

THE SUPREME COURT'S SANOFI DECISION: THREE YEARS LATER*

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ABSTRACT

In 2008, the Supreme Court of Canada's decision in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.* restated the test for anticipation under Canadian patent law to expressly include enablement. *Sanofi* also provided an analytical approach for obviousness and provided the option of using the "obvious to try" test in areas where inventions are often won by experimentation. This article reviews the most important cases from 2008 to 2011 that have applied the *Sanofi* decision.

RÉSUMÉ

En 2008, la décision de la Cour suprême du Canada dans l'affaire *Apotex Inc. c. Sanofi-Synthelabo Canada Inc.* a reformulé le critère de l'antériorité en vertu de la loi canadienne sur les brevets de façon à y inclure la notion de « caractère réalisable ». Elle a aussi établi la méthode analytique à adopter concernant l'évidence, et a offert la possibilité d'appliquer le critère de l'« essai allant de soi » dans les domaines où les inventions sont souvent le fruit de l'expérimentation. L'article passe en revue les plus importantes causes qui ont utilisé la décision *Sanofi* entre 2008 et 2011.

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1.0 INTRODUCTION

In *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*,¹ the Supreme Court of Canada introduced two new aspects into Canadian law relating to anticipation and obviousness—namely, enablement and “obvious to try.” To evaluate the practical impact *Sanofi* has made to anticipation and obviousness disputes, we reviewed all Canadian patent decisions issued in the three years since the *Sanofi* decision was released by the Supreme Court on November 6, 2008. The subsequent decisions that focused on the new anticipation or obviousness tests introduced by the Supreme Court of Canada are discussed in more detail below.

1.1 The New Anticipation Test

Until *Sanofi*, in respect of anticipation, Canadian courts typically looked at a single piece of prior art and asked whether it disclosed something that, if practised, would inevitably fall within the scope of the claims of the patent in issue. Although expressed in different words, courts likely applied the test set out in *Beloit Canada Ltd. v. Valmet Oy*,² one of the enumerated variations set out in *Reeves Brothers*,³ or even that enunciated by the House of Lords in *General Tire & Rubber Co. v. Firestone Tyre & Rubber Co.*⁴ Relying on the more recent House of Lords decision in *Synthon B.V. v. SmithKline Beecham plc*,⁵ in *Sanofi*, the Supreme Court held that for a prior art document to be anticipatory it must meet the two-part test of disclosure and enablement. In respect of disclosure, the Court retained the *Beloit* test and said that the single prior art document must disclose the invention subsequently claimed in the patent at issue. Consistent with previous case law, trial and error is not permit-

¹ 2008 SCC 61, [2008] 3 S.C.R. 265 [*Sanofi*].

² (1986), 8 C.P.R. (3d) 289 (F.C.A.) [*Beloit*].

³ *Reeves Brothers Inc. v. Toronto Quilting & Embroidery Ltd.* (1979), 43 C.P.R. (2d) 145 (F.C.T.D.).

⁴ [1972] R.P.C. 457.

⁵ [2006] 1 All E.R. 685 (H.L.) [*Synthon*].

ted at the disclosure stage of the analysis. In addition, however, the new anticipation test requires the prior art to enable the claimed invention—that is, it must provide sufficient information to enable a person skilled in the relevant art to reproduce the subsequently claimed invention. During the enablement stage of an anticipation analysis, the skilled person is allowed to experiment, but not to the extent that it requires undue burden. Although not exhaustive, the Supreme Court indicated that the enablement analysis includes:

1. the nature of the invention and the common general knowledge of a person skilled in the art;
2. a review of the whole prior art document overlooking obvious errors or omissions; and
3. the degree of trial and error experimentation required.

1.2 The New Obviousness Test

Prior to the Supreme Court’s decision in *Sanofi*, lower court judges applied different (and sometimes confusing) tests as to whether experimentation was permissible for the purposes of an obviousness analysis. While some decisions⁶ allowed routine experimentation to support a finding of obviousness, others such as *Bayer Aktiengesellschaft v. Apotex Inc.*⁷ and *Beloit*⁸ said that if any amount of experimentation was required, the invention was not obvious.

In *Sanofi*,⁹ the Supreme Court put this issue to rest by introducing “obvious to try” and “ought to work” tests for obviousness in cases where advances are often won by experimentation.¹⁰ This represents a change in Canadian law from earlier decisions such as *Bayer*.¹¹

1.3 How We Conducted the Review

In early July 2011, we retrieved post-*Sanofi* decisions relating to anticipation or obviousness issued by the Patent Appeal Board, Federal Court, and Federal Court of Appeal by searching the CanLII, QuickLaw, and WestLaw databases. The scope of the search included decisions arising from final rejections, infringement actions, impeachment actions, or under the *Patented Medicines (Notice of Compliance) Regulations*. We used the search terms “Patent & (anticipation or obviousness or novelty)” to ensure the production of all potentially relevant decisions.

⁶ *Novopharm Limited v. Janssen-Ortho Inc. and Daiichi Pharmaceutical Co., Ltd.*, 2007 FCA 217 at para. 25(6) (per Sharlow J.A., Nadon and Malone J.J.A. concurring).

⁷ (1995), 60 C.P.R. (3d) 58 (Ont. S.C.).

⁸ *Beloit*, *supra* note 2.

⁹ *Sanofi*, *supra* note 1 at para. 67.

¹⁰ *Ibid.* at para. 69.

¹¹ *Ibid.*

The searches yielded a total of 126 decisions. Of the decisions, 36 raised the issue of anticipation and 54 raised the issue of obviousness. Nine of these proceedings made their way to the Federal Court of Appeal and yielded a decision in which anticipation or obviousness was discussed. Each case was reviewed for substantive discussion on either an “enablement” or “obvious to try” analysis, the most relevant of which are discussed below.

2.0 ANTICIPATION

2.1 What Did Sanofi Do Regarding Enablement?

Before turning to a discussion of enablement, we must first understand why it is important that the Supreme Court introduced the enablement component into the anticipation analysis. There are many ways for an invention to be disclosed in such a manner that it becomes available to the public in Canada or elsewhere.¹² Any one of a public disclosure of a picture, scientific article, recipe, lab notebook, or public sale may meet the test for disclosure, yet that disclosure may not provide a person of skill with sufficient information to reproduce the invention claimed in the patent at issue. For example, Leonardo DaVinci is credited with disclosing the first helicopter. His published drawings clearly disclose a machine with an Archimedean screw and a human propelled rotor. Yet these drawings would not allow a person of skill to make a helicopter that would actually fly. Hence, because DaVinci disclosed a helicopter but did not enable it, his drawings would not anticipate a subsequent claim to a helicopter.

Another good example of enablement is the factual matrix presented in the House of Lords *Synthon* decision discussed by Justice Rothstein in *Sanofi*.¹³ The patent at issue in the *Synthon* decision claimed a particular crystalline form of a paroxetine salt (PMS). A prior patent contained instructions for producing a crystalline compound described as something other than PMS. The issue before the House of Lords was whether the prior art patent anticipated the subsequent claim to PMS. First, on the issue of disclosure, the House of Lords recognized that disclosure can take many forms including providing a recipe for making the compound. In this respect it did not matter that the compound described by the prior patent was labelled differently. The more important question was what did the recipe produce. As such, the House of Lords found that the prior art patent met the disclosure requirements of anticipation. Regarding enablement, the patent challenger hired experts to follow the instructions of the prior art patent to see whether the recipe would produce the subsequently claimed PMS. This exercise was complicated because the counter-solvent used in the prior art patent was not suitable for crystallizing out the material in solution. The experts reproducing the prior art testified that a person skilled in the art of crystallization would know that the described counter-solvent was in-

¹² This language tracks the relevant statutory provision—namely, s. 28.2 of the *Patent Act*, R.S.C. 1985, c. P-4.

¹³ *Synthon*, *supra* note 5.

appropriate and would use an appropriate counter-solvent from which to crystallize the material. The experts were able to crystallize out a compound and the material that formed as a result of this crystallization was PMS. Thus, experimentation was permitted at this enablement stage. On the basis of this testimony, the House of Lords held that because the prior art both disclosed and enabled the production of PMS, it was anticipatory.

By formalizing the enablement requirement into Canadian law, the Supreme Court is ensuring that the anticipation test mirror the policy objectives of not defeating novel inventions by disclosures that do not allow the public to practise the claimed invention. In other words, if a subsequent patentee is adding to the publicly available knowledge, there is still room for the grant of a patent.

2.2 Post-Sanofi Enablement Decisions

Five post-*Sanofi* anticipation decisions have involved the question of enablement. The Canada Patent Appeal Board Decision in *Re Sloan-Kettering Institute for Cancer Research Patent Application No. 2,072,017*¹⁴ provides a good example of enablement. The applicant sought an amended claim 1 to an antibody or antigen-binding fragment thereof, other than murine monoclonal antibody M195 with an amino acid sequence capable of binding to the epitope to which M195 binds. The Board found that the two prior art references at issue did not disclose the subject matter of the claims sought by *Sloan-Kettering*. Despite having done so, the Board continued its analysis to include enablement and in so doing applied the four non-exhaustive factors enumerated by the Supreme Court in para. 37 of its *Sanofi* decision regarding permissible trial and error experimentation for enablement.¹⁵

In this step of the analysis,¹⁶ the Board found that possession of the M195 antibody was a necessary starting point for the production of the invention sought to be claimed by *Sloan-Kettering*. While this M195 antibody had been publicly disclosed, the Board found that the M195 antibody was neither commercially available nor publically available in a biological material depository before the relevant date. Because making the M195 antibody would require a person of skill to engage in a cause of “hopeful yet prolonged and arduous experimentation,”¹⁷ the Board found the prior art references did not anticipate the claims sought by *Sloan-Kettering*. The Board did go out of its way to suggest that its finding was limited to the “somewhat unique” facts it was considering and should not be taken to stand for the principle that a prior art reference is not anticipatory unless it also provides a publically available source of the required biological starting material.

¹⁴ 2009 LNCPAT 8 [*Sloan-Kettering*].

¹⁵ Even though the Supreme Court in *Sanofi* called these factors non-exhaustive, they were applied in an exhaustive manner by the Patent Appeal Board.

¹⁶ *Ibid.* at paras. 87-106.

¹⁷ *Ibid.* at para. 105.

Justice Snider's decision in *Merck & Co. Inc. v. Apotex Inc.*¹⁸ provides a similar analysis. Merck's patent claimed lovastatin, a cholesterol-lowering agent sold by Merck under the brand name MEVACOR. Merck's patent described the process of isolating lovastatin from a strain of *Aspergillus terreus*. Apotex alleged that depending on how fermentation was performed on red yeast rice, lovastatin may be present in minute quantities. Apotex argued that this amounts to anticipation. There was no evidence that the particular fermentation process Apotex said produced lovastatin was actually used before Merck's claim date to ferment red yeast rice. Justice Snider rejected Apotex's anticipation allegations for two reasons. First, she did not accept that lovastatin was present in the red yeast rice produced before the claim date.¹⁹ Second, she said that there was no disclosure because it is not inevitable that lovastatin would be produced following the prior art fermentation processes.²⁰ Although Justice Snider did not have to deal with the issue of enablement, this fact pattern differs from that in *Synthon* where a person of skill was trying to obtain crystalline material as described above. In *Merck*, there was no direction to extract lovastatin even if it was present in the red yeast rice.

Another aspect of a post-*Sanofi* enablement analysis can be seen in *Sanofi-Aventis Canada Inc. v. Hospira Health Care Corp.*²¹ A prior art article, referred to by Justice Zinn as the "GV Article," disclosed a formulation of docetaxel in a 1:1 solvent vehicle of polysorbate to ethanol. No indication was given in the GV Article regarding the suitability of the disclosed formulation for use in an infusion formulation as claimed in *Sanofi's* patent. Justice Zinn's finding that *Sanofi's* invention was obvious likely influenced his anticipation analysis. Nonetheless, at paras. 196-201, Justice Zinn held that the GV Article did not anticipate *Sanofi's* patent because a person of skill (a formulation scientist and not a doctor) would not know the range of docetaxel necessary for an infusion preparation.

In *AstraZeneca Canada Inc. v. Apotex Inc.*,²² the patent at issue claimed esomeprazole, one of the stereoisomers of enalapril. The prior art German patent application referenced by Justice Hughes as DE '455 disclosed a method for producing what was described as "optically pure compounds from the diastereomers" of a class of compounds, including omeprazole.²³ Apotex filed expert evidence showing that a modification of some of the examples of the DE '455 disclosure would result in the production of esomeprazole in sufficiently pure form. AstraZeneca, on the other hand, filed evidence showing that, when scientists had previously carried out similar experiments, esomeprazole of adequate purity could not be obtained. The

¹⁸ 2010 FC 1265, 91 C.P.R. (4th) 1 [*Merck*].

¹⁹ *Ibid.* at para. 598.

²⁰ *Ibid.* at paras. 607-608.

²¹ 2009 FC 1077, 78 C.P.R. (4th) 327 [*Sanofi-Aventis*].

²² 2011 FCA 211 [*AstraZeneca*].

²³ *Sanofi-Aventis, supra* note 21 at para. 96.

question was whether such trial and error experimentation constituted an “undue burden” within the meaning of the Supreme Court *Sanofi* decision. Justice Hughes found that the allegation of anticipation was not justified because a person of skill practising DE '455 would at best only occasionally result in a product with a purity level stipulated in claim 8 of AstraZeneca’s patent.²⁴

Perhaps the best example of a case that truly turns on the issue of enablement is the Federal Court and Federal Court of Appeal decision in *Easton Sports Canada Inc. v. Bauer Hockey Corp.*²⁵ In *Easton*, the claimed invention was an improved hockey skate boot, having a one-piece quarter with an angular profile. The quarter is the piece of the skate that covers the heel and the ankle and is visible from the side or rear of the skate. Prior art skates comprised two sections stitched together at the rear of the skate. The one-piece quarter avoided the stitch at the back of the skate, resulting in a stronger heel portion, which was easier to manufacture, more durable, and allowed for the skate to have a more angular profile. Presumably these attributes give the skater better positioning and support at the rear of the skate. Although there were allegedly several public uses of the prototype skates that were said to be anticipatory, the one that provides the best example of enablement relates to the use of a skate prototype in a test league. The hockey players involved in the test league were either employees of Bauer or persons who had signed confidentiality agreements. As such, disclosure to these individuals did not amount to a public disclosure. However, the test league games took place in a public arena. There was no doubt that the skates were disclosed. The question at issue, however, was whether such use enabled a person of skill to reproduce the claimed skate. At trial, Justice Gauthier found that a visual inspection, without dismantling the skate, would not have enabled one of skill to make the claimed skate.²⁶ In paras. 65-71 of the appeal decision, the Federal Court of Appeal upheld Justice Gauthier’s reasoning.²⁷

2.3 Sanofi Changes the Federal Court of Appeal’s Analysis in *Baker Petrolite*

Any analysis of Justice Rothstein’s decision in *Sanofi* would be incomplete without a comparison to his previous Federal Court of Appeal decision of *Baker Petrolite v. Canwell Industries*.²⁸ In *Baker Petrolite*, the technology at issue was a chemical used to sweeten natural gas streams—that is, to remove hydrogen sulfide from sour gas. The company that originally developed the invention had sold some of its product before the relevant claim date. The sweetening chemical was itself a reaction product of two other chemicals, and the question on appeal was whether the

²⁴ *Ibid.* at para. 125.

²⁵ (2011), 92 C.P.R. (4th) 103 (F.C.A.), aff’g (2010), 83 C.P.R. (4th) 315 (F.C.) [*Easton*].

²⁶ *Ibid.* (F.C.) at para. 221.

²⁷ *Ibid.* at paras. 65-71.

²⁸ (2002), 17 C.P.R. (4th) 478 (F.C.A.) [*Baker Petrolite*].

sale of a chemical disclosed the invention in such a manner that it became available to the public. In other words, could the sweetening chemical be reverse engineered? Starting at para. 30 of the Court of Appeal decision, Justice Rothstein set out his view on what constitutes anticipation by prior use or sale. Similar to his later *Sanofi* decision, he said that the prior use or sale must amount to an enabling disclosure. Remember that in para. 37 of *Sanofi*, Justice Rothstein said that “experiments or trials and errors are not to be prolonged even in fields of technology in which trials and experiments are generally carried out.” Contrary to *Sanofi*, however, in *Baker Petrolite*, Justice Rothstein said the degree of experimentation required for enablement was irrelevant:

7. The amount of time and work involved in conducting the analysis is not determinative of whether a skilled person could discover the invention. The relevant consideration, in this respect, is only whether inventive skill was required. In *FISONS plc v. Packard Instruments B.V.*,^[29] ... , the Board of Appeal of the European Patent Office stated at pages 21-22:

The likelihood or otherwise of such a skilled person either reading such a written description, or analysing such a prior sold product, *and the degree of burden (i.e. the amount of work and time) involved* in such reading or in analysing, *is in principle irrelevant* to the determination of what constitutes the state of the art.

There must be some evidence from which the use of inventive skill may be inferred. Complexity or time and work involved alone are insufficient.³⁰

In the result, there is no doubt that *Sanofi* constitutes a restrictive change in the level of experimentation permissible for an enablement analysis.

2.4 Conclusions on Enablement

The post-*Sanofi* cases seem to boil down to three general categories. In the first category of cases (*Sloan-Kettering* and *Merck*), enablement required a person of skill to conduct undue experimentation to arrive at the subsequently claimed invention. In the second (*Sanofi* and *AstraZeneca*), pieces of prior art came close to disclosing the invention. Although these pieces of prior art did not meet the test for anticipation, they were sufficiently close to render the claimed invention obvious. The third category (*Easton*) is similar to the *Baker Petrolite* situation, where the alleged prior art was the public use or sale of the product claimed by the patent. These cases turn on the nature of the invention involved and the difficulty of reverse engineering the product in question.

²⁹ E.P.O. case number T 0952/92—3.4.1, August 17, 1994.

³⁰ *Baker Petrolite*, *supra* note 28 at para. 7 (emphasis added).

3.0 OBVIOUSNESS

3.1 What Did Sanofi Do Regarding Obviousness?

The *Sanofi* decision did two main things regarding obviousness:

1. It recommended the use of the *Windsurfing/Pozzoli* approach leading up to deciding whether the alleged invention was obvious.
2. It concluded that, in circumstances where inventions are the result of experimentation, the “obvious to try” test should be used.

It also reminded us that:

3. We should consider all relevant factors when determining obviousness.

The *Windsurfing/Pozzoli* approach, as expressed in *Sanofi* is:

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?³¹

It is important to note³² that the *Windsurfing* approach was developed in the context of the U.K. *Patents Act 1977*,³³ which provides that a patent may only be granted for an invention if “it involves an inventive step.”³⁴ Although s. 2 of the Canadian *Patent Act* says that the term “invention” means “any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement

³¹ *Sanofi*, *supra* note 1 at para. 67.

³² As did Donald H. MacOdrum, in “Update on Patents: Legislative Changes and Case Law in 2008,” presented at the 13th Annual Intellectual Property Law—The Year in Review, Law Society of Upper Canada, Toronto, Canada, January 15, 2009.

³³ 1977, c. 37.

³⁴ *Ibid.*, s. 1(1):

1(1) A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say—

- (a) the invention is new;
- (b) it involves an inventive step;
- (c) it is capable of industrial application. (Emphasis added.)

in any art, process, machine, manufacture or composition of matter,” the courts decided that, in order to be an invention, it has to be “inventive.” There is, however, no requirement in the Canadian *Patent Act* that there be an “inventive step.”

Thus, to “Canadianize” the *Windsurfing/Pozzoli* approach, at least for old Act patents, step 2 could be translated to read:

2. Identify the invention 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 invention of the claim as construed.

With the test phrased in respect of “the invention of the claim,” the fourth question could be rephrased as:

4. Viewed without any knowledge of the alleged invention as claimed, would the invention as claimed have been obvious to the person skilled in the art or did it require any degree of invention?

3.2 Sanofi Applies to New Patent Act Cases

Sanofi was an old Act patent case; however, since *Sanofi*, Canadian courts have adopted the *Windsurfing/Pozzoli* approach to new Act patents.

The new Canadian *Patent Act* (unlike the old Act) has a specific provision regarding obviousness: s. 28.3, which provides:

28.3 The subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to

(a) information disclosed more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant in such a manner that the information became available to the public in Canada or elsewhere; and

(b) information disclosed before the claim date by a person not mentioned in paragraph (a) in such a manner that the information became available to the public in Canada or elsewhere.

Note that according to the test defined by the statute, it is the “subject matter defined by a claim ... that would not have been obvious on the claim date,” not “the inventive concept of the claim” as referred to in *Sanofi*.³⁵ Accordingly, it is arguable that the *Windsurfing/Pozzoli* approach could be modified to be consistent with the statutory requirement of non-obviousness under the new Act, as follows:

³⁵ *Sanofi*, *supra* note 1.

1. Identify the invention of the claim in question or, if that cannot readily be done, construe it.
2. Identify what, if any, differences exist between the matter cited as forming part of the “state of the art” and the invention of the claim as construed.
3. Viewed without any knowledge of the alleged invention as claimed, would the invention as claimed have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to the information referred to in ss. 28.3(a) and (b)?

The first express application of the *Sanofi* obviousness test by the Federal Court of Appeal related to a “new” Canadian *Patent Act* patent in *Apotex Inc. v. Pfizer Canada Inc. et al.*,³⁶ a proceeding under the *Patented Medicines (Notice of Compliance) Regulations* (PMNOC Regulations).³⁷ Apotex sought approval to sell a generic version of sildenafil citrate (Pfizer’s product was sold under the familiar brand name VIAGRA), and made allegations that Pfizer’s patent was invalid for obviousness. Justice Noël recognized that the Supreme Court’s test required a very high predictability of success:

According to this [the *Sanofi*] 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.³⁸

In so holding, the Federal Court Judge [in *Apotex v. Pfizer*] drew the line precisely where the Supreme Court drew it in *Sanofi-Synthelabo* when it held that (para. 66) “the mere possibility that something might turn up is not enough.”³⁹

The Federal Court of Appeal quoted evidence relied on by the applications judge that the invention was not self-evident, including:

He states that prior to the publication of Pfizer’s positive results with sildenafil citrate, it was not obvious to scientists working in the field that a PDE5 inhibitor could be used to treat ED *and it also was not obvious that oral administration of a PDE5 inhibitor would work.*⁴⁰

The Federal Court of Appeal concluded that the applications judge had applied the correct test, in that more than possibilities were required to establish obviousness.⁴¹

³⁶ 2009 FCA 8 [*Apotex v. Pfizer*].

³⁷ SOR/93-133.

³⁸ *Apotex v. Pfizer*, *supra* note 36 at para. 29

³⁹ *Ibid.* at para. 37

⁴⁰ *Ibid.* at para. 31 (emphasis added).

⁴¹ *Ibid.* at para. 46.

3.3 What Is the Invention/Inventive Concept for Each Claim?

Although *Sanofi* stated that the “inventive step” may be found elsewhere than in the claims, as discussed above, the language of the new *Patent Act* suggests that the test of obviousness should be limited to a consideration of the invention *as claimed*. The Federal Court of Appeal in *Apotex v. Pfizer* did not address this difference when it applied the *Sanofi* test to a new Act patent.

In *Apotex Inc. v. ADIR and Servier Canada Inc.*,⁴² the appellant submitted that the trial judge erred by directing the obviousness inquiry to the claims of the '196 Patent and, in so doing, she specifically and erroneously rejected as relevant what the disclosure taught about inventiveness.⁴³ The Court (without explaining in what circumstances, other than when dealing with a selection patent, resort could be had to the disclosure to determine the inventive step) endorsed and adopted the reasoning in *Angiotech Pharmaceutical Inc. v. Conor Medsystems Inc.*,⁴⁴ where Lord Hoffman stated:

[T]he invention is the product specified in a claim and the patentee is entitled to have the question of obviousness determined by reference to his claim and not to some vague paraphrase based upon the extent of his disclosure in the description.⁴⁵

The Federal Court of Appeal considered the *Angiotech* approach to be consistent with *Sanofi* where, in describing the appropriate framework for an obviousness inquiry, Justice Rothstein stated 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.”⁴⁶ The Court further found Justice Snider’s obviousness determinations to be consistent with the *Sanofi* framework.⁴⁷

Thankfully, the Federal Court of Appeal appears to have taken the approach that, where the claims for a combination have been properly construed, it is not necessary to discern the inventive concept. In *Corlac*,⁴⁸ the Court said:

Although they maintain that the judge did not specifically identify the inventive concept of the patent (as contemplated at *Pozzoli* step two), they acknowledge that he did refer to the patent’s three “key concepts” in his reasons. In any event, the second step indicates that it will be sufficient to construe the patent if the inventive concept is not readily discernible from its claims. As indicated earlier in these reasons, the judge properly construed the patent’s claims. Moreover, the '937 Patent is a combination

⁴² *Apotex Inc. v. ADIR and Servier Canada Inc.*, 2009 FCA 222 [*ADIR*].

⁴³ *Ibid.* at para. 68.

⁴⁴ [2008] UKHL 49.

⁴⁵ *Ibid.* at para. 19.

⁴⁶ *ADIR*, *supra* note 42 at para. 69.

⁴⁷ *Ibid.* at para. 90.

⁴⁸ *Corlac Inc. et al. v. Weatherford Canada Ltd.*, 2011 FCA 228 [*Corlac*].

patent. Therefore, its essence lies in the unique combination claimed even though individual elements of the invention, considered in isolation, may not have been inventive. As recently explained by this Court, “[i]t is not fair to a person claiming to have invented a combination invention to break the combination down into its parts and find that, because each part is well known, the combination is necessarily obvious”: *Bridgeview Manufacturing Inc. v. 931409 Alberta Ltd.*⁴⁹

3.4 Some Introductory Comments Regarding “Obvious to Try” in Sanofi

In *Sanofi*, as in other cases, the courts have warned us (and other judges) not to become too enamoured of secondary analogies for “obvious” such as “directly and without difficulty.” In *Janssen-Ortho*,⁵⁰ the Federal Court of Appeal deprecated the use of such phrases:

I would also repeat the caution of Justice Hughes that catchphrases derived from this list or from the jurisprudence are not to be treated as though they are rules of law. I agree with the following comment of Justice Hughes from paragraph 113 of his reasons:

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*.⁵¹

Justice Kelen may have missed the distinction between semantics and substance when he held in *Pfizer v. Novopharm*⁵² that the Supreme Court had “changed semantically the threshold for obviousness.” Justice Rothstein, reflecting on the U.S.

⁴⁹ 2010 FCA 188, 87 C.P.R. (4th) 195, para. 51 [*Bridgeview*], leave to appeal dismissed, [2010] S.C.C.A. No. 346, quoted in *Corlac*, *supra* note 48 at para. 69.

⁵⁰ *Janssen-Ortho Inc. v. Novopharm Ltd.*, 2007 FCA 217 [*Janssen-Ortho*].

⁵¹ [1972] R.P.C. 195 at 211-12, quoted in *Janssen-Ortho*, *supra* note 50 at para. 28.

⁵² *Pfizer Canada Inc. v. Novopharm Limited*, 2009 FC 638. See para. 52, where Kelen J. states:

The Supreme Court recently examined in detail the legal test for obviousness in *Apotex Inc. v. Sanofi-Synthelabo*, 2008 SCC 61, 381 N.R. 125. Justice Rothstein reformulated the test for obviousness at paragraph 66:

[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.

In so formulating the test, the Supreme Court changed semantically the threshold for obviousness. Rather than showing that a person skilled in the art could “come directly and without difficulty to the solution taught by the patent to establish obviousness,” now a person challenging the patent need show that “it was more or less self-evident to try” with more than a mere possibility of success.

*KSR*⁵³ decision stated that “in most matters in which a judge or a jury is called upon to make a factual determination, rigid rules are inappropriate unless mandated by statute.”⁵⁴ The “correctness of a decision upon an issue of obviousness does not depend upon whether the decider has paraphrased the words of the Act” or made use of “some particular verbal formula.”⁵⁵

Yet the obvious-to-try test is the perfect example of such a secondary analogy for obviousness, which risks misapplication of its principles simply because of its name. Obvious to try is an oxymoron. “Obvious” means self-evident, plain as day, crystal clear. Something that is obvious is clear beforehand; its outcome is predictable with a high, if not complete, degree of certainty. But the term “try,” in and of itself, suggests uncertainty. “Trying” something suggests that you’ve never done it before; you don’t know whether you will like it or whether it will work. This unfortunate moniker has its roots in its predecessor: the English “worth a try” test that held for many years that if something was worth trying, and no invention was required to try it out, then it was obvious.

From the late 1960s until *St. Gobain* in 2005, the “worth a try” test was the test for obviousness in the United Kingdom:

It is enough that the person versed in the art would assess the likelihood of success as sufficient to warrant actual trial.⁵⁶

In 2005, the U.K. law of obviousness underwent a sea change in *Saint-Gobain PAM SA v. Fusion Provida Ltd.*⁵⁷ Using logic similar to that expressed in the Canadian *Hoechst*⁵⁸ case, Lord Justice Jacob held that in order for the obvious-to-try test to be satisfied, there needed to be an “expectation of success”:

More possible inclusion of something within a research programme on the basis you will find out more and something might turn up is not enough. If it were otherwise there would be few inventions that were patentable. The only research which would be worthwhile (because of the prospect of protection) would be into areas totally devoid of prospect. *The “obvious to try” test really only works where it is more or less self-evident that what is being tested ought to work.*⁵⁹

⁵³ *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007).

⁵⁴ *Sanofi*, *supra* note 1 at para. 63.

⁵⁵ *Ibid.*, quoted in *Corlac*, *supra* note 48 at para. 67.

⁵⁶ *Johns-Manville Corporation’s Patent*, [1967] R.P.C. 479 at 495.

⁵⁷ [2005] E.W.C.A. Civ. 177 [*St. Gobain*]; Tomos Shillingford of the U.K. law firm of Bird & Bird entitled a case comment regarding the *Saint-Gobain* decision, “Has the ‘Obvious to Try’ Test Been Buried?” and concluded with the statement, “For the moment, at least, the *Johns-Manville* test is dead, buried and possibly corroding” (April 6, 2005), online: <http://www.twobirds.com/English/News/Articles/Pages/Has_the_obvious_to_try_test_been_buried.aspx>.

⁵⁸ *Farbwerke Hoechst v. Halocarbon (Ontario) Limited et al.* (1979), 42 C.P.R. (2d) 145 (S.C.C.) [*Hoechst*].

⁵⁹ *Saint-Gobain*, *supra* note 57 at para. 35 (emphasis added).

The *St. Gobain* case, in part, inspired Justice Rothstein to adopt the obvious-to-try test in *Sanofi*. We suggest that it should instead have been named the “obvious it will work” test.

Unfortunately, in what appears to have been a departure from the test elsewhere articulated (and perhaps was a misstatement or use of imprecise language), Justice Rothstein twice asked whether it would have been “self-evident to try” to obtain the invention, first, in stating the law:

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*.⁶⁰

Then, in addressing the evidence:

I conclude that the prior art and common general knowledge of persons skilled in the art at the relevant time were not sufficient for it to be more or less self-evident *to try to find the dextro-rotatory isomer*.⁶¹

This wording was unfortunate because, read in isolation, it can muddy the inquiry. It suggests that the question is: “Was it obvious to try to obtain the invention?” and start the search versus: “Was it obvious that you had found the invention?” because it was more or less self-evident that it ought to work. If you knew it was going to work, you can hardly be “trying” it. “Trying” suggests an experiment, the outcome of which you do not know beforehand—hardly something whose outcome is “obvious.”

Thankfully, in *Sanofi*, the Supreme Court clarified this issue when it went on to say elsewhere in the decision that the invention must be self-evident:

The invention must be self-evident from the prior art and common general knowledge in order to satisfy the “obvious to try” test.⁶²

It observed that the mere possibility of getting the invention was insufficient:

Mere possibility that something might turn up is not enough.⁶³

It is true that at the relevant time there was evidence that a skilled person would know that the properties of a racemate and its isomers might be different. However, a possibility of finding the invention is not enough.⁶⁴

⁶⁰ *Sanofi*, *supra* note 1 at para. 66 (emphasis added). This language was repeated in *Eli Lilly Canada Inc. et al. v. Novopharm Limited*, 2010 FCA 197 at para. 55.

⁶¹ *Sanofi*, *supra* note 1 at para. 92 (emphasis added).

⁶² *Ibid.* at para. 85.

⁶³ *Ibid.* at para. 66.

⁶⁴ *Ibid.* at para. 85.

It appears that only part of the *Sanofi* obviousness test was applied in *Abbott Laboratories v. Canada (Health)*,⁶⁵ a proceeding under the PMNOC Regulations. The applications (trial level) judge held that the patent at issue was anticipated. In *obiter* reasons relating to the issue of obviousness, the applications judge appears to have applied Justice Rothstein's "to try" statement in para. 66 of *Sanofi*: the applications judge found that *it would have been self-evident* to a person skilled in the art *to try* the solubility of the crystalline form *to see whether* it would work.⁶⁶ The applications judge concluded that testing for solubility was routine.⁶⁷ He concluded that it was self-evident that a person skilled in the art would test the solubility of any newly identified crystal to determine whether it was soluble at a rate sufficient to give therapeutic utility⁶⁸ and concluded that the invention was obvious. He did not ask, however, whether it was more or less self-evident that what was being tested ought to work, as required by para. 69(1) of *Sanofi*. These findings were not disturbed by the appeal court in *Abbott Laboratories*, after it also found that the patent was anticipated.⁶⁹

3.5 "Obvious to Try" Is Not Applicable to All Cases

The Canadian Supreme Court said that, in cases where advances are often won by experimentation, an obvious-to-try test might be appropriate to use in the fourth step of the *Windsurfing* obviousness approach.⁷⁰

The behaviours of mechanical and electrical systems are generally predictable. A skilled mechanical or electrical engineer can look at a technical drawing or a circuit diagram and predict its behaviour, just as a person skilled in reading sheet music can "hear" how a piece of music will sound.

The same may not be true of chemical and pharmaceutical products. Their behaviours in the human body (and particularly their side effects) can be inherently unpredictable. One may not be sure how a pharmaceutical will behave with certainty until it is tested on a patient. As noted by Justice Rothstein in *Sanofi*:

i. When Is the "Obvious to Try" Test Appropriate?

[68] 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 inter-related variables with which to experiment. For example, some inventions *in the pharmaceutical industry* might warrant an "obvious to try" test since *there may be*

⁶⁵ 2008 FC 1359 [*Abbott Laboratories*].

⁶⁶ *Ibid.* at para. 96.

⁶⁷ *Ibid.* at para. 98.

⁶⁸ *Ibid.* at para. 99.

⁶⁹ 2009 FCA 94.

⁷⁰ *Sanofi*, *supra* note 1 at para. 68.

many chemically similar structures that can elicit different biological responses and offer the potential for significant therapeutic advances.⁷¹

In addition, some pharmaceutical compounds are often developed by iteration: a molecule that works is modified slightly and tested for efficacy. The behaviour of the modified molecule can be unpredictable. If so, only research in the form of experimentation (finding out that which is not yet known) will determine its usefulness. As a result of this lack of predictability, its behaviour (and whether or not it will work) is not obvious.

Not all cases involve experimentation of the sort in *Sanofi* and the obvious-to-try test should not be applied to them. The obvious-to-try test was not applied in:

- *UView Ultraviolet Systems Inc. v. Brasscorp Ltd.*,⁷² a case involving a mechanical invention—a closed, pressurized air conditioning system. The obvious-to-try test was not applied because, as stated by the trial judge,⁷³ “the case does not deal with the type of case the Supreme Court suggested said the ‘obvious to try’ test would be appropriate.”
- *Bridgeview Manufacturing Inc. et al. v. 931409 Alberta Ltd. c.o.b.a. Central Alberta Hay Centre et al.*,⁷⁴ a case involving a mechanical device, and although the obvious-to-try test was appropriate where, in the relevant art, advances are won by experimentation, this was not a case where the *Sanofi* refinement had any application.

The obvious-to-try test was also not applied in a pharmaceutical case:

- *Bristol-Myers Squibb Canada Co. v. Apotex Inc.*,⁷⁵ presumably because no experimentation was needed to conclude that the invention was obvious. Using the *Windsurfing* questions, the Court concluded that the difference between the prior art and the inventive concept was the identification that the hydration of the crystalline dehydrate was a monohydrate, and that it had “temperature stability.” The Court concluded that the prior art taught that all salts had excellent stability, that the alleged invention was more-or-less self-evident and, therefore, obvious.⁷⁶

⁷¹ *Ibid.* at para. 68 (emphasis added).

⁷² 2009 FC 58.

⁷³ *Ibid.* at para. 189.

⁷⁴ 2010 FCA 188 at para. 42.

⁷⁵ 2009 FC 137.

⁷⁶ *Ibid.* at paras. 157-159.

Oddly, in *Herskovitz v. Tyco Safety Products Canada Ltd.*,⁷⁷ Justice Martineau, after holding that a telephone line coupler (an electrical circuit) was “pretty obvious”⁷⁸ and that prior art circuit arrangements “would have easily led to any new circuit arrangement taught in the patents in suit,”⁷⁹ using the more traditional language of an obviousness analysis, volunteered, in language that imperfectly echoes the obvious-to-try test, that one piece of prior art made “it obvious that a ‘series connection,’ if tried by a person skilled in the art, may work as well.”⁸⁰ Given that it was an electrical circuit (in a field, electronics, where experimentation was probably not needed to predict utility), the obvious-to-try test was probably not applicable in this case. In any event, “may work” is hardly “self-evident.”

Therefore, as suggested by Justice Rothstein, the obvious-to-try test might be appropriate to use in the fourth step of the *Windsurfing* obviousness approach⁸¹ in cases in the pharmaceutical and chemical arts, where behaviour can be unpredictable, but it is not applicable in the mechanical, electrical, and computer program arts where behaviour is much more predictable.

3.6 Applying “Obvious to Try”

3.6.1 Self-Evident

In *Abbott Laboratories v. Canada (Health) and Sandoz*,⁸² the Court, when dealing with the *Sanofi* “self-evident” question, dealt sequentially with each of the differences between the prior art and the alleged invention, then considered evidence relating to the factors why the chosen polymer would not have been a likely choice for a skilled person for creating an extended release version of a nearly insoluble drug such as clarithromycin,⁸³ and finally observed that there was nothing in the prior art that would suggest that this formulation would be suitable.⁸⁴ The Court also referred to other prior art that negated the success of the invention and the failure of other prior users to make the invention.

3.6.2 Nature and Amount of Effort Required: Routine Trials or Prolonged and Arduous?

In *Ratiopharm Inc. v. Pfizer Limited*,⁸⁵ the Court found the alleged invention to be obvious. The inventors were asked to look at amlodipine maleate and see whether

⁷⁷ 2009 FC 256 at paras. 137-147.

⁷⁸ *Ibid.* at para. 142.

⁷⁹ *Ibid.* at para. 143.

⁸⁰ *Ibid.* at para. 142.

⁸¹ *Sanofi, supra* note 1 at para. 68.

⁸² 2009 FC 648.

⁸³ *Ibid.* at paras. 123-134.

⁸⁴ *Ibid.* at para. 125.

⁸⁵ 2009 FC 711.

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. They tried adjusting formulations, a routine task. 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. Although besylate would not be everyone’s first choice, it was not an unreasonable choice.⁸⁶ The besylate salt worked well enough to pass on to the next step for final formulation and seek regulatory approval.⁸⁷ Perhaps because such salt screening tests were routine, the Court held the choice of the besylate salt to be obvious:

- the prior art provided not only the means of creating acid addition salts but also predicted the results, which Pfizer merely had to verify through routine testing; and
- [t]he type of experiments used by Pfizer’s scientists to verify the physico-chemical characteristics of each salt were held not to be equivalent to the trial and error procedures often employed to discover a new compound where the prior art gave no motivation or suggestion to make the new compound nor a reasonable expectation of success.⁸⁸

The *Ratiopharm* case appears to be similar to the second half of the invention in *Sanofi*: the choice of a salt and, therefore, a departure from *Sanofi*. Perhaps because the selection of a salt was the result of routine testing from a finite number of options, although the final choice was not immediately apparent (and therefore not obvious), the court did not consider the minimal experiments to meet the threshold of inventiveness.

3.7 The Old Considerations re Obviousness Still Apply

Prior to *Sanofi*, the most recent Canadian comprehensive obviousness checklist was that of Justice Sharlow from *Novopharm Limited v. Janssen-Ortho Inc. and Daiichi Pharmaceutical Co., Ltd.*, the levofloxacin infringement case:⁸⁹

1. the invention,
2. the hypothetical skilled person referred to in the *Beloit* quotation,
3. the body of knowledge of the person of ordinary skill in the art,
4. the climate in the relevant field at the time the alleged invention was made,

⁸⁶ *Ibid.*, at para. 168.

⁸⁷ *Ibid.*, at para. 169.

⁸⁸ The language of the decision suggests that the final salt was not necessarily “obvious” because it was one of many tested to see whether it would work in the circumstances—and thus was not so “self-evident that it would work.”

⁸⁹ 2007 FCA 217 at para. 25.

5. the motivation in existence at the time the alleged invention to solve a recognized problem, and
6. the time and effort involved in the invention.

Secondary factors:

7. commercial success, and
8. meritorious awards.

Although this list is sure to reappear in future cases considering obviousness, Justice Sharlow emphasized that it was not to be slavishly followed:

I emphasize that this list is a useful tool, but no more. It is not a list of legal rules to be slavishly followed; nor is it an exhaustive list of the relevant factors. The task of the trial judge in each case is to determine, on the basis of the evidence, sound judgment and reason, the weight (if any) to be given to the listed factors and any additional factors that may be presented.⁹⁰

In *Garford Pty Ltd. v. Dywidag Systems International, Canada, Ltd.*,⁹¹ as part of a bifurcation motion, the Court found as unconvincing the plaintiff's submission that financial information regarding the defendant's sales was required with respect to the defence of obviousness. Justice Zinn said " 'Commercial success' is no longer a central component of the test for obviousness [citing *Sanofi*], therefore, the financial information which is clearly relevant to the remedy phase is not relevant to the assessment of the obviousness invalidity attack." With respect, Justice Zinn's analysis is likely flawed because *Sanofi* never discarded commercial success as a secondary (and therefore relevant) consideration for determining obviousness. As pointed out by the Federal Court of Appeal in *Corlac*,⁹² *Sanofi* said that an "expansive and flexible approach that would include 'any secondary considerations that [will] prove instructive' will be useful."⁹³

3.8 Conclusions on Obviousness

Each of us knows, in our daily lives, what is or should be obvious to us and others like us. What becomes difficult is when the Court has to look through the eyes of someone else, skilled in a field with which it is not familiar.

The *Windsurfing/Pozzoli* approach is probably applicable to all obviousness cases, but should be applied with some care. We hope that it will be further tailored away from its U.K. statutory roots to evaluate the invention as what is defined by properly construed claims rather than search for the "inventive step" required by the U.K. *Patent Act*.

⁹⁰ *Ibid.* at para. 27.

⁹¹ 2010 FC 581.

⁹² *Corlac*, *supra* note 48 at para. 67, citing *Sanofi*, *supra* note 1 at para. 63.

⁹³ *Sanofi*, *supra* note 1 at para. 63.

Borrowing from our everyday experience, we can discern this general rule:

- a predictable solution may be obvious, but
- an unpredictable outcome cannot be an obvious solution.

Sanofi is merely an articulation of this obvious truth. With respect to inventions won by experimentation⁹⁴ (typically, for example, in the pharmaceutical and chemical arts, where the behaviour of a molecule is relatively unpredictable, and therefore its outcome as a solution is not obvious before experimentation is done) the obvious-to-try test might be useful. In arts, where behaviour is predictable (such as the mechanical and electrical arts and some areas of chemistry and pharmaceuticals), the obvious-to-try test need not be used and traditional obviousness tests can be applied.

⁹⁴ *Ibid.* at para. 69.

