

OBVIOUSNESS: ARE WE MOVING TOWARD THE EYE OF THE BEHOLDER?*

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ABSTRACT

This paper examines the changes to the test for obviousness in recent times, especially in the light of the Supreme Court of Canada's decision in *Sanofi*. A determination of obviousness, although stated to be an objective test conducted through the lens of the person of ordinary skill, is subjectively applied. Regardless of the framework used and no matter the semantics of the test employed, a fundamental question remains: when is an invention obvious? How does one determine where the shadows of obviousness end and the brilliance of invention begins? The tests for obviousness are easy to articulate, but they can be difficult to apply. By considering some recent applications of the test, this paper aims to shed some light on how obviousness is currently adjudged in Canada and whether we have moved closer to an "eye of the beholder" test.

RÉSUMÉ

Cet article vise à étudier les modifications apportées au critère d'évidence au cours des dernières années, plus particulièrement à la lumière de l'arrêt de la Cour suprême du Canada dans l'affaire *Sanofi*. Bien que défini comme un examen objectif mené en utilisant la perception d'une personne dotée de compétences usuelles, ce critère est appliqué de manière subjective. Peu importe la démarche et la sémantique employées, une question demeure fondamentale : À quel moment une invention est-elle évidente? Comment une personne fait-elle pour déterminer où prennent fin les zones d'ombre de l'évidence et où commencent les zones de lumière de l'invention? Les critères de l'évidence sont faciles à exprimer avec cohérence, mais ils peuvent être difficiles à appliquer. En considérant certaines demandes récentes d'application de ce critère, nous espérons que cet article pourra éclairer le lecteur sur la façon dont on rend actuellement une décision en ce qui concerne l'évidence au Canada et indiquer si nous sommes rapprochés d'un critère qu'on pourrait définir comme « les yeux de celui qui regarde ».

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Nobody ... has told me, and I do not suppose anybody ever will ... what is the precise characteristic or quality the presence of which distinguishes invention from a workshop improvement. Day is day, and night is night, but who shall tell where day ends or night begins?¹

1.0 INTRODUCTION

How does one determine where the shadows of obviousness end and the brilliance of invention begins? Until recently, and for the last two decades, practitioners and the courts tried to answer this question by applying a legal test that can be recited by rote—that is, whether the ordinary skilled person, armed with the literature and common general knowledge generally available on the date of invention, would have come *directly and without difficulty* to the solution taught by the invention. This test is easy to articulate, but can be difficult to apply, at least in a vacuum. In recent times, the Federal Court and Federal Court of Appeal, while adhering to the articulation of the test, and recognizing the need for context, enhanced the framework within which the test should be applied. The courts described a *principled and objective* framework within which key factors should be identified and subsequently weighted in advance of applying the test. More recently still, in late 2008, the Supreme Court of Canada, in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*,² adopted—or rather imported—a different articulation of the framework and reworked the operative question.

Regardless of the framework used and no matter the semantics of the test employed, a fundamental question remains. When is an invention obvious? This question must be answered by an individual judge. True, the law supplies a framework and provides an objective standard to be applied, but ultimately the application of the test comes down to the views of a particular judge hearing a particular case.

Recently, this writer conducted an informal straw poll among a number of colleagues by asking the simple question, “What does obviousness mean to you?” One remark was memorable: “Obviousness is like obscenity; you know it when you see it.” The honesty of the answer underscores the point. One person’s art is another person’s filth. Is obscenity the true analogue of obviousness? If so, results in one case will not serve as a predictor of future cases, and we will have moved to a world where the validity of the essential feature of a patent—the inventive step—is subject to the eye of the beholder.

This paper tracks the changes to the test for obviousness in recent times, in particular, in the light of the Supreme Court's decision in *Sanofi*. By considering some recent applications of the test, I hope to shed some light on how obviousness is currently adjudged in Canada and whether we have moved closer to an eye-of-the-beholder test.

This paper is not the C.I.P.R.'s first foray into the *Sanofi* decision. In June 2009, the journal published a paper by Don Cameron and Yuri Chumak, "Apotex Inc. v. Sanofi-Synthelabo Canada Inc.: A Landmark Patent Case Decided by the Supreme Court of Canada."³ That work, which readers of this paper are encouraged to review, covered the subject matter dealt with by the Supreme Court and was based on a submission made in 2008. The present paper, prepared as a talk on the subject of obviousness, provides a narrower focus, and, I hope, a fresh perspective on the issue of obviousness itself in the light of some of the developments that had arisen up to the time of my talk in September 2009.

2.0 THE HISTORICAL VIEW OF OBVIOUSNESS

Each of us at one point in law school or in the formative years of our practices has heard the truism that it is enough to sustain an invention to show a *scintilla* of inventiveness. How does one know if one has a spark or trace of inventiveness? At the start of the last century, the answer to that question was derived from analyzing the result of the inventive effort:

After all, what is invention? It is finding out something which has not been found out by other people.⁴

While this articulation sounds like a novelty approach, the focus of inquiry was on the result of the effort and not the inventive process. Indeed, it did not matter whether other people could have replicated the inventive process and arrived at the invention:

There are many instances in various branches of science of independent investigators making the same discovery. That does not prevent the one who first applies and gets a patent from having a good patent And if this is the case when a person can show that he actually made the discovery, surely that is a much stronger case [when] the objector does not say that he did discover, but only that if he had experimented he would have discovered.⁵

In the mid-1980s, the obviousness test was eloquently formulated in the now classic judgment of Justice Hugessen:

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.⁶

What did we take from this test?

1. We do not focus on the inventive effort of the inventor.
2. We answer the question from the perspective of the person of ordinary skill.
3. We frame and answer the legal test, and examine whether the result of the inventive effort—the solution—was obvious.
4. We look for guidance on how to apply the test.

Dealing with this last point, and winking at the writer's cheekiness (although in fairness there has probably not been a case in which this passage of *Beloit* has not been read out with emphasis to the court on behalf of a patentee in a patent case), the fundamental failing of the law of obviousness was that, while it had yielded a legal test that was capable of being crisply articulated, there was very little guidance on how to apply it.

Therefore, from time to time, the application of the test tended to result in an examination of the inventive process, rather than strictly the result of the effort. Concepts such as "worth a try," "routine experimentation," and "mere verification" entered the analysis and, in some cases, became the central focus of the inquiry.

3.0 ENTER THE PRINCIPLED AND OBJECTIVE APPROACH

In 2006, Justice Hughes criticized the use of buzz words and loaded phrases.⁷ Rather, while still working with and applying the classic *Beloit* test, Justice Hughes introduced an analytical structure to put the obviousness question into a contextual framework. The case before the court was one involving the inventiveness of the resolution of two enantiomers from a previously known racemate. The arguments on either side of the issue, firmly based in jurisprudence, show the binary outcomes that could be arrived at with an application of the same test:

1. Pro-patentee: The resolution of the racemate had yielded new information; in advance of resolving the racemate, a skilled person could not have predicted and could not have expected the biological properties of the resolved enantiomer. The skilled person would not have been led directly and without difficulty to the invention.
2. Pro-obviousness: The skilled person would have resolved the racemate as a matter of routine testing; she would have been motivated to do so, having identified resolution as something worth trying to improve biological activity. The skilled person would have been led directly and without difficulty to the invention.

As arguments, both sound equally plausible. Which was correct? Ultimately, the former was held to be correct, but Justice Hughes wrote that the *Beloit* test cannot be applied formulaically. Obviousness is not the application of trite semantic tests. Rather, he held that obviousness was to be determined on a “principled and objective basis,” by deriving the context in which the question was to be determined. Under this *principled and objective* approach, the court was required to take into consideration a number of factors. Although Justice Hughes specifically set out certain factors (which will be discussed below), the list is non-exhaustive:

These factors may vary in number and importance dependant upon the circumstances of the case. The Court is not a scientific body, thus it must take the facts of the case, the opinions of the experts and the circumstances as presented into consideration and come up with a weighed decision.⁸

This exercise appears to be one in which the court considers the evidence, articulates the factors to be considered, assesses the weight to be afforded to each factor, and then, with the appropriate factual backdrop in mind, answers the question. Obviousness is the ultimate conclusion drawn by the court after creating the framework and performing this principled and objective factual inquiry.

In the case before Justice Hughes, the factors that the court considered included the following, set out below with the court’s commentary:⁹

1. What is the invention *as claimed*? The claim or claims at issue, as construed by the Court, is what [is] at issue. The “invention” as generally expressed in the patent or by the inventors is *not* the issue, it is the claim as properly construed.
2. Who is the *person skilled in the art* to whom the patent is addressed? To that extent the uninventive and unimaginative person postulated in the *Beloit* quotation has been supplanted by the Supreme Court of Canada in *Whirlpool* The Court said that while such a person is deemed to be uninventive as part of his future personality he or she is thought to be reasonably diligent in keeping up with advances in the field to which the patent relates. The common knowledge of skilled workers undergoes continuous evolution and growth.
3. What *body of knowledge and information* would the ordinary person skilled in the art be expected to have, or to be reasonably able to obtain, as of the date of the alleged invention? Not all knowledge is found in print form, much is simply commonly known and passed from person to person. Just as one might learn to cook at mother’s elbow, it is not all in the recipe book. Similarly, not all knowledge that has been written down, perhaps fleetingly, becomes part of the knowledge that an ordinary person skilled in the art is expected to know or find.
4. What is the *climate in the relevant field* at the time the alleged invention was made? The general state of the art includes not only knowledge and information but also attitudes, trends, prejudices and expectations.
5. What *motivation* existed at the time the alleged invention was made to solve a recognized problem? There may have been a general motivation such that

everybody in the particular area was looking for a solution. The more unique and personal the motivation was, apart from any general motivation, the more one might be expected to be inventive. If motivation came from an outside source, and common place thought and techniques can come up with a solution, the less one is expected to have exercised inventive ingenuity. ...

6. What *effort and time* [were] involved? Were the efforts randomized or focused? In this regard phrases such as “worth a try” and “directly and without difficulty” and “routine testing” have been used by the courts. It is not useful to use such phrases as they tend to work their way into expressions of law or statements of expert witnesses. Sachs L.J. deprecated the coining of such phrases in *General Tire & Rubber Company v. Firestone Tyre & Rubber Company Limited* The length of time and expense involved in the efforts are not, in themselves, useful considerations as an invention may be the result of a lucky hit, or be simply the uninventive application of routine, of time consuming and expensive techniques.

The court also considered some secondary factors, although these were relegated to marginal importance, if any at all.

7. *Commercial success*. Was the subject of the invention quickly and anxiously received by relevant consumers? This may reflect a fact that many persons were motivated to fill the commercial market. This may also reflect things other than inventive ingenuity such as marketing skills, market power and features other than the invention.
8. *Subsequently recognized advantages*. The inventors may have perceived only certain advantages, yet later those inventors or others may determine that other, previously unrecognized advantages lay in the alleged invention. This factor is of limited usefulness in considering inventive ingenuity as of the date of the invention. The recognition of later advantages, if unexpected, may themselves be the subject of a patent. To the extent that the United States Courts in cases such as *Re Zenitz* ... have placed weight upon subsequently discovered advantages that is not the law here. Little, if any, weight should be put on this factor.
9. *Meritorious awards*, if in fact directed to the alleged invention may be recognition that the appropriate community of persons skilled in the art believed that activity to be something of merit.

Justice Hughes also underscored one factor that was to be avoided at all costs.

10. *Hindsight*. It is far too easy to see how the alleged invention could have been arrived at, even easily, once it has been done. As some cases say, simplicity does not negate invention. However, if the number of decisions to be made in arriving at the solution were few, and commonplace, hindsight may merely confirm that no inventive ingenuity was required so as to arrive at the solution. If the points for decision were many and choices abundant, there may be inventiveness in making the proper decisions and choices.

What did the *principled and objective* approach bring to the obviousness analysis? For one, it invited the court to look at the inventor's time, effort, and actual work product. This was a marked departure from *Beloit* and the historical view. With this new approach, it was no longer just the result of the inventive effort, but also the process that mattered (although the cautionary words used by the court permit an argument that this factor should be given lesser weight). Moreover, the court provided a helpful framework within which the ultimate question could be answered: *Think of these things, and others if you think they are important, and once you've done so, ask the question: is the invention obvious?*

That the approach was helpful is evidenced by its affirmation: an appeal from Justice Hughes's decision was dismissed by the Federal Court of Appeal in 2007, which approved Justice Hughes's principled and objective approach.

4.0 SANOFI: A NEW APPROACH, A NEW TEST

In 2008, the Supreme Court of Canada released its decision in *Sanofi*.¹⁰ In this case, the court dealt squarely with the criticism that the application of the *Beloit* test was an injustice to those challenging patents. Curiously, although the Supreme Court canvassed the law in both the United States and the United Kingdom, no mention was made of the recent jurisprudence of the Federal Court or the Federal Court of Appeal, in which the principled and objective approach was described. In any event, to some extent, the Supreme Court did what Justice Hughes and the Federal Court of Appeal had done: it laid down an analytical, contextual framework. However, the court went one step further and reworked the legal test.

In *Sanofi*, the Supreme Court of Canada adapted a four-step approach:¹¹

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?

When it came to the loaded word "obvious," Justice Rothstein was straightforward. The court held that the meaning of "obvious" was "very plain" or "more or less self-evident." Thus, we moved from "directly and without difficulty" to "more or less self-evident." This is more or less self-evident from the *Sanofi* decision and a Federal Court of Appeal decision¹² on point.

However, immediately following *Sanofi*, it was not abundantly clear how the more or less self-evident test was to be applied. This requires a bit of explanation. One of the upshots of *Sanofi* is that a more relaxed “obvious to try” standard may be appropriate to consider in certain circumstances:

I am of the opinion that the “obvious to try” test will work only where it is very plain or, to use the words of Jacob L.J., *more or less self-evident that what is being tested ought to work*.

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. (Emphasis added.)¹³

Clever counsel examining the highlighted passages above seized on a potential ambiguity. This ambiguity became particularly important in cases where the invention was realized through experimentation. To show something to be obvious, did you have to show that a particular compound ought to work, even though the testing had not been completed? Or was it enough to show that the specific compound would have been selected, among a number of others in a testing program, to try—that is, it was more or less self-evident to try this, that, and the other thing to obtain the solution?

This question was answered relatively quickly by the Federal Court of Appeal. While the language used by Justice Rothstein did, with respect, leave some wiggle room to argue that the test is “more or less self-evident to try,” the Federal Court of Appeal in *Apotex Inc. v. Pfizer Canada Inc.* shut this argument down:

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.¹⁴ (Emphasis added.)

Thus, for an invention to be obvious, even on the obvious-to-try standard, it must be shown that it is more or less self-evident that what is being tested—that is, the *invention* and not merely some universe of choices—ought to work. Simply put, a challenger to a patent must show that it was more or less self-evident to try with more than a mere possibility of success.¹⁵

When it comes to the obvious-to-try analysis, Justice Rothstein proposed a non-exhaustive list of factors that may apply:

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 that the patent addresses?
4. What was the actual course of conduct that culminated in the making of the invention, including whether time, money, and effort were expended?¹⁶

It is not wholly clear, however, when the obvious-to-try analysis ought to be engaged. Under the heading “When Is the ‘Obvious To Try’ Test Appropriate?” the court simply stated:

In areas of endeavour where advances are often won by experimentation, an “obvious to try” test might be appropriate. In such areas, there may be numerous interrelated variables with which to experiment. For example, some inventions in the pharmaceutical industry might warrant an “obvious to try” test since there may be many chemically similar structures that can elicit different biological responses and offer the potential for significant therapeutic advances.¹⁷

All we really know is that if an obvious-to-try test is warranted, the above-noted factors should be taken into consideration.

4.1 Conclusions from Sanofi

What do we glean from *Sanofi*? First, “worth a try” is not the law. That being said, “obvious to try” is also not the law. Indeed, one might say that “obvious to try” will be engaged in every case, in the sense that whether the application of the obvious-to-try test is warranted, it appears to be a specific factual question to which the court must turn its mind. Evidence must be led to assist the court in making this determination. Thus, and second, the invention story must be led so that the court can assess and weigh all appropriate factors. (To this extent, *Sanofi* is consistent with what the Federal Court and Federal Court of Appeal were trying to achieve in the “principled and objective” framework.) Third, the semantics of the legal test have changed from “directly and without difficulty” to “more or less self-evident to try with more than a mere possibility of success.”

The stricture of the obviousness test does not seem to have changed much. The court was well aware of the jurisprudence coming out of the United States and the United Kingdom where “worth a try” and “reasonable expectation of success” have been used to invalidate corresponding U.S. or U.K. patents. However, the court did not opt for those differing (lower, less patent-friendly) standards. Rather, our courts seem to encourage judges to set up the factors to consider, weigh them, and then ask whether the solution is “more or less self-evident” in the light of that particular constellation of facts. This is where the real change will be seen because now the same test can be used to arrive at different results.

5.0 POST-SANOFI TREATMENT

Following *Sanofi*, a number of cases have considered obviousness.¹⁸

In the VIAGRA® cases,¹⁹ a claim to the use of sildenafil for the treatment of erectile dysfunction was not obvious because the state of the art did not go beyond raising mere possibilities that something could be tried. A choice to be tried has to be more than just a possibility; it has to be more or less self-evident.

In *Abbott Laboratories v. Canada (Minister of Health)*,²⁰ Justice Hughes was confronted with a claim to a particular crystalline, or polymorphic, form of an antibiotic. The patentee had argued that it was not known that the particular medicinal ingredient could exist in several crystalline forms—that is, if a person skilled in the art produced or came across a previously unknown crystalline form, that person would not know whether that new form could be used to treat infection and, in particular, whether it would be sufficiently soluble. One of the experts in the case had said that an insoluble material would pass through the body when ingested “like a child swallowing a penny.” Justice Hughes rejected the inventiveness of the invention:

To say that if something is insoluble, then it will not work is simply stating the obvious. But that is not the question when considering obviousness. The question for obviousness purposes is that as stated by the Supreme Court of Canada in *Sanofi* at paragraph 66: [W]as it more or less self-evident to a person skilled in the art to try the solubility of the crystal form to see if it would work? ...

Solubility would be in the mind of any person skilled in the art. There is no evidence to suggest that testing for solubility would be anything other than routine.

... [I]t is self-evident that a person skilled in the art would test the solubility of any newly identified crystal to determine if it was soluble at a rate sufficient to give therapeutic utility.²¹

In *UView Ultraviolet Systems Inc. v. Brasscorp Ltd.*,²² Justice O’Keefe considered a mechanical device relating to mechanical injection devices used in air conditioning systems. After reviewing *Sanofi*, Justice O’Keefe succinctly held that the differences between the state of the art and the inventive concepts were inventive. The court also held that the obvious-to-try test would not be appropriate on the facts before it. Presumably, this was because the invention related to a mechanical device and did not emanate from the pharmaceutical industry, where advances are often won by experimentation.

In *Bristol-Myers Squibb Canada Co. v. Apotex Inc.*,²³ Justice Hughes considered the inventiveness of a claim to a monohydrate form of a medicinal ingredient. One of the key factual questions was whether the identification of the monohydrate form of a particular salt as having “temperature stability” was obvious in the light of a prior art document that stated that all salts have excellent stability. On the facts, the court found that only one data point was given to support the unexpected advantages of the invention. The test that generated the datum was not inventive:

It is unexpected that given a class of materials all having excellent stability, that one member of the class, when tested once, would exhibit superiority over another? All members of a professional basketball team are accomplished players, it is not unexpected that on a particular day one player will perform better than one of the other players. That does not mean that such a player is surprisingly or unexpectedly better than all or most of the rest of the team.

... This does not indicate any unexpected result: it is more-or-less evident that within a group having "excellent" properties one member, tested once, would be better than another.²⁴

Accordingly, the court held that the essential element of the invention, the temperature stabilizing the monohydrate was more or less self-evident.

In *Lundbeck Canada Inc. v. Canada (Minister of Health)*,²⁵ Justice Harrington had to consider another case involving the resolution of the racemate. He considered and applied the *Sanofi* factors. The court reviewed the invention story and the effort required by Lundbeck's inventors to resolve the racemate into the two constituent enantiomers. This evidence had an obvious effect:

To take the example set out by Mr. Justice Rothstein in paragraph 71 of [*Sanofi*], the inventors and their team did not reach "... the invention quickly, easily, directly and relatively inexpensively, in light of the prior art and common general knowledge, [which] may be evidence supporting a finding of obviousness" ...

... [I]t was certainly not self-evident that what was being tried ought to work

All the chemists called by the respondents are naturally and properly imbued with a sense of professional pride. Had they been asked prior to June 1988 to resolve [the racemate] they believed they could have done so without difficulty, or at least properly [instruct] lab technicians how to do so. The fact of the matter is that not one of them had ever attempted to resolve [racemates], and it is now a fairly straightforward task.

These experts have not sufficiently shed their 20 years of after-acquired knowledge and returned to the days of their relative youth. Although the poem describes a judge, judges and chemists have sufficient common bonds to bring into play what Whittier said in *Maud Muller*:

God pity them both! And pity us all, Who vainly the dreams of youth recall;

For of all sad word of tongue or pen, The saddest are these: "it might have been!"²⁶

Given the fact that it was not possible in 1988 to resolve the racemate without after-acquired knowledge, Justice Harrington concluded that the resolution had to be inventive.

In *Abbott Laboratories v. Canada (Minister of Health)*,²⁷ Justice Heneghan considered patents relating to extended-release formulations of an antibiotic. The court identified five specific differences between the state of the art and the inventive concept. In concluding that the patents were not obvious, the court identified those

elements that would have been self-evident. Of particular note is the fact that, as historic as the case was, the applicants did not file any evidence on the course of conduct followed by the inventors in arriving at the inventions. However, Justice Heneghan noted that there was evidence of a prior user who had failed to achieve the invention in question. This was a factor that served as evidence of invention.

In *Sanofi-Aventis Canada Inc. v. Apotex Inc.*,²⁸ Justice Snider reviewed the validity of a claim in which the inventive concept was the combination of the tail, or backbone, of a prior-art molecule with a particular novel head group. Following the teachings of the Supreme Court of Canada's decision in *Sanofi*,²⁹ Justice Snider, in this case involving *Sanofi-Aventis*, engaged in a detailed factual analysis and concluded that the particular head structure would have been obvious to try on the prior art tail. She held that the case before her was not one in which the prior art merely alerted the person skilled in the art to the possibility that something might be worth trying. On the particular facts of the case before her, Justice Snider held that the invention was "more or less self-evident."

So concluding, Justice Snider explained why she had reached what might be considered by some to be an opposite conclusion from a previous case:

I am well aware that, in *Perindopril*, ... I came to an opposite conclusion on the question of obviousness. There are a number of reasons why I have reached a different outcome in these proceedings. In very general terms, a reader of the two decisions would note two important distinctions. The first is that the patents and their claims are different. Secondly, in each case, I was presented with a unique and fundamentally different record.³⁰

The *Perindopril* decision was a prior decision of Justice Snider.³¹ In that case, another pharmaceutical manufacturer obtained a patent for a molecule with a side chain, or backbone, as appeared in the prior art, but with a different head group. Justice Snider was not persuaded that the addition of that particular head to the side chain was obvious. On June 30, 2009, one day after the release of the *Ramipril* decision, the Federal Court of Appeal confirmed that Justice Snider's determinations in *Perindopril* were consistent with the Supreme Court of Canada's *Sanofi* framework.

In *Ratiopharm Inc. v. Pfizer Limited*,³² Justice Hughes reviewed an invention of a particular salt of a medicinal ingredient. This was a decision in an action after a trial of all issues. Justice Hughes had already considered this particular patent in a prior *Patented Medicines (Notice of Compliance)* proceeding, in which he stated, *in obiter*, that he would have found the patent to be invalid on the basis of obviousness.³³ Following a full trial, Justice Hughes held that the invention story was one of routine testing as opposed to invention:

In the present case, unlike *Sanofi*, we are presented with a situation where the inventors were given a task, to look at amlodipine maleate and see if they could make it work sufficiently so as to pass it on for final formulation for regulatory approval. They quickly determined that there were two problems, stability and stickiness, only the first of which is mentioned in the patent. They tried adjusting formulations, a routine

task. In fact, a suitable formulation for maleate was eventually found but not mentioned in the patent except as a besylate formulation. They also tried other salts through a well known process, salt screening. They tried a number of salts, including sulphonates, of which besylate is one. While besylate would not be everyone's first choice, it was not an unreasonable choice

All of this is routine for a person skilled in the art at the time. In the first set of salts screened the inventors found a few salts, particularly the sulphonic acid salts, including besylate, good enough, so they stopped there. [Why] bother testing more?³⁴

Concluding, Justice Hughes came to the same factual conclusions that the U.S. Court of Appeals for the Federal Circuit did in the case on the corresponding patent in the United States.³⁵ What is perhaps interesting about this case is the fact that the patent in issue had twice gone to the Federal Court of Appeal and been sustained.³⁶ In one of these cases, the Federal Court of Appeal held in the context of *Patented Medicines (Notice of Compliance)* proceedings at court that the invention of amlodipine besylate was the result of empirical research and not mere verification or routine work.

6.0 CONCLUSION

With our review of *Sanofi* concluded, we return to where this paper started—namely, whether there has been a sea change in the law of obviousness. Two comments are, perhaps, noteworthy.

First, whether by chance or circumstance, the same type of invention that was held to be valid in *Perindopril* was held to be invalid in *Ramipril*. The court explained that this difference resulted from different patents, different claims in issue, and a different factual record. Be that as it may, the difference underscores the fact that obviousness is a factual inquiry that will always expose the risk that different results will flow from different cases. This is a departure from predictability. For this reason, I suggest that we have moved a bit further away from a bright-line test to a situation in which the inventive step depends on the subjective eye of the beholder.

Second, following *Sanofi*, the court has to consider the invention story and (possibly) the obvious-to-try test. The amlodipine decision is an example of a patent that, while found to be valid under the *Beloit* decision (and even valid post-*Sanofi*), was invalidated under an obvious-to-try analysis.

Who can tell where night ends and day begins? It is submitted that you will not be able to tell in advance. Rather, the answer will be given, seemingly as a factual matter, by the eye of the beholder in each specific case—likely after trial.

ENDNOTES

¹ Tomlin J., in *Samuel Parkes & Co. v. Cocker Bros.*, as cited in *Diversified Products Corp. v. Tye-Sil Corp.* (1991), 35 C.P.R. (3d) 350 (F.C.A.).

² *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265 (*Sanofi*).

- ³ Don Cameron and Yuri Chumak, “Apotex Inc. v. Sanofi-Synthelabo Canada Inc.: A Landmark Patent Case Decided by the Supreme Court of Canada” (2008), 25 *C.I.P.R.* 65.
- ⁴ *Pope Alliance Corp. v. Spanish River Pulp & Paper Mills, Ltd.*, [1929] 1 D.L.R. 209, at 216 (P.C.).
- ⁵ *Ibid.*, at 217.
- ⁶ *Beloit Canada Ltd. v. Valmet Oy* (1986), 8 C.P.R. (3d) 289, at 294 (F.C.A.).
- ⁷ *Janssen-Ortho Inc. v. Novopharm Ltd.*, 2006 FC 1234.
- ⁸ *Ibid.*, at para. 113.
- ⁹ *Ibid.* [Emphasis added.]
- ¹⁰ *Sanofi*, *supra* note 2.
- ¹¹ *Ibid.*, at para. 67.
- ¹² *Apotex Inc. v. Pfizer Canada Inc.*, 2009 FCA 8.
- ¹³ *Sanofi*, *supra* note 2, at paras. 65-66.
- ¹⁴ *Apotex v. Pfizer*, *supra* note 12, at para. 29.
- ¹⁵ *Pfizer Canada Inc. v. Novopharm Limited*, 2009 F.C. 638, at para. 52.
- ¹⁶ *Sanofi*, *supra* note 2, at paras. 69-71.
- ¹⁷ *Ibid.*, at para. 68.
- ¹⁸ Some of these cases are those in which I, or others in my office, have been engaged; some are still before the courts. I have therefore refrained from commenting on the decisions beyond reporting on the outcome of the cases.
- ¹⁹ *Apotex v. Pfizer*, *supra* note 12; *Pfizer v. Novopharm*, *supra* note 15.
- ²⁰ *Abbott Laboratories v. Canada (Minister of Health)*, 2008 FC 1359.
- ²¹ *Ibid.*, at paras. 96-99.
- ²² *UView Ultraviolet Systems Inc. v. Brasscorp Ltd.*, 2009 FC 58.
- ²³ *Bristol-Myers Squibb v. Apotex*, 2009 FC 137.
- ²⁴ *Ibid.*, at paras. 160 and 166.
- ²⁵ *Lundbeck Canada Inc. v. Canada (Minister of Health)*, 2009 FC 146.
- ²⁶ *Ibid.*, at paras. 102-107.
- ²⁷ *Abbott Laboratories v. Canada (Minister of Health)*, 2009 FC 648.
- ²⁸ *Sanofi-Aventis v. Apotex Inc.*, 2009 FC 676 (*Ramipril*).
- ²⁹ See *supra* note 2 and text accompanying notes 10 and 11.
- ³⁰ *Ramipril*, *supra* note 28, at para. 320.
- ³¹ *Laboratoire Servier v. Apotex Inc.*, 2008 FC 825.
- ³² *Ratiopharm Inc. v. Pfizer Ltd.*, 2009 FC 711; an appeal of this decision, *Perindopril*, scheduled to be heard in June 2010, has not been released as of this date.
- ³³ *Pfizer Canada Inc. v. Pharmascience Inc.*, 2008 FC 500.
- ³⁴ *Ibid.*, at paras. 167-169.
- ³⁵ See *Pfizer Inc. v. Apotex Inc.*, 480 F.3d (2006).
- ³⁶ *Pfizer Canada Inc. v. Ratiopharm Inc.*, 2006 FCA 214; *Apotex Inc. v. Pfizer Canada Inc.*, 2009 FCA 216.