dr. Fox, however, do not support it, and authoritative cases to the contrary existed in Canada in 1969.[13] No rationale is offered by Dr. Fox as to why "experimenting, serious thought, or research" must automatically be held by the factfinder to constitute inventive ingenuity. It is submitted such a rigid test cannot be the law.

32. Similarly, the "English 'worth a try' test" is not a formulaic test in English law. Rather, the English test encourages flexibility, depending on the nature of the invention and the circumstances. The cases cited by the application judge for the alleged universal rule that "the English 'worth a try' test" is not applicable in Canada, such as *Genpharm* and *Bayer*, do not consider English case law in any depth, nor articulate why it is unsatisfactory, nor provide any statutory evidence or policy rationale as to why Canadian law should be different.

33. The expression "worth a try" first arose in English law in *Johns Manville*.[14] The facts were simple: there was a known process. The patent was for the old process using the new agent. It was held obvious as being "well worth trying out". Diplock LJ said:

> It is enough that the person versed in the art would assess the likelihood of success as sufficient to warrant actual trial.

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[12] FC Reasons, AR, Vol 1, Tab 2, paragraph 78; Fox at CGPA' B of A, Tab 24.
[13] Ron A. Bouchard, "Should Scientific Research in the Lead-Up to Invention Vitiate Obvious under the Patented Medicines (Notice of Compliance) Regulations: To Test or Not to Test?" (2007) 6 C.J.L.T. 1 at 8-10, CGPA' B of A, Tab 25.
[14] [1967] R.P.C. 479, [1967] F.S.R. 327 at 331, CGPA' B of A, Tab 11. As noted by Lord Jacob in *Angiotech Pharmaceuticals v. Conor Medsystems Inc.*, [2007] EWCA Civ 5 at paragraph 39 (16 January 2007) ("*Angiotech*"), CGPA' B of A, Tab 2.

34. Lord Justice Jacob of the U.K. Court of Appeal recently quoted Lord Diplock's reasons in *Johns Manville* to make clear there is no formulaic "worth a try" test in England. The emphasis is on flexibility. *Depending on the nature of the invention and the circumstances*, it may be appropriate for the court to consider as a factor whether the invention was worth a try. The ultimate question is an objective one: was the invention obvious?

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

In the end the question is simply "was the invention obvious?" This involves taking into account a number of factors, for instance the attributes and cgk [common general knowledge] of the skilled man, the difference between what is claimed and the prior art, whether there is a motive provided or hinted by the prior art and so on. Some factors are more important than others. Sometimes commercial success can demonstrate that an idea was a good one. In others "obvious to try" may come into the assessment. But such a formula cannot itself necessarily provide the answer. Of particular importance is of course the nature of the invention itself.[15] (Emphasis added).

35. It is instructive to consider the most frequently cited test for obviousness in the England, set out by Oliver LJ in *Windsurfing*:

There are, we think, four steps which require to be taken in answering the jury question. The first is to identify the inventive concept embodied in the patent in suit. Thereafter, the court has to assume the mantle of the normally skilled but unimaginative addressee in the art at the priority date and to impute to him what was, at that date, common general knowledge in the art in question. The third step is to identify what, if any, differences exist between the matter cited as [forming part of the state of the art] and the alleged invention. Finally, the court has to ask itself whether, viewed without any knowledge of the alleged invention, those

[15] *Angiotech*, at paragraphs 44, 45, CGPA' B of A, Tab 2.

differences constitute steps which would have been obvious to the skilled man or whether they require any degree of invention.[16]

36. *Windsurfing* has been applied in a pharmaceutical patent case in a manner which makes clear that whether the "worth a try" or "obvious to try" approach is appropriate depends on the nature of the invention and surrounding facts.

> The fourth step [in the *Windsurfing* test] is to consider, without knowledge of the invention, whether the difference between the prior art and the invention of claim 1 was obvious. In my view it was. Anybody who read Murray and Rajfer would have realised that PDE_v inhibitors were likely to be effective in the treatment of MED. There was nothing inventive in trying them out for that purpose. The work involved to identify those that worked was routine and, in any case, it was conceded that the screening process did not involve invention. …
>
> What would have been obvious will depend on all the circumstances. As I said *in Norton Healthcare Ltd v Beecham Group Plc* CA (unreported) 19th June 1997.
>
> "When deciding whether a claimed invention is obvious, it is often necessary to decide whether a particular avenue of research leading to the invention was obvious. In such circumstances the extent of the different avenues of research and the perceived chances of any one of them providing a successful result can be relevant to the decision whether the invention claimed was obvious. Whether the subject matter was obvious may depend upon whether it was obvious to try in the circumstances of that particular case and in those circumstances it will be necessary to take into account the expectation of achieving a good result. But that does not mean that in every case the decision whether a claimed invention was obvious can be determined by deciding whether there was a reasonable expectation that a person might get a good result from trying a particular avenue of research. Each case depends upon the invention and the surrounding facts. No formula should be substituted for the words of the statute. In every case the Court has to weigh up the evidence and decide whether the invention was obvious."[17]

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[16] *Windsurfing International Inc. v. Tabur Marine (Great Britain) Limited,* [1985] R.P.C. 59 at 73 ("*Windsurfing*"), CGPA' B of A, Tab 22.

[17] *Lilly ICOS Llc v Pfizer Ltd. (No. 1),* [2002] EWCA Civ 1 at paragraphs 52, 57 (23rd January, 2002), CGPA' B of A, Tab 13. Contrast the Canadian lower court decision granting prohibition on the Canadian equivalent patent: *Pfizer Canada Inc. v. Apotex Inc.*,

37. The Supreme Court of the United States has similarly had occasion recently to remind the Federal Circuit Court of Appeals not to bring an unduly "rigid approach" to the assessment of obviousness. "Rigid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it." The correct test is expansive and flexible. In particular, the lower court was in error in automatically rejecting the "obvious to try" approach.[18]

38. *KSR* was recently cited in an American pharmaceutical patent case involving the separation of stereoisomers:

> Requiring an explicit teaching to purify the 5(S) stereoisomer from a mixture in which it is the active ingredient is precisely the sort of rigid application of the TSM ["teaching, suggestion or motivation"] test that was criticized in KSR…
>
> However, if it is known that some desirable property of a mixture derives in whole or in part from a particular one of its components, or if the prior art would provide a person of ordinary skill in the art with reason to believe that this is so, the purified compound is *prima facie* obvious over the mixture even without an explicit teaching that the ingredient should be concentrated or purified.[19]

It is submitted a similar result is appropriate in the instant appeal.

39. The American *KSR* decision, incorporating the long-standing test for assessing obviousness in *Graham*,[20] is similar in approach to the *Windsurfing* test as interpreted in English jurisprudence. In both, the analysis is an objective one.[21]

2007 FC 971, rejecting the "worth a try" approach: paragraphs 123 – 126, CGPA' B of A, Tab 15.

[18] *KSR International Co. v. Teleflex Inc. et al*., (2007) 127 S.Ct. 1727 at 1739, 1742 ("*KSR*"), Apotex' B. of A., Vol 3, Tab 49, pp. 8, 10.

[19] *Aventis Pharma Deutschland GMBH v. Lupin, Ltd*., 499 F.3d 1293 at 1301 (Fed. Cir. 2007), Apotex' B. of A., Vol 1, Tab 7, p. 7.

[20] *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 at 17 (1966) (USSC) ("*Graham*"): "Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary

40. The *Beloit* decision, almost invariably cited by Canadian courts as the test for obviousness,[22] differs from the *Windsurfing* or *Graham* tests in that it offers little guidance as to the objective factors the factfinder should consider:

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

41. Far from indicating the factfinder's analysis of obviousness must be objective i.e. even-handed, *Beloit* appears to indicate the factfinder must apply a subjective analysis; he or she should be predisposed to find inventive ingenuity. There must be a complete absence ("no scintilla") of inventiveness and imagination attributed to the notional technician skilled in the art (he must be "wholly devoid of intuition"), regardless of the nature of the technology or the circumstances. No effort or ordinary innovation may be attributed to him (it must be shown he "would … have come directly and without difficulty to the solution taught by the patent"). The test is said to be, in general, "a very difficult test to satisfy."[23]

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considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.", CGPA' B of A, Tab 9

[21] *Nichia Corp v. Argos Ltd.*, [2007] EWCA Civ 741 at paragraph 23 (19 July 2007) ("*Nichia*"), CGPA' B of A, Tab 14.

[22] *Beloit* at 294, Apotex' B. of A., Vol 1, Tab 12, cited below at FC Reasons, AR, Vol 1, Tab 2, paragraph 75 and FCA Reasons, AR, Vol 1, Tab 4, paragraph 38.

[23] In fairness to Justice Hugessen and the other members of the *Beloit* panel, nothing in the reasons indicates that they intended or could have expected the decision to articulate the test for anticipation and obviousness cited in virtually all later patent cases for decades. Only one authority is cited – on a point irrelevant to obviousness or anticipation. Analysis of the case law on anticipation and obviousness may not have appeared necessary on the facts, because the Court seemed to have no difficulty finding

42. One judge, well-versed in patent law, has recently observed that the *Beliot* test is "perilously close to the test for anticipation".[24] This would indeed appear to be the case, particularly on facts such as those in the instant appeal where there is only one significant piece of prior art.

43. It may be time to reconsider whether the courts and the public are well-served by constant judicial citation of the test in *Beloit*, particularly as applied in the restrictive manner used by the courts below in this appeal. For all its eloquence and familiarity to patent lawyers, *Beloit* has perhaps outlived its usefulness as a judicial tool in assessing obviousness. Rather than setting out an objective test for assessing obviousness, *Beloit* requires that the evidence be weighed by the factfinder subjectively using a mindset in which the interests of the patentee are to be preferred over those of the public.

44. If the "results of ordinary innovation" are not entitled to exclusive patent rights in the US for fear that "otherwise patents might stifle, rather than promote, the progress of the useful arts,"[25] and the English courts have held the US approach is similar to their own,[26] Canada's law as to what constitutes a non-obvious invention is strikingly different, if the decisions below are permitted to stand.[27]

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neither was made out. Both the plaintiff and defendant had obtained, and asserted against the other, a patent on the same invention. The Panel found this, among other factors, meant the defendant could not succeed with an argument the plaintiff's patent was invalid for anticipation and obviousness.

[24] *Janssen-Ortho Inc. v. Novopharm Ltd*., 2006 FC 1234 at paragraph 112. The *Beloit* test was nevertheless cited in the affirming reasons of the Federal Court of Appeal, 2007 FCA 217 at paragraph 23, Sanofi' B of A, Vol 1, Tab 9.

[25] *KSR* at 1746, Apotex' B. of A., Vol 3 Tab 49, p. 12.

[26] *Nichia*, at paragraph 23, CGPA' B of A, Tab 14.

[27] Yet one looks in vain for any significant difference in the definition of "invention" in Canada's statute, as compared for example with the U.S. definition, *Harvard College v. Canada (Commissioner of Patents)*, [2002] 4 S.C.R. 45, 2002 SCC 76 at paragraph 3, CGPA' B of A, Tab 10.

45. It is respectfully submitted the rigid approach of the courts below is incorrect.[28] Just as the construction of the patent claims must be "reasonable and fair to both patentee and the public," [29] the proper test for obviousness must be objective and even-handed. Potentially useful tools such as the "worth a try" or "obvious to try" approach must be available to the factfinder, if warranted by the circumstances and the nature of the invention.

[28] The rigid approach which some fact-finders in Canada have applied to assessing obviousness is perhaps best illustrated by recent decisions which appear to hold that if the invention is a selection from a known genus, the analysis need go no further; a selection patent is "by definition" non-obviousness, *Pfizer*, *supra.* note 4, paragraphs 67 – 68, 78.
[29] *Whirlpool*, at paragraph 49(g), CGPA' B of A, Tab 21.