Introduction

Canada has recently adopted “obvious to try” with the decision of the Supreme Court of Canada in Apotex Inc. v. Sanofi-Synthelabo Canada Inc. (PLAVIX)[1] in late 2008. The previous, long-standing Canadian obviousness test was more narrow and thus favoured patentees. It was derived from the approach of the U.K. courts before they adopted “obvious to try” decades ago and then expanded it to mere “worth a try,” leading the U.K. to be perceived as patent-hostile.

Now that Canada has adopted the U.K. and U.S. approach, the question is whether the climate for patentees will change. But the Supreme Court of Canada was careful to say that “obvious to try” would only invalidate where the invention was “more or less self evident” and cautioned that it is not “a panacea for infringers.” Subsequently, in deciding cases under the new obviousness standard, Canadian courts have been careful to apply the Supreme Court’s formulation, and not the U.K. “worth a try” test. Thus, overall, the Canadian obviousness test has been reformulated, but not substantially changed.

The Supreme Court’s Decision in PLAVIX

The judge at first instance had upheld the patent at issue based on the prior, long-standing obviousness test:

“…The question to be asked is whether [the person of ordinary skill] 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.”[2]

The Supreme Court emphasized that obviousness is essentially a question of fact to be decided without verbal formulae[3], a “jury question.” It spoke of bringing Canadian law into harmony with U.S. and U.K. law, and particularly on the basis of the decision of the United States Supreme Court in KSR.[4] However, it ultimately adopted the four-step obviousness analysis of the English Court of Appeal in Pozzoli SPA v. BDMO SA[5]:

"(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?”[6]

It is in step (4) that “obvious to try” may arise. It depends on the field of technology. It applies where there is experimentation and empirical testing. The pharmaceutical field was specifically identified.[7]
In adopting “obvious to try” the Supreme Court added a warning that it would not be a panacea for infringers.[8] Then, very significantly, it introduced the limitation formulated by the English Court of Appeal in the Saint-Gobain case[9]:

“[66] For a finding that an invention was “obvious to try,” there must be evidence to convince a judge on a balance of probabilities that it was more or less self-evident to try to obtain the invention. Mere possibility that something might turn up is not enough.”[10]

The “obvious to try” branch of the test was in turn broken down into non-exhaustive factors to be weighted according to the evidence in each case:

1. Is it more or less self-evident that what is being tried ought to work? Are there a finite number of identified predictable solutions known to persons skilled in the art?
2. What is the extent, nature and amount of effort required to achieve the invention? Are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine?
3. Is there a motive provided in the prior art to find the solution the patent addresses?
4. The invention story, particularly fruitless alternatives pursued by the inventors.[11]

In the result the Supreme Court upheld the patent at issue applying the new obviousness test essentially based on the findings of fact of the judge at first instance.

How “Obvious to Try” Is Being Applied in Canada

The first, and most important decision on “obvious to try” after PLAVIX was that of the Federal Court of Appeal in Apotex v. Pfizer (VIAGRA)[12] in which the proper formulation of the “obvious to try” test and its application were determinative. At first instance, Pfizer’s second medical use patent for VIAGRA (sildenafil) for erectile dysfunction was held valid under the pre-PLAVIX obviousness test which excluded “obvious to try.”[13] In the U.K. however, several years earlier the Pfizer U.K. counterpart patent was found invalid as “worth a try” at trial and on appeal.[14] In its appeal in the Canadian proceeding, generic drug maker Apotex relied on the U.K. decisions as the blueprint for applying “obvious to try.”

The Court of Appeal had two main legal issues before it: firstly, does “worth a try” equate to “obvious to try,” and secondly whether an invention can be “obvious to try” even if expectations of success are that there is but a mere possibility that the invention will work.

On the first issue the Court concluded that “obvious to try” is to be applied precisely as formulated by the Supreme Court of Canada, and that it must be more or less self-evident that the invention will work, consistent with the Court’s emphasis on “very plain.” It was stressed that the mere possibility that something might turn up is not enough. Thus “worth a try” equates to something that is worthwhile trying, but not necessarily obvious.[15]

The second issue was essentially a corollary to the first. In both the Canadian and English cases it was found as a fact that expectations were that using sildenafil could work, and that it would be worthwhile trying. Sildenafil and compounds like it were one of many options. But in the U.K. this was combined with evidence of strong motive and the result was the invention was “obvious to try.” Essentially because the commercial upside of developing a successful oral erectile dysfunction medicine was so high, anything that could work would be tried and hence was “obvious to try”. But in Canada the Court of Appeal rejected this aspect of the U.K. approach.[16]
The obvious to try test has been similarly applied in other cases involving pharmaceuticals at both the appellate[17] and trial levels.[18]

“Obvious to try” is having an effect in two particular areas in the pharmaceutical industry. These are salt selection inventions and drug formulations.

In the pharmaceutical field, the active medicinal ingredient is often commercialized in a salt form which gives it superior handling, processing, and storage properties. Some medicines are chemically unstable and salt selection can be the solution. However, there are about fifty pharmaceutically acceptable salts, and generally it is a matter of prioritizing the likely successful candidates and doing routine synthesis and formulation work until one or more are successful. This brings into play the “finite number of solutions” factor. Thus, Pfizer’s AMLODIPINE salt selection patent was held invalid under the new test.[19] Of course not all salt selection cases fit this fact pattern.

Drug formulations are used to facilitate administration of active medicinal ingredients, for example, to facilitate or improve oral dosing in tablet or capsule form. Formulation inventions which are a combination of known techniques, each of which has been selected and applied after experimentation, may not survive “obvious to try.”[20] The court has to be persuaded that the invention is more than the product of routine experimentation. Again, the result will be fact-driven and depend on the nature of the invention.

Conclusion

The obviousness test has been reformulated by the Supreme Court of Canada in PLAVIX, but not substantially changed. “Obvious to try” is only satisfied if it is “more or less self-evident” that the invention will work. In applying the new obviousness test, the Federal Court of Appeal has distinguished it from mere “worth a try” and said that strong motivation will not render something obvious to try where expectations of success are merely that it might work.

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[3] PLAVIX, supra, note 1, para. 59
[4] PLAVIX, supra, note 1, para. 60
[6] PLAVIX, supra, note 1, para. 67
[7] PLAVIX, supra, note 1, para. 67
[8] PLAVIX, supra, note 1, para. 64
[10] PLAVIX, supra, note 1, para. 66
[11] PLAVIX, supra, note 1, para. 69
[16] Apotex, supra, note 12, paras. 43-45
[18] Sanofi-Synthelabo v. Apotex (Ramipril), 2009 FC 676, and e.g. Eli Lilly v. Apotex, 2009 FC 991, appeal pending as of March, 2010