

Chapter 7 Obviousness

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"Necessity is the mother of invention."

Jonathan Swift

"Necessity may be the mother of invention, but play is certainly the father."

Roger von Oech

"I don't think necessity is the mother of invention – invention, in my opinion, arises directly from idleness, possibly also from laziness. To save oneself trouble."

Agatha Christie¹

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Agatha Christie, An Autobiography [1977] quoted in *Anderson et al.* v. Les *Machineries Yvon Beaudoin Inc.* (1994), 58 C.P.R. (3d) 449 per Tremblay-Lamer J. at p. 449.

Executive Summary:

The Windsurfing case approach:

- (1) Identify:
 - (a) the notional "person skilled in the art";
 - (b) the relevant common general knowledge of that person;
- (2) Identify the invention (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?

Indicators of obviousness:

- Motivation:
 - O What were the prejudices for maing the invention?
 - Were others moving in that direction?
 - O What were the prejudices against making the invention?
 - O What was the motivation of the inventor?
- For inventions resulting from experiments: Predictability:
 - o Was it more or less self evident that it ought to work?
- Empirical evidence:
 - o How easy was it for the inventor? Did it take much trial and error?
 - If there was a long felt need, was the invention commercially successful for reasons other than just marketing?
- Was it "crystal clear", "plain as day" or would the person skilled in the art, without any inventive ability, have arrived at the invention "directly and without difficulty"?

The third requirement for a patentable invention is that the invention be "inventive" or "non-obvious".

7.1 Introduction to Obviousness

7.1.1 What does "obvious" mean?

Some courts have described "obvious" as "very plain"², or something arrived at "directly and without difficulty":³

"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 Clapman omnibus of patent law) would, in the light of the state of the art and 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."

7.1.2 What Things are Obvious?

Perhaps the best way of determining what is obvious in the context of a patent is to determine what is obvious in the context of everyday life, and apply the characteristics learned from such an analysis to the context of patents.

For example: The answer to the question "What is 2 + 2?" is obvious, likely because (a) we've solved that problem before and we remember (analogous to anticipation) or (b) because we are using common skills (the ability to add two numbers) in a routine way to come up with the solution.

Then is the answer to the question "What is 248 + 786?" also obvious? Although it takes a bit more work, the same mechanical arithmetic skills (and no creative skills) are used. Likewise, the solution to that problem is probably obvious. Is the same true when much larger numbers are being added together? Probably, yes. Although the solution is not known before performing the calculation, only routine skills are being brought to bear.

The problem comes in knowing how far the analogy can be stretched. From these mathematical analogies, can we formulate a general rule that all products of routine tasks are obvious? No. This is because routine experiments can sometimes reveal unexpected or surprising results. There is nothing unexpected or surprising in the summation of numbers.

What is obvious also changes as human knowledge advances. What is the answer to this question: "What is the volume (being the space occupied by) your hand, as measured in cubic centimeters?" Prior to Archimedes discovering, in his "Eureka!" moment, that his body

General Tire & Rubber Co. v. Firestone Tyre & Rubber Co., Ltd., [1972] R.P.C. 457 at pp. 497-498

Xerox of Canada Ltd. et al. v. IBM Canada Ltd., (1977), 33 C.P.R. (2d) 24 (F.C.T.D. per Collier J.) at p. 53

⁴ Beloit Canada Ltd. v. Valmet Oy (1986), 8 C.P.R. (3d) 289 (F.C.A. per Hugessen J.A.) at p. 294

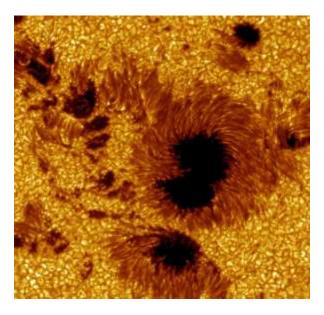
displaced an equal volume of water in his bath, the problem of calculating the volume of irregularly shaped objects was difficult if not impossible. Today, with knowledge of Archimedes principle, it is obvious.

7.1.3 The sunspot analogy

The "2+2" example given above is an example of coming up with an obvious solution by using everyday skills. In the area of patent law, our arithmetic skills are considered to be in our "personal toolbox" of what is referred to as "common general knowledge": facts or skills that we all have available to use.

A further example can be the case of the door that closes by itself. As a child, we learned that we can keep our bedroom door open by putting a book in front of it to keep it from otherwise naturally swinging closed. As an adult, confronted with a spring-loaded door, we might try to use a book to keep that door open, recycling a solution we used beforehand. If that doesn't work to keep the door open, the obvious solution is to combine our prior solution ("use a book to keep a door open) with some common general knowledge ("bigger books weigh more than smaller books" or "more books weigh more than lighter books") to arrive at the solution of "use a bigger book" or "use several books". In engineering, such an approach is sometimes referred to as "the brute force approach": if something doesn't work, make it bigger.

Thus around every old solution, we can imagine a halo of obvious solutions that are a combination of our old solution and our common general knowledge. This is analogous to a sunspot: the black central region (the umbra in astronomical parlance) being our prior solution and the grey halo surrounding the umbra (the penumbra) being the region occupied by the obvious solutions nearby. Stretching the analogy further, outside of the penumbras, in the yellow region, is what is beyond the obvious: the inventive.



In his book, "Where Good Ideas Come From – The Natural History of Innovation", ⁵ author Peter Johnson refers to the area immediately surrounding our current state of the art as the

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⁵ Penguin Group US, October 2010.

"immediately possible" because all the components are available to make the next thing happen.

7.1.4 Use of Prior Art that is not in the Common General Knowledge

The notional person of ordinary skill in the art ("posita") is not limited to mosaicing a single piece of prior art with common general knowledge. The posita may also combine art that is public but not commonly known, but the court should examine closely as to why such a combination would be "obvious"?

If one piece of prior art refers to another, it may be obvious to refer to the second document.⁶ Likewise, if one or both documents would be found in a literature search of the kind a skilled person would routinely carry out before attempting to find a solution to the problem the patent addresses.⁷

Sometimes art arising after the filing date can be considered as evidence of what was commonly known or what was part of the state of the art at the relevant time.⁸

7.1.5 Analogous solutions: Taking ideas from other fields

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7.1.6 Obviousness in Patent Law

Originally, the requirement that a patentable invention be "inventive" (or its counterpart: "non-obvious") was judge-created. Without it, anything "new" and "useful" would be patentable, even if it was merely a routine improvement over the prior art.

Although section 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 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".

The concept makes sense: if someone merely makes an obvious change to something that is old, one should not be permitted a patent for such obvious variants of what was old. This is particularly so if the skilled person uses only the "tools of his or her trade", namely the common general knowledge known to all in the field of the alleged invention.

Scinopharm Taiwan Ltd. v. Eli Lilly & Co. [2009] EWHC 631 (Pat. per Kitchin, J.), [2009] All E.R. (D) 282 (Mar) at paras. 83 & 84, quoted in Eli Lilly and Company et al v. Apotex Inc. 2009 FC 991 (F.C. per Gauthier J.) at para. 419.

Scinopharm Taiwan Ltd. v. Eli Lilly & Co. [2009] EWHC 631 (Pat. per Kitchin, J.), [2009] All E.R.
 (D) 282 (Mar) at paras. 83 & 84, quoted in Eli Lilly and Company et al v. Apotex Inc. 2009 FC 991 (F.C. per Gauthier J.) at para. 419.

⁸ Eli Lilly and Company v. Apotex Inc. 2009 FC 991 (F.C. per Gauthier J.) at para. 421.

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As the court said in *Diversified Products* v. *Tye-Sil*⁹:

There is no specific section on the *Patent Act* relating to the requirement for inventiveness or inventive ingenuity, but it has been held and is no longer questioned that by the use of the words "invention" and "inventor" throughout the Act, inventiveness or inventive ingenuity is required to obtain a valid patent…"

Lord Herschell introduced the concept in the late 1800's in *American Braided Wire*¹⁰ and in *Vickers* v. *Siddell*¹¹.

In the *Crosley Radio* case, the Supreme Court of Canada adopted the standard previously adopted by the House of Lords which required "a degree of ingenuity" to be present.¹²

Although it has been a component of U.K. statutory patent law for some time¹³, it was only added to the Canadian *Patent Act* as <u>s. 28.3</u> in 1993.¹⁴

"The Supreme Court of Canada has recently said that to be valid, a claimed invention must be new, that is, not previously disclosed, whether or not it was inventive; it must be useful; and it must possess inventive ingenuity. (*Biolyse Pharma Corp.* v. *Bristol-Myers Squibb Co.*, [2005] 1 S.C.R. 533 at para. 1, 2005 SCC 26). The patent monopoly should be purchased with the hard coinage of new, ingenious, useful and unobvious disclosure (*Apotex Inc.* v. *Wellcome Foundation Ltd.*, [2002] 4 S.C.R. 153 at para. 37, 2002 SCC 77). The requirement that a patent claim which is "novel" has sometimes been considered by the courts in terms of its antithesis was the claimed invention "anticipated".

"that the invention, so far as claimed in any claim of the complete specification, is obvious and does not involve any inventive step having regard to what was known or used before the priority dare of the claim in the United Kingdom."

Diversified Products Corp. v. Tye-Sil Corp. et al (1991), 35 C.P.R. (3d) 350 (F.C.A.)

^{10 (1889) 6} R.P.C. 518 at 528

¹¹ (1890) 7 R.P.C. 292 at 305

Crosley Radio Corp. v. Canadian General Electric Co., [1936] S.C.R. 551 (S.C.C. per Rinfret J.) at p. 555-556

As of 1972 s. 32(1)(f) of the U.K. *Patent Act* provided:

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.

Similarly, the requirement of inventive ingenuity has sometimes been considered by the courts as being of its antithesis "obviousness"." ¹⁵

But how do you define that "extra something"? It is not based on simplicity: some of the best inventions are simple. 16

"Inventiveness, however, may be present notwithstanding that there was no difficulty putting an idea into effect once it was conceived. An invention is not to be considered obvious because of its simplicity." ¹⁷

It has been difficult to characterize. Some judges have simply said, it can't be defined but "I knows it when I sees it":

"Nobody, however, has told me, and I do not suppose anybody ever will tell me, 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?" ¹⁸

A wise observation was made by Lord Justice Sachs in the *General Tire* ¹⁹ case:

"We agree, however, with what was said by Diplock, L.J. (as he then was) and Willmer, L.J. in the *Johns-Manville* case [1967] R.P.C. 478 at 493 and 496 deprecating "coining" phrases which may later be suggested to be of general application. "Obvious" is, after all, a much-used word and it does not seem to us that there is any need to go beyond the primary dictionary meaning of "very plain"."

Justice Hughes also deprecated such phrases as "worth a try" and "directly and without difficulty" and "routine testing" (and his deprecation was approved by the Federal Court of

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¹⁵ 2006 FC 1234 (F.C. per Hughes J.) <u>online</u> at para. 99; aff'd without discussion of this point *Novopharm Limited* v. *Janssen-Ortho Inc. and Daiichi Pharmaceuticals Co., Ltd.* 2007 FCA 27 (F.C.A per Sharlow J.A., Nadon and Malone JJ.A.) <u>online</u>

Electrolier Manufacturing Company Ltd. v. Dominion Manufacturers Limited [1934] S.C.R. 436 (per Rinfret, J.) at p. 441

Bayer v. Apotex Inc. (1995), 60 C.P.R. (3d) 58 at 80-81 (Ont. Gen Div. per Lederman J.) affd (1998), 82 C.P.R. (3d) 526 (Ont. C.A.) at p. 84 referring to *The King* v. *Uhlemann Optical Co.* (1949), 11 C.P.R. 26 at p. 46, [1950] Ex.C.R. 142, 10 Fox Pat. C. 24; affirmed 15 C.P.R. 99 at pp. 105-6, [1952] 1S.C.R. 143, 12 Fox Pat.C. 65

¹⁸ The King v. Uhlemann Optical Co. [1952] 1 S.C.R. 143, 15 C.P.R. 99 (S.C.C. per Rinfret J.) at p. 105.

General Tire & Rubber Company v. Firestone Tyre & Rubber Company Limited [1972] R.P.C. 457
 (H.L. per Sach L.J., Buckley and Orr concurring) at p. 497

Janssen-Ortho Inc. and Daiichi Pharmaceutical Co., Ltd. v. Novopharm Limited 2006 FC 1234 (F.C. per Hughes J.), T-2175-04, October 17, 2006, at para. 113.6

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Appeal²¹) but as will be seen below, some have nevertheless been used by the Supreme Court of Canada as tests of obviousness and must be applied and used by counsel accordingly.

7.1.6.1 The New Patent Act Statutory Requirement

Patents that were applied for after October 1, 1989²² are governed by s. 28.3 of the *Patent Act* which states:

- "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 (as will be discussed further in Chapter 7.4 below) 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 discussed in *Sanofi.*²³

7.2 Question of Fact

Obviousness is a question of fact.²⁴ Obviousness means that while the claimed invention may not have been presumably known, it is nonetheless not something that a person can monopolize since it is something that a person skilled in the art would have been expected to come up with in any event.²⁵

Janssen-Ortho Inc. v. Novopharm Ltd. 2007 F.C.A. 217 (F.C.A. per Sharlow J.A., Malone and Nadon J.J.A., concurring) at para. 28.

²² Patent Act s. 78.4 & 78.5.

²³ [2008] 3 S.C.R. 265, 2008 SCC 61.

General Tire & Rubber Co. v. Firestone Tyre & Rubber Co., Ltd., [1972] R.P.C. 457 at pp. 504; Martinray Industries v. Les Fabricants National Dagendor (1991), 41 C.P.R. (3d) 1 (F.C.T.D.) at p. 30; Imperial Tobacco Ltd. v. Rothmans Benson & Hedges Inc. (1993), 47 C.P.R. (3d) 188 (FC.A.) at 198, [1993] F.C.J. No. 135 (QL).

^{25 2006} FC 1234 (F.C. per Hughes J.) online at para. 100; aff'd without discussion of this point Novopharm Limited v. Janssen-Ortho Inc. and Daiichi Pharmaceuticals Co., Ltd. 2007 FCA 27 (F.C.A per Sharlow J.A., Nadon and Malone JJ.A.) online

Although one Court said it is not a matter for evidence or expert witnesses,²⁶ much effort and time is spent by experts on that question (See Chapter 7.14 below).

7.3 Various ways of defining Obviousness/Inventiveness

In has been difficult for the Court to express a test for "inventiveness".

7.3.1 Proper Subject Matter

Some have differentiated on the basis of whether the concept is "proper subject matter", for example, combinations are patentable but aggregations are not:

Was the invention a new combination of steps or ideas, or simply a collection of old ones?²⁷

7.3.2 The inventive step

Inventiveness has been described as a "scintilla" ²⁸, a "spark" ²⁹ – sounding somewhat smaller than the light bulb that appears over the heads of creative cartoon characters.

Sometimes it was defined as a quantum leap over the prior art, without quantifying the quantum.

It has often being described as an inventive step,³⁰ an apocryphal illustration of which is given below having a height, presumably, of at least one scintilla.

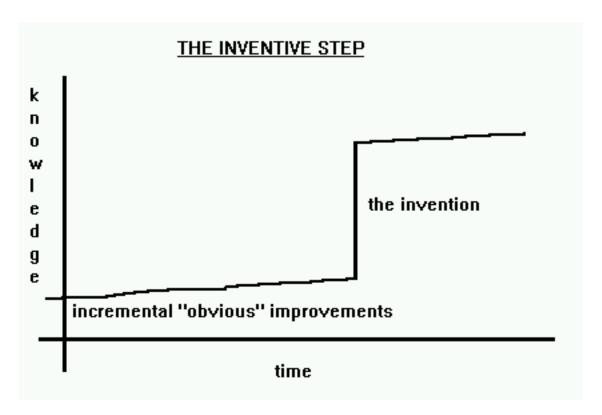
Technograph Printed Circuits Ltd. v. Mills & Rockley (Electronics) Ltd., [1969] R.P.C. 395 (C.A. per Harman, L.J.) at pp. 404-405.

General Tire & Rubber Co. v. Firestone Tyre & Rubber Co., Ltd., [1972] R.P.C. 457 at pp. 497-498

²⁸ Samuel Parkes & Co. Ltd. v. Crocker Bros. Ltd. (1929), 46 R.P.C. 248 (per Tomlin J.) at p. 248.

Martinray Industries v. Les Fabricants National Dagendor (1991), 41 C.P.R. (3d) 1 (F.C.T.D.) at <u>p. 30</u>

Canadian Gypsum Co. Ltd. v. Gypsum, Lime & Alabastine Canada Ltd., [1931] Ex. C.R. 180 (Ex. Ct. per Maclean J.) at p. 187



7.3.3 The path

Other tests have focused on the path one would have had to have taken to arrive at the invention. For example, in *Savage v. Harris & Sons* (Apotex tab 45) at p. 370:

"Did the invention lie so much out of track with what was known at the time that it would not have suggested itself to someone who turned their mind to the problem?"³¹

Others look at the path taken by the inventor: 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.³²

Justice Collier said in the Xerox case:

"... the route to obviousness must be a flagstone path, plainly perceptible in either the dark or the light." 33

³¹ Savage v. Harris & Sons (1896), 13 R.P.C. 364 (per Lopes, L.J.) at p. 370

Janssen-Ortho Inc. and Daiichi Pharmaceutical Co., Ltd. v. Novopharm Limited Federal Court per Hughes J., T-2175-04, October 17, 2006, 2006 FC 1234 at para. 113.10

Xerox of Canada Ltd. et al. v. IBM Canada Ltd., (1977), 33 C.P.R. (2d) 24 (F.C.T.D. per Collier J.) at p. 62; Beloit Canada Ltd. v. Valmet Oy (1986), 8 C.P.R. (3d) 289 (F.C.A. per Hugessen J.A.) at p. 294

As discussed below, the Cripps question refers to the skilled person being led "directly and without difficulty."³⁴

Other Courts have commented that the path taken by the inventor is irrelevant. In the *I.G. Farbenindustrie*³⁵ case, Maugham J. stated:

"The Court is concerned, so far as subject matter is concerned, only with the results. The invention must, of course, add something of a substantial character to existing knowledge; but the Courts do not inquire into the way in which the conquest was achieved. If the language of metaphor may be used, the citadel may be captured either by a brilliant coup-de-main or by a slow and laborious approach by sap and mine according to the rules of the art; the reward is the same. The language used by eminent judges in analogous cases supports the same view (see *Taylor & Scott v. Annand*, (1901) 18 R.P.C. 53, at pp. 62-3; *Lancashire Explosives Co. Ld. v. The Roburite Explosives Co. Ltd.*, (1895) 12 R.P.C. 470 at p. 475)."

7.3.4 The creator's mind

Other tests focus on the mind that created it – Was it the creation of an inventive mind?³⁷

As with the size of the inventive step, it has sometimes been ambiguously defined:

"There must be a substantial exercise of the inventive power or inventive genius, though it may in cases be very slight." 38

The more pedestrian converse is: "Any fool could have done that." 39

The test that has been generally accepted for inventiveness or non-obviousness is a negatively phrased, convoluted hypothetical. It is a more articulate version of "Any fool could have done that."

The "Cripps Question" (discussed in more detail below) is: **Would a non-inventive mind have though of it?**

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Beloit Canada Ltd. v. Valmet Oy (1986), 8 C.P.R. (3d) 289 (F.C.A. per Hugessen J.A.) at p. 294

³⁵ I.G. Farbenindustrie A.G.'s Patent, [1930] 47 R.P.C. 289 (Ch. D per Maugham J.)

ibid, at p. 322.

Canadian Gypsum Co. Ltd. v. Gypsum, Lime & Alabastine Canada Ltd., [1931] Ex. C.R. 180 (Ex. Ct. per Maclean J.) at p. 187

Canadian General Electric Co. v. Fada Radio, Ld. (1930) A.C. 97 at 101 per Lord Warrington of Clyffe approving the opinion of Maclean J. in [1927] Ex. C.R. 134 and reversing [1928] S.C.R. 239.

³⁹ Beloit Canada Ltd. v. Valmet Oy (1986), 8 C.P.R. (3d) 289 (F.C.A. per Hugessen J.A.) at p. 293

If the answer is "No", then the purported invention is inventive or non-obvious and patentable. If the answer is "Yes", then the purported invention was obvious and not patentable.

It should be noted that an examination of how the inventor came up with the alleged invention is not always useful. 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.⁴⁰

7.4 Obviousness Checklist

Judges dislike checklists, or say they do, but they keep making them.

In *Sanofi*,⁴¹ Mr. Justice Rothstein adopted the United Kingdom courts' four-step approach to determine obviousness as expressed in the *Windsurfing* case,⁴² and as updated in the *Pozzoli* case⁴³:

- (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?⁴⁴

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:⁴⁵

1. The invention

Janssen-Ortho Inc. and Daiichi Pharmaceutical Co., Ltd. v. Novopharm Limited Federal Court per Hughes J., T-2175-04, October 17, 2006, 2006 FC 1234 at para. 113.6

Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd., [1985] R.P.C. 59.

⁴⁴ Apotex Inc. v. Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265, 2008 SCC 61, para. 67.

⁴¹ [2008] 3 S.C.R. 265, 2008 SCC 61.

⁴³ Pozzoli SPA v. BOSO SA, [2007] F.S.R. 37, [2007] ENCA Civ 588.

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

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

Secondary factors

- 7. Commercial success
- 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." ⁴⁶

If this checklist is mapped onto the Sanofi/Windsurfing list, we have:

	Sanofi/Windsurfing		Novopharm v. Janssen-Ortho
1(a)	Identify the notional "person skilled in the art";	2	The hypothetical skilled person referred to in the <i>Beloit</i> quotation
1(b)	Identify the relevant common general knowledge of that person;	3	The body of knowledge of the person of ordinary skill in the art
2	Identify the inventive concept of the claim in question or, if that cannot readily be done, construe it;	1	The invention
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;		

⁴⁶

	Sanofi/Windsurfing		Novopharm v. Janssen-Ortho
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?		
		4	The <u>climate in the relevant field</u> at the time the alleged invention was made.
		5	The motivation in existence at the time the alleged invention to solve a recognized problem
		6.	The <u>time and effort</u> involved in the invention
			Secondary Factors
		7	Commercial success
		8	Meritorious awards

Each of these topics is discussed in separate sections below, linked to the sections of this Chapter by the hyperlinks in the table above.

7.5 Setting up the Question: The Windsurfing Approach

In its landmark late-2008 decision in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*,⁴⁷ the Supreme Court of Canada refined the test for obviousness under Canadian patent law and said that "[i]t will be useful in an obviousness inquiry to follow the four-step approach" taken in the *Windsurfing* case,⁴⁹ and as updated in the *Pozzoli* case⁵⁰

Apotex Inc. v. Sanofi-Synthelabo Canada Inc. 2008 SCC 61 at para. 67, quoted in Corlac Inc. et al v. Weatherford Canada Ltd., 2011 FCA 228 (F.C.A. per Layden-Stevenson J.A., Nadon & Evans JJ.A. concurring) at para. 67.

⁴⁷ 2008 SCC 61.

Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd., [1985] R.P.C. 59.

⁵⁰ Pozzoli SPA v. BOSO SA, [2007] F.S.R. 37, [2007] ENCA Civ 588.

- (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?⁵¹

In adopting the *Windsurfing* approach, the Court did not establish a compulsory legal test. To the contrary, its approval of existing jurisprudence warned against adopting an "overly rigid rule that limits the obviousness inquiry." Rothstein J. explained 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".⁵² The "correctness of a decision upon an issue of obviousness does not depend upon whether or not the decider has paraphrased the words of the Act" or made use of "some particular verbal formula".⁵³ Rather, an "expansive and flexible approach that would include 'any secondary considerations that [will] prove instructive' will be useful".⁵⁴

Failure to explicitly follow the structure of the *Windsurfing* approach does not, in and of itself, constitute an error of law.⁵⁵

7.5.1 Application of the Sanofi Approach to New Patent Act cases

The Federal Court of Appeal implicitly approved of the use of the "obvious to try" analysis of Sanofi to "New Act" patents in Apotex v. Pfizer⁵⁶ (which related to a New Act patent) because

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⁵¹ Apotex Inc. v. Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265, 2008 SCC 61, para. 67.

Apotex Inc. v. Sanofi-Synthelabo Canada Inc. 2008 SCC 61 at para. 63, quoted in Corlac Inc. et al v. Weatherford Canada Ltd., 2011 FCA 228 (F.C.A. per Layden-Stevenson J.A., Nadon & Evans JJ.A. concurring) at para. 67.

Apotex Inc. v. Sanofi-Synthelabo Canada Inc. 2008 SCC 61 at para. 61, quoted in Corlac Inc. et al v. Weatherford Canada Ltd., 2011 FCA 228 (F.C.A. per Layden-Stevenson J.A., Nadon & Evans JJ.A. concurring) at para. 67.

Apotex Inc. v. Sanofi-Synthelabo Canada Inc. 2008 SCC 61 at para. 63, quoted in Corlac Inc. et al v. Weatherford Canada Ltd., 2011 FCA 228 (F.C.A. per Layden-Stevenson J.A., Nadon & Evans JJ.A. concurring) at para. 67.

Corlac Inc. et al v. Weatherford Canada Ltd., 2011 FCA 228 (F.C.A. per Layden-Stevenson J.A., Nadon & Evans JJ.A. concurring) at para. 68.

Apotex Inc. v. Pfizer Canada Inc. 2009 FCA 8 (F.C.A. per Noël J.A., Létourneau and Blais JJ.A. concurring)

the trial judge "... rejected the contention that the invention was obvious based on mere possibilities or speculation and looked for evidence that the invention was more or less self-evident" noting that the *Sanofi* "obvious to try" test is not the same as the U.K. "worth a try" test which was "based on the possibility that something might work." ⁵⁸

The *Sanofi* "obvious to try" test was also applied to a New *Act* patent in *Abbott* v. *Canada* (*Health*)⁵⁹ however, contrast Justice Hughes' (in my opinion, incorrect) paraphrasing of the *Sanofi* test:

"The question for obviousness purposes is that as stated by the Supreme Court of Canada in *Sanofi* at paragraph 66, was 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." ⁶⁰

Apotex Inc. v. Pfizer Canada Inc. 2009 FCA 8 (F.C.A. per Noël J.A., Létourneau and Blais JJ.A. concurring) at para. 30. At paragraph 33, the court noted:

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

At paragraph 35:

"The Federal Court Judge goes on to confirm that the most that he could gather from the prior art at the priority date was that using orally administered sildenafil to treat ED was "worth a try" ... In so saying, the Federal Court Judge equates the expression "worth a try" with "a possibility worth exploring" as Dr. Ringrose had characterized the matter when he suggested that sildenafil be tried as a treatment for impotence (Reasons, para. 61). "

At paragraph 37:

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

Apotex Inc. v. Pfizer Canada Inc. 2009 FCA 8 (F.C.A. per Noël J.A., Létourneau and Blais JJ.A. concurring) at paras. 45: and 28 where he said:

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

⁵⁹ 2008 FC 1359

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Abbott Laboratories v. Canada (Health) 2008 FC 1359 (F.C. per Hughes J.) at para. 96; aff'd but not discussed on appeal at Abbott Laboratories v. Canada (Health) 2009 FCA 94 (F.C.A. per Richard C.J., Pelletier and Layden-Stevenson JJ.A. concurring). The only issue was whether a particular crystal form was sufficiently soluble so as to provide therapeutic use [para. 97]. After having found the patent to be anticipated, the Court held that it was self-evident that a person skilled in the art would test the solubility of any newly identified crystal to determine if it was

The "obvious to try" test is not "to see if it would work" but to use it, rather, because it is more or less self-evident (obvious) that it will work.

Like *Sanofi*, the olanzapine case⁶¹ related to another selection patent. The Court adopted the Sanofi approach:

"At the fourth stage of the Windsurfing approach, the issue of "obvious to try" arises. To find that an invention was "obvious to try", and therefore invalid for obviousness, *Sanofi* teaches "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" (para. 66). The "obvious to try" inquiry will be appropriate in areas of endeavour where advances are often won by experimentation, such as in the pharmaceutical industry. A non-exhaustive list of factors to be taken into consideration is proposed at paragraph 69 of Sanofi.

- 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 trials would not be considered routine?
- 3. Is there a motive provided in the prior art to find the solution the patent addresses?

7.5.2 1(a) person skilled in the art

It is necessary to identify the skills possessed by the hypothetical person of ordinary skill in the art.⁶⁴

The hypothetical non-inventor of the Cripps question is no ordinary person. He or she (the skilled worker on the Clapham omnibus of Patent Law)⁶⁵ has been deemed by the Courts to have certain skills and lack others, to have certain knowledge, and access to other knowledge.

soluble at a rate sufficient to give therapeutic utility [para. 99] and, if it were necessary to do so, it would find that claim 5 of the '527 patent was obvious [para. 100].

- Eli Lilly Canada Inc. et al v. Novopharm Limited, 2010 FCA 197 (Layden-Stevenson J.A., Nadon and Sharlow JJ.A. concurring) at paras. 54-64.
- Eli Lilly Canada Inc. et al v. Novopharm Limited, 2010 FCA 197 (Layden-Stevenson J.A., Nadon and Sharlow JJ.A. concurring) at paras. 55.
- Eli Lilly Canada Inc. et al v. Novopharm Limited, 2010 FCA 197 (Layden-Stevenson J.A., Nadon and Sharlow JJ.A. concurring) at paras. 55.
- Novopharm Limited v. Janssen-Ortho Inc. and Daiichi Pharmaceuticals Co., Ltd. 2007 FCA 27 (F.C.A per Sharlow J.A., Nadon and Malone JJ.A.) at para. 25(1). online
- ⁶⁵ Beloit Canada Ltd. v. Valmet Oy (1986), 8 C.P.R. (3d) 289 (F.C.A. per Hugessen J.A.) at 294

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The Court must first determine to whom the patent is addressed. The court must first examine and understand the prior art. Then the court must ask, based on this, to whom would the invention be obvious?⁶⁶ Of course, it would be addressed to some skilled worker in the art of the patent.

It would not make sense to ask if the invention would have been obvious to an inventor, because they are, by definition, inventive. 67 Nor does it make sense to ask whether the invention would be obvious to the judge today. 68

The Court, in considering the issue of obviousness, should place itself in the position of the notional technician, skilled in the art, who might have been trying to solve the problem prior to the alleged invention.⁶⁹

This hypothetical skilled person should:

- be ordinary⁷⁰
- lack imagination,⁷¹ inventiveness or intuition⁷²
- have no benefit of foresight and no assurance of success.⁷³ He has merely a sense of what possibilities may hold better potential for yielding results.⁷⁴

Mr. Justice Hugessen summarized this person's characteristics most poetically in the *Beloit* case:

"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

67 Beloit Canada Ltd. v. Valmet Oy (1986), 8 C.P.R. (3d) 289 (F.C.A. per Hugessen J.A.) at p. 294

Rado v. Tye [1969] F.S.R. 563 (Lord Upjohn) at p. 565-6

Eli Lilly & Co. v. Marzone Chemicals Ltd. (1977) 37 C.P.R. (2d) 3 (F.C.T.D. per Gibson J.) at pp. 32-33; aff'd 37 C.P.R. (2d) 37 (F.C.A.)

Eli Lilly & Co. v. Marzone Chemicals Ltd. (1977) 37 C.P.R. (2d) 3 (F.C.T.D. per Gibson J.) at pp. 32-33; aff'd 37 C.P.R. (2d) 37 (F.C.A.)

Xerox of Canada Ltd. et al. v. IBM Canada Ltd.(1977), 33 C.P.R. (2d) 24 (per Collier, J.) at p. 53

Beecham Canada Ltd. v. Proctor & Gamble Co. (1982), 61 C.P.R. (2d) 3 (F.C.A. per Urie, J.) at <u>p. 27</u>

⁷² Beloit Canada Ltd. v. Valmet Oy (1986), 8 C.P.R. (3d) 289 (F.C.A. per Hugessen J.A.) at p. 294

Eli Lilly & Co. v. Marzone Chemicals Ltd. (1977) 37 C.P.R. (2d) 3 (F.C.T.D. per Gibson J.) at pp. 32-33; aff'd 37 C.P.R. (2d) 37 (F.C.A.)

Eli Lilly & Co. v. Marzone Chemicals Ltd. (1977). 37 C.P.R. (2d) 3 (F.C.T.D. per Gibson J.) at pp. 32-33; aff'd 37 C.P.R. (2d) 37 (F.C.A.)

Clapman omnibus of patent law) would, in the light of the state of the art and 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."⁷⁵

7.5.3 1(b) relevant common general knowledge

The common knowledge of the hypothetical person of ordinary skill in the art includes what the person may reasonably be expected to know and to be able to find out. The hypothetical skilled person is assumed to be reasonably diligent in keeping up with advances in the field to which the patent relates. The presumed knowledge of the hypothetical skilled person undergoes continuous evolution and growth. Not all knowledge is found in print form. On the other hand, not all knowledge that has been written down becomes part of the knowledge that a person of ordinary skill in the art is expected to know or find. The presumed to know or find. The presumed knowledge that a person of ordinary skill in the art is expected to know or find.

The notional skilled worker is deemed to have certain knowledge:

A. "common general knowledge" – the normal skill and knowledge that workers in the field or fields of the patent ought to know⁷⁸ or ought to be able to find out⁷⁹ based on their general training and experience.

It is not a memory test. Skilled people may be permitted to refer to standard texts or resources to "look things up". 80

B. "public knowledge" – publicly available information that may not be generally known but which could be found by the public.

This knowledge forms the starting point from which this notional person departs: Was he invention obvious based on this information that was available at the relevant time?⁸¹ (See accessibility, below)

⁷⁵ Beloit Canada Ltd. v. Valmet Oy (1986), 8 C.P.R. (3d) 289 (F.C.A. per Hugessen J.A.) at p. 294

Whirlpool Corp. v. Camco Inc. 2000 SCC 67; online; (2001) 9 C.P.R. (4th) 129 (S.C.C. per Binnie J.) at para. 74.

Novopharm Limited v. Janssen-Ortho Inc. and Daiichi Pharmaceuticals Co., Ltd. 2007 FCA 27 (F.C.A per Sharlow J.A., Nadon and Malone JJ.A.) online at para. 25.

The General Tire & Rubber Company v. The Firestone Type and Rubber Company Limited and Others, [1972] R.P.C. 457 at pp. 499-500

Novopharm Limited v. Janssen-Ortho Inc. and Daiichi Pharmaceuticals Co., Ltd. 2007 FCA 27 (F.C.A per Sharlow J.A., Nadon and Malone JJ.A.) at para. 25(2). online affirming 2006 F.C. 1234.

Novopharm Limited v. Janssen-Ortho Inc. and Daiichi Pharmaceuticals Co., Ltd. 2007 FCA 27 (F.C.A per Sharlow J.A., Nadon and Malone JJ.A.) at para. 25(3). online affirming 2006 F.C. 1234.

Sakharam D. Mahurkar v. Vas-Cath of Canada Limited et al. (1988), 18 C.P.R. (3d) 417 (F.C.T.D. per Strayer J.) at p. 432

7.5.3.1 Elsewhere: mosaicing

When dealing with obviousness, it is permissible to "mosaic" the prior art, that is, to combine prior art references to create the invention. For example, where A and B are prior art:

A + B =the invention

Although mosaicing is permitted, it is not always persuasive, particularly where features of the invention can be found in the prior art, but never in one place nor combined in a way suitable for the invention.⁸² Either the documents themselves, or the art, may provide a motivation for combining the prior art references, or, on the other hand, direct one away from combining them (See "Motivation", below).

Caution should be exercised by someone attacking a patent to limit the number of prior art references that need to be combined: the more that are necessary, the less obvious and less direct the path to the invention.

The uninventive skilled technician is supposed to be able to assimilate the contents of scores of specifications, ⁸³ however, the Court can question the ease with which the references would be found or how relative importance would be applied to them. (See "<u>accessibility</u>", below).

7.5.3.2 common general knowledge

The notional skilled worker is considered to posses the "common general knowledge". It is by the standards of the common general knowledge of someone skilled in the art that one tests whether the invention was obvious or not.⁸⁴

What does the literature teach about attempts to try the invention before or to use the patented method towards the intended solution? If there is no evidence that anyone had tried this before, then there is not evidence that there is common general knowledge which would have made the invention obvious to the relevant worker.⁸⁵

The skilled worker is not be considered to have knowledge of every publication affecting the relevant branch of industry or art simultaneously in his or her mind. The person skilled in the art should be presumed to know what a real person competently skilled would know without burdening him with constructive notice of other things.⁸⁶

Sakharam D. Mahurkar v. Vas-Cath of Canada Limited et al. (1988) 18 C.P.R. (3d) 417 (F.C.T.D. per Strayer J.) at p. 435

Technograph Printed Circuits Ltd. v. Mills & Rockley (Electronics) Ltd., [1972] R.P.C. 346 (per Lord Reid) at p. 355

General Tire & Rubber Co. v. Firestone Tyre & Rubber Co., Ltd., [1972] R.P.C. 457 at pp. 481-482

Technograph Printed Circuits Ltd. v. Mills & Rockley (Electronics) Ltd., [1969] R.P.C. 395 (per Sachs, L.J.) at pp. 407-408

General Tire & Rubber Co. v. Firestone Tyre & Rubber Co., Ltd. [1972] R.P.C. 457 at pp. 499-500

Common general knowledge can include, among other things, patent specifications and widelyread publications. Patent specifications generally are not common knowledge unless they are so well known in the relevant industry that they form part of the knowledge.⁸⁷

For something to be common general knowledge, it is not enough that it appear in a scientific journal, be widely circulated or even be widely read by the relevant community. It must also be generally regarded as a good basis for further action.⁸⁸

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.⁸⁹

The state of common general knowledge at the relevant time is a question of fact based on evidence. The burden of adducing this evidence is upon the party attacking the patent. 90

7.5.3.3 public knowledge

The notional skilled workman may also possess "public knowledge": all publications that would have been available to the public at the time of the invention. This "universal library" is a two-edged sword: damaging prior art combined with the "common general knowledge" can destroy the inventiveness of an invention, even if the inventor never has access to the specific prior art. At the same time, the Courts can view with scepticism the likelihood that the notional skilled worker would find and apply the specific prior art reference out of the mountain of information available.

Not all knowledge that has been written down becomes part of the knowledge that a person of ordinary skill in the art is expected to know or find. 91

Individual patent specifications and their contents do not normally form part of the relevant common general knowledge, though some may be. 92

General Tire & Rubber Company v. Firestone Tyre & Rubber Company Limited, [1971] F.S.R. at pp. 439-440

The General Tire & Rubber Company v. The Firestone Type and Rubber Company Limited and Others, [1972] R.P.C. 457 at pp. 482-483

Janssen-Ortho Inc. and Daiichi Pharmaceutical Co., Ltd. v. Novopharm Limited Federal Court per Hughes J., T-2175-04, October 17, 2006, 2006 FC 1234 at para. 113.3

The General Tire & Rubber Company v. The Firestone Type and Rubber Company Limited and Others [1972] R.P.C. 457 at p. 484

Janssen-Ortho Inc. v. Novopharm Ltd., 2007 FCA 217 (F.C.A. per Sharlow J.A.), 366 N.R. 290, at para. 25 (citing factors developed by Justice Hughes in Janssen-Ortho Inc. v. Novopharm Ltd., 2006 FC 1234, 301 F.T.R. 166; quoted in Eli Lilly and Company et al v. Apotex Inc., 2009 F.C. 991 (F.C. per Gauthier J.) at para. 99.

7.5.3.4 can't focus on selected prior art in isolation

The prior art will contain the chaff as well as the relevant art.

One cannot assess obviousness in light of only a selected group of publications rather than the whole of the relevant prior art. The entire prior art may suggest a different result than would the carefully-selected prior art having the invention in mind.⁹³

A defendant attacking a patent will try to limit the prior art to a few publications. A plaintiff defending a patent should point to other (equally accessible) prior art which takes the reader away from the direction taken by the invention and to all other information dredged up by the defendant in efforts to find the selected prior art.

7.5.3.5 accessibility

In the case of "public knowledge", weight can be given to it according to its accessibility and the efforts expended to find it. The notional worker is expected to have access to information available as the result of reasonably prudent searches of public archives. ⁹⁴ The search would be like those done by research groups employed by large-scale concerns. The extent of the appropriate search is a question of fact in each case. ⁹⁵

It seems bizarre that the notional skilled worker would have available every publicly available document, however old, in whatever language, and wherever located. It seems a contradiction to assume that a discarded scrap of paper buried in some archive should render an invention obvious. It is somewhat artificial to assume that each patent specification for the last 50 years resting on a dusty patent office shelf in any country is part of the relevant public knowledge. Nevertheless, that is the test.

The test is based on what was available to the unimaginative skilled technician at the time. If prior activities were not publicly available, such as experiments performed by individuals that were not made public, they would not form part of the knowledge of the competent addressee.⁹⁸

- The General Tire & Rubber Company v. The Firestone Type and Rubber Company Limited and Others, [1972] R.P.C. 457 at pp. 482-483 quoted in Eli Lilly and Company et al v. Apotex Inc., 2009 F.C. 991 (F.C. per Gauthier J.) at para. 97.
- General Tire & Rubber Company v. Firestone Tyre & Rubber Company Limited and Others, [1971] R.P.C. 173 (per Graham, J.) at pp. 245-246
- Technograph Printed Circuits Ltd. v. Mills & Rockley (Electronics) Ltd., [1969] R.P.C. 395 (per Sachs, L.J.) at p. 355 and p. 408
- General Tire & Rubber Co. v. Firestone Tyre & Rubber Co., Ltd., [1972] R.P.C. 457 at p. 463
- Technograph Printed Circuits Ltd. v. Mills & Rockley (Electronics) Ltd., [1969] R.P.C. 395 (per Sachs, L.J.) at p. 355 and p. 408
- The General Tire & Rubber Company v. The Firestone Tyre and Rubber Company Limited and Others [1972] R.P.C. 457 at p. 463
- ⁹⁸ Beecham Canada Ltd. et al. v. Procter & Gamble Co. (1982) 61 C.P.R. (2d) 7 at p. 27

7.5.3.6 paper patents are viewed with scepticism

The disclosure must be known and accepted generally by those who are engaged in the art to which the disclosure relates. ⁹⁹ They should have been a "good basis for further action". ¹⁰⁰

It cannot be assumed that, in looking for references in the prior art, the notional skilled technician would go outside the art at issue to consider art in other fields.¹⁰¹

When assessing an attack based on obviousness, the Court is entitled to consider the absence of testimony on:

all the relevant prior art, whether it pointed to or away from the impugned invention:

the field of prior art researched and explored;

the ease or difficulty experienced or encountered in unearthing the prior art;

the time and resources expended in the search;

the particular researchers into the prior art and their skill;

how readily available or otherwise the piece or pieces of prior art would have been to the notional skilled worker. 102

7.5.4 2. inventive concept

Prior to determining obviousness, the Court must determine "What is the invention as claimed" because it is the claims at issue as properly construed that are at issue in determining obviousness. 103 This is "claim construction" and is discussed in Chapter 4.

British Acoustic Films 53 R.P.C. 221 at p. 250 quoted in General Tire & Rubber Co. v. Firestone Tyre & Rubber Co., Ltd. [1972] R.P.C. 457 at pp. 482-483

General Tire & Rubber Co. v. Firestone Tyre & Rubber Co., Ltd. [1972] R.P.C. 457 at pp. 482-483

Eli Lilly & Co. v. Marzone Chemicals Ltd. (1977) 37 C.P.R. (2d) 3 per Gibson J. at pp. 34-35 (F.C.T.D.), aff'd 32 C.P.R. (2d) 37 (F.C.A.)

Xerox of Canada Ltd. v. IBM Canada Ltd. (1977), 33 C.P.R. (2d) 24 (F.C.T.D. per Collier J.) at pp. 61-62; See also Sakharam D. Mahurkar v. Vas-Cath of Canada Limited et al. (1988) 18 C.P.R. (3d) 417 (F.C.T.D. per Strayer J.) at p. 435-6

Janssen-Ortho Inc. and Daiichi Pharmaceutical Co., Ltd. v. Novopharm Limited Federal Court per Hughes J., T-2175-04, October 17, 2006, 2006 FC 1234 at para 113.1; approved in Novopharm Limited v. Janssen-Ortho Inc. and Daiichi Pharmaceuticals Co., Ltd. 2007 FCA 27 (F.C.A per Sharlow J.A., Nadon and Malone JJ.A.) online at para. 25(1).

In *Sanofi*, the Supreme Court of Canada modified this test slightly to ask, in the second step of the *Windsurfing* approach, what is "the inventive concept of the claim in question." The inventive concept must be determined for each claim in issue. ¹⁰⁵

It is important to note¹⁰⁶ that the *Windsurfing* approach was developed in the context of the U.K. *Patents Act 1977*¹⁰⁷ which provides that a patent may only be granted for an invention "if it involves an inventive step". ¹⁰⁸ There was no corresponding statutory requirement in the "Old" Canadian *Patent Act* under which *Sanofi* was decided.

Normally, an analysis of the claim would reveal what was the invention. In *Sanofi*, the determination of the "inventive concept" for the selection patent at issue required the Court to look to the disclosure. The claims in the Sanofi selection patent simply claimed the compound (the right-handed enantiomer of the racemate), its pharmaceutically acceptable salt and processes for obtaining them. The genus patent disclosed the racemate and the enantiomer, but not the advantages of the right-handed enatiomer. The claims of the Sanofi patent made no mention of the difference between these compounds and those of the genus patent, because there were no differences in the compounds themselves. Unable to find an "inventive step" in the claim itself, the Supreme Court looked outside the claim to find it:

"A bare chemical formula in a patent claim may not be sufficient to determine its inventiveness. In such cases, I think it must be acceptable to read the specification in the patent to determine the inventive concept of the claims." 110

The "inventive concept" of the claims in the Sanofi case was held to be "a compound useful in inhibiting platelet aggregation which has greater therapeutic effect and less toxicity than the

¹⁰⁴ Apotex Inc. v. Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265, 2008 SCC 61, para. 67.

Eli Lilly and Company et al v. Apotex Inc. 2009 FC 991 (F.C. per Gauthier J.) at para. 544; Bauer Hockey Corp. v. Easton Sports Canada Inc. 2010 FC 361 (F.C. per Gauthier J.) at para. 250.

As was noted by Donald H. MacOdrum in his *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.

¹⁰⁷ (U.K.) c. 37, 1977

U.K. Patents Act 1977, section 1(1)(b).

A similar circumstance occurred in the olanzapine case *Eli Lilly Canada Inc. et al* v. *Novopharm Limited*, 2010 FCA 197 (Layden-Stevenson J.A., Nadon and Sharlow JJ.A. concurring), another selection patent case. The trial judge had concluded that the choice of olanzapine as a development compound was not obvious but had held that it did not have surprising and unexpected properties, or anything that set olanzapine apart from the other genus patent compounds [at para. 58, quoting from paras. 147 & 148 of the trial judge's decision]. The trial judge's findings that olanzapine was both non-inventive and non-obvious were inconsistent [para. 61]. The trial judge's finding that the conditions of a valid selection patent had not been met included consideration of evidence that was not to be considered as part of the obviousness inquiry. Rather, it goes to utility. [para. 61]. Olanzapine was thus non-obvious [para. 64].

¹¹⁰ Apotex Inc. v. Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265, 2008 SCC 61, para. 77.

other compounds of the genus patent and the methods for obtaining that compound". 111 None of these characteristics were set out in the claims. 112

By adopting a test that permits one to find "the inventive concept" elsewhere than in the claims, it appears that the Supreme Court may have resurrected "the spirit of the invention" or the ghost of the "pith and substance of the invention" from older cases, ¹¹³ which concepts had been expressly put to death in the consideration of claim construction in the *Free World* ¹¹⁴ case.

For New Act patents, s. 28.3 of the Patent Act requires:

- 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.

7.5.5 3. What are the differences between prior art and the inventive concept?

The Sanofi case did not deal with this aspect of the process.

7.5.6 4. Are the differences steps that would have been obvious?

The fourth step of the *Windsurfing* approach merely brings us back to the original question: Was the invention obvious?

The *Windsurfing* approach re-states the obviousness question:

¹¹¹ Apotex Inc. v. Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265, 2008 SCC 61, para. 78.

Presumably. in non-selection patent cases, the claim need merely be construed.

See, for example, *Smith Incubator Co. v. Seiling* [1936] S.C.R. 251 per Rinfret J. at 259; and *C. Ven Der Lely N.V. v. Bamfords Ltd.* [1963] R.P.C. 61 at 75 (H.L. per Lord Reid).

Free World Trust v. Électro Santé Inc. et al., (2001) 9 C.P.R. (4th) 168 (S.C.C. per Binnie J.) at 184, para. 31(d):

[&]quot;The language of the claims thus construed defines the monopoly. There is no recourse to such vague notions as the "spirit of the invention" to expand it further."

Viewed without hindsight, do the differences between the prior art and the inventive concept constitute steps which would have been obvious to the person skilled in the art, or do they require any degree of invention? 115

Interestingly, the question has changed from a single step (what is the "inventive step" - singular) to multiple steps ("do the differences ... constitute steps").

The fourth step of the *Windsurfing* approach transmogrifies the metaphor of an "inventive step" into what sounds like the actual physical or procedural steps which would need to be taken to go from the prior art to the invention. The latter part of the question would appear to answer itself; if the steps require a degree of invention, they would not be obvious. But in the case of new chemicals or pharmaceuticals, these steps often constitute trial and error (and, sometimes, routine) experimental procedures performed until a new and improved compound is found. Is this test meant to ask whether the steps that would have been taken to go from the prior art to the alleged invention have been obvious to the person skilled in the art? That question has echoes of the "worth a try" test. Requiring a degree of invention along the way also seems to put the test too high.

Sanofi dealt with a special case: selection patents and inventions created through experimentation. This chapter will therefore look at the law of obviousness in general, followed by a look at the special case of inventions borne from experimentation and selection patents in particular.

7.6 Motivation: The Climate of the invention

Although the prior art provides a hypothetical background to the hypothetical considerations of the notional skilled person, the actual environment that that person would have found themselves in also needs to be considered.

The general state of the art includes not only knowledge and information but also attitudes, trends, prejudices and expectations. 116

Until recently, Canadian courts did not generally deal with the question of motivation. It now deals with two kinds of motivation:

- 1. that of the industry (including the literature); and
- 2. that of the inventor(s).

In *Novopharm Limited* v. *Janssen-Ortho Inc. and Daiichi Pharmaceutical Co., Ltd.*¹¹⁷ Justice Sharlow characterized that environment as having two components:

Apotex Inc. v. Sanofi-Synthelabo Canada Inc., 2008 SCC 61 at para 67.

Novopharm Limited v. Janssen-Ortho Inc. and Daiichi Pharmaceuticals Co., Ltd. 2007 FCA 27 (F.C.A per Sharlow J.A., Nadon and Malone JJ.A.) online at para. 25.

²⁰⁰⁷ FCA 217 (F.C.A. per Sharlow J.A, Nadon and Malone JJ.A. concurring), 59 C.P.R. (4th) 116, 366 N.R. 290 at para. 25.

"4. 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. The motivation in existence at the time the alleged invention to solve a recognized problem

"Motivation" in this context may mean the reason why the claimed inventor made the claimed invention, or it may mean the reason why one might reasonably expect the hypothetical person of ordinary skill in the art to combine elements of the prior art to come up with the claimed invention. If within the relevant field there is a specific problem that everyone in the field is trying to solve (a general motivation), it may be more likely that the solution, once found, required inventive ingenuity. On the other hand, if there is a problem that only the claimed inventor is trying to solve (a unique or personal motivation), and no one else has a reason to address that problem, it may be more likely that the solution required inventive ingenuity. However, if commonplace thought and techniques can come up with a solution, there may be a reduced possibility that the solution required inventive ingenuity.

The various criteria discussed by the Federal Court of Appeal in *Janssen-Ortho Inc.* v. *Novopharm Ltd.*, ¹¹⁸ and particularly the climate in the relevant field at the time the alleged invention was made, criteria which includes attitudes, trends, prejudices and expectations as well as secondary factors such as commercial success and meritorious awards, may still be relevant and are not inconsistent with the approach set out in *Sanofi*. ¹¹⁹

7.6.1.1 Motivation in the field: attitude, trends, prejudices and expectations

As expressed by Hughes J. in Janssen-Ortho et al v. Novopharm, one should consider:

"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." 120

On appeal, Justice Sharlow adopted this language virtually verbatim. 121

The degree of motivation cannot transform a possible solution into an obvious one. Motivation is relevant in determining whether the skilled person has good reason to pursue "predictable" solutions or solutions that provide "a fair expectation of success" (see respectively the passages

²⁰⁰⁷ FCA 217 (F.C.A. per Sharlow J.A, Nadon and Malone JJ.A. concurring), 59 C.P.R. (4th) 116, 366 N.R. 290 at para. 25.

Bauer Hockey Corp. v. Easton Sports Canada Inc. 2010 FC 361 (F.C. per Gauthier J.) at para. 223.

Janssen-Ortho Inc. and Daiichi Pharmaceutical Co., Ltd. v. Novopharm Limited Federal Court per Hughes J., T-2175-04, October 17, 2006, 2006 FC 1234 at para 113.4-113.5

Novopharm Limited v. Janssen-Ortho Inc. and Daiichi Pharmaceuticals Co., Ltd. 2007 FCA 217 (F.C.A per Sharlow J.A., Nadon and Malone JJ.A.) at para. 25(2). online

in KSR International Co. v. Teleflex Inc., 127 S. Ct. 1727 (2007) at page 1742 and Angiotech Pharmaceuticals Inc. v. Conor Medsystems Inc., [2008] UKHL 49, at paragraph 42, both of which are referred to with approval in Sanofi-Synthelabo, supra, at paragraphs 58 and 59). 122

If selected pieces of prior art led to the invention, but the common general knowledge biased one away from the invention, then the invention is not obvious. 123

In 2002, in the <u>sertraline/Zoloft</u> case, ¹²⁴ Dawson J. found that "preliminary results suggested that drugs", including the drug at issue "should have anti-panic activity". ¹²⁵ She also found that the drug at issue was "clearly advocated and recommended" for use in the treatment of obsessive compulsive disorder ("OCD") and panic disorder ("PD"). She held that the discovery that the use of the drug would aid in the treatment of PD and OCD was obvious.

An odd twist of logic has arisen in some of the case law: if everyone was looking for the solution, it may be more obvious than not. If within the relevant field there is a specific problem that everyone in the field is trying to solve (a general motivation), it may be more likely that the solution, once found, required inventive ingenuity. On the other hand, if everyone was looking for <u>a</u> solution to a problem, but the inventor was the first to come up with <u>the</u> solution to the problem, that would tend to prove that the invention was not obvious (or everyone else would have come up with it right away).

7.6.1.2 motivation of the inventor or person skilled in the art

"Motivation" in this context may mean the reason why the claimed inventor made the claimed invention, or it may mean the reason why one might reasonably expect the hypothetical person of ordinary skill in the art to combine elements of the prior art to come up with the claimed invention. 128

In *Novopharm* v. *Janssen-Ortho*, Justice Sharlow considered motivation from the point of view of the inventor and of the notional skilled person in the art: why would the latter assemble the prior art into that combination?:

" "Motivation" in this context may mean the reason why the claimed inventor made the claimed invention, or it may mean the reason why one might

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Apotex Inc. v. Pfizer Canada Inc. 2009 FCA 8 (F.C.A. per Noël J.A., Létourneau and Blais JJ. A. concurring) at para. 44.

General Tire & Rubber Co. v. Firestone Tyre & Rubber Co., Ltd., [1972] R.P.C. 457 at pp. 505-506

¹²⁴ Pfizer Canada v. Apotex Inc. (2002), 22 C.P.R. (4th) 466 (F.C.T.D. per Dawson J.)

Pfizer Canada v. Apotex Inc. (2002), 22 C.P.R. (4th) 466 (F.C.T.D. per Dawson J.) at para. 114.

¹²⁶ Pfizer Canada v. Apotex Inc. (2002), 22 C.P.R. (4th) 466 (F.C.T.D. per Dawson J.) at para. 114.

Novopharm Limited v. Janssen-Ortho Inc. and Daiichi Pharmaceuticals Co., Ltd. 2007 FCA 27 (F.C.A per Sharlow J.A., Nadon and Malone JJ.A.) online at para. 25.

Novopharm Limited v. Janssen-Ortho Inc. and Daiichi Pharmaceuticals Co., Ltd. 2007 FCA 27 (F.C.A per Sharlow J.A., Nadon and Malone JJ.A.) online at para. 25.

reasonably expect the hypothetical person of ordinary skill in the art to combine elements of the prior art to come up with the claimed invention." 129

Justice Sharlow echoed the question "If it was so obvious, why didn't you do it?":

"If within the relevant field there is a specific problem that everyone in the field is trying to solve (a general motivation), it may be more likely that the solution, once found, required inventive ingenuity." ¹³⁰

With respect, her next statement didn't follow from the last:

"On the other hand, if there is a problem that only the claimed inventor is trying to solve (a unique or personal motivation), and no one else has a reason to address that problem, it may be more likely that the solution required inventive ingenuity." ¹³¹

The last statement by Justice Sharlow unfortunately sounds hauntingly like the old U.K. "worth-a-try" test:

"However, if commonplace thought and techniques can come up with a solution, there may be a reduced possibility that the solution required inventive ingenuity." ¹³²

7.7 Determining Obviousness Itself

7.7.1 The relevant date to ask the question

Under the "first to invent" system, the relevant date for obviousness was the "date of invention". Under the "first to file' system, the relevant date is the "claim date" (essentially, the priority filing date).

7.7.1.1 first to invent system

The knowledge of the notional skilled technician with the characteristics noted above is to be assessed as of the date of the invention. Art arising after the date of invention is not relevant. ¹³³ It is the art predating the patent that is relevant. ¹³⁴

Novopharm Limited v. Janssen-Ortho Inc. and Daiichi Pharmaceuticals Co., Ltd. 2007 FCA 217 (F.C.A per Sharlow J.A., Nadon and Malone JJ.A.) at para. 25(5). online

Novopharm Limited v. Janssen-Ortho Inc. and Daiichi Pharmaceuticals Co., Ltd. 2007 FCA 217 (F.C.A per Sharlow J.A., Nadon and Malone JJ.A.) at para. 25(5). online

Novopharm Limited v. Janssen-Ortho Inc. and Daiichi Pharmaceuticals Co., Ltd. 2007 FCA 217 (F.C.A per Sharlow J.A., Nadon and Malone JJ.A.) at para. 25(5). online

Novopharm Limited v. Janssen-Ortho Inc. and Daiichi Pharmaceuticals Co., Ltd. 2007 FCA 217 (F.C.A per Sharlow J.A., Nadon and Malone JJ.A.) at para. 25(5). online

¹³³ Xerox of Canada Ltd. v. IBM Canada Ltd. (1977), 33 C.P.R. (2d) 24 at p. 86

Imperial Chemical Industries, Ltd. (Haggis') Application [1975] R.P.C. 403 at pp. 415-416

7.7.1.2 first to file system

In 1993, the *Patent Act* was amended to introduce the concept of a "claim date" which was the earlier of the actual filing date in Canada or the filing date of a previously regularly-filed application (such as the priority date).

Section 28.3¹³⁵ provides:

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.

"Information ... available to the public" may be broader than information "generally known" by persons in the relevant art at the relevant time. 136

7.7.2 Examples of Obviousness

7.7.2.1 Confirmatory and Predictable Experiments are not inventive

A good experiment is supposed to be reproducible: if you set up the same experimental conditions, the same result should flow.

So if you have done an experiment beforehand and you repeat it, the result (assuming the experimental procedure is reproduced) is predictable. In essence, you already know the answer before you do the experiment. To repeat it is to confirm the results – a confirmatory experiment. There is no invention in confirming what people already knew. Such earlier knowledge would anticipate the new results.

Likewise, verifying attributes of already known compounds is not inventive.

In KSR, the U.S. Supreme Court recognized that choosing between identified, predictable solutions is not inventive:

"When there is a design need or market pressure to solve a problem and there are a finite number of **identified**, **predictable solutions**, a person of ordinary skill has good reason to pursue the known options within his or her technical

¹³⁵ 1993, c. 15, s. 33

Merck & Co., Inc. et al v. Pharmascience Inc. et al, 2010 FC 510 (F.C. per Hughes J.) at para. 37.

grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense."¹³⁷ [emphasis added]

This concept was adopted (without express attribution to KSR) by Rothstein J. in the test he formulated for obviousness of inventions involving experimentation in Sanofi:

"Are there a finite number of identified predictable solutions known to persons skilled in the art?" 138

(Unpredictability was found to be the basis for inventiveness in cases before Sanofi. 139)

7.7.2.2 Following the Instructions or Predictions of others is not inventive

People who only carry out what they were instructed to do by others, are not inventors. When determining inventorship, the inventors are the people who came up with the invention; the tradespeople who actually machined it or the technician who first operates it are not inventors. For example, cornflakes cereal was invented by scientists or engineers at Kelloggs and not by the technicians who first operated it according to the designers instructions.¹⁴⁰

Apotex Inc. v. Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265, 2008 SCC 61, para. 69(1); Saint-Gobain PAM SA v. Fusion Provida Ltd., [2005] EWCA Civ 177 at para. 35 and KSR International Co. v. Teleflex Inc. et al.. 127 S.Ct. 1727 (2007) at 1742.

Janssen-Ortho Inc. and Daiichi Pharmaceuticals Co., Ltd. v. Novopharm Limited 2006 FC 1234 online at para. 114(3):

"The person skilled in the art would know that Ofloxacin is racemic and, I find on the evidence, that each of the optical isomers which comprise the racemate would be expected by such a person to possess properties different from the racemate, but that the degree of difference would be unknown and whether each of the properties would differ to the same degree in the same direction would be unknown. One would have to make it and try it out. I find that the evidence including that of Drs. Wentland, Klibanov, Hooper, Caldwell, Low and Collicott, is that the properties of the individual optical isomers would not be predictable and that each of the properties of antimicrobial activity and toxicity may vary differently; they are not linked. One could not know until one derived the optical isomer and tried it and, whether it would have enhanced properties in one or more areas, or detrimental properties that would outweigh the enhancements."

Kellogg Company v. Helen L. Kellogg, [1942] Ex. C.R. 87, at p. 97) related to whether Kellogg Jr. was an inventor. He operated the machine designed by others [at p. 97]:

"His [Kellogg Jr.'s] operation of the gun with Swartz, which they were directed to do, was purely a mechanical act, with an instrumentality purchased by the Kellogg company to do the very thing that was done by it. It seems to me utterly untenable to say that this of itself was invention, or was an element contributed by Kellogg Jr. in making the invention. It might well have happened that Kellogg Jr. would have been off duty at the important lunch hour in question here and replaced by some other of the Experimental Department staff, and there would not seem to be any reason why any one else could not have achieved the same result with the same gun. I can conceive of no ground whatever for suggesting that anything Kellogg Jr. did had any of the elements of invention in it."

^{137 127} S.Ct. 1727 (2007) at 1742.

If a person merely verifies another's previous predictions, the person is not an inventor. 141

In some circumstances, it can amount to an anticipation of the invention. The mere verification of the predictions of others is not an invention. The invention of the invention.

In the *Hoescht* case, the Supreme Court of Canada¹⁴⁴ approved of the Cripps question (discussed below) as applied by the trial judge, Justice Collier. Paraphrasing his test: "Was it obvious that he could <u>successfully</u> make or carry out the invention?" As discussed <u>below</u> in the context of inventions resulting from experimentation, was it clear that in order for something to be obvious, it is necessary that it be more or less self-evident that it ought to work.

The converse is obviously true: if you cannot predict whether something will work, how can it be said that it is an obvious solution to the problem being faced? For example, where preliminary experimental results suggested that drugs, including sertaline, should also treat panic disorder, the use of sertaline to treat panic disorder was obvious.¹⁴⁵

Verification of predictions must be contrasted to following up on the suggestions of others. The latter may constitute an invention (See "Obvious to try", below).

See also Re May & Baker Ltd. and Ciba Ltd. (1948), 65 R.P.C. 255 (High Court per Jenkins J.) at p. 281.

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Apotex Inc. v. Wellcome Foundation Ltd. (2000) 10 C.P.R. (4th) 65 (F.C.A. per Sexton J.A., Rothstein and Malone JJ.A.) at <u>para. 33</u> citing Re May & Baker Ltd. and Ciba Ltd. (1948), 65 R.P.C. 255 (High Court per Jenkins J.) at <u>p. 281</u>.

If the prior art document gives directions which will inevitably result in something within the claims, then it is an anticipation. If the prior publication contains a clear description of or clear instructions to do or make something that would infringe the patentee's claims if carried out after the grant of the patentee's patent, the patentee's claim will have been shown to lack the necessary novelty, that is to say, it will have been anticipated The General Tire & Rubber Company v. The Firestone Tyre and Rubber Company Limited and Others [1972] R.P.C. 457 at p. 485-486. See also Eli Lilly & Co. v. Marzone Chemicals Ltd., (1977), 37 C.P.R. (2d) 3 (F.C.T.D. per Gibson J.) at p. 32.

Sharp & Dohme Inc. v. Boots Pure Drug Company Ld. (1928), 45 R.P.C. 153 (C.A. per Sargeant L.J.) at p. 191:

[&]quot;... what the Plaintiffs really did was, not to invent anything themselves, but only to verify, in the four specific cases described in the Specification, the predictions of *Nencki*, *Clemmensen* and Johnson. As regards the rest of the higher alkyl resorcinols, the Plaintiffs have not added anything whatever to the information already disclosed in the prior publications."

Farbwerke Hoechst v. Halocarbon (Ontario) Limited et al (1979), 42 C.P.R. (2d) 145 (S.C.C.), 1979 CarswellNat 636 (S.C.C.) paras. 33-35.

Pfizer Canada Inc. v. Apotex Inc, (2002), 22 C.P.R. (4th) 466 (F.C.T.D. per Dawson J.) at paras. 114-115.

7.7.2.3 "Sufficiently predictable" results are obvious

In physical systems, 100% predictability that something will work is virtually impossible. The behaviour of a simple mechanical device or a simple electrical circuit is quite predictable. The more complex a system becomes however, often the more difficult it is to predict its behaviour with a high degree of predictability or certainty (i.e. the weather, complex biological systems and what will be a body's reaction to a pharmaceutical).

If the expectation of success is sufficiently predictable, and the effort involved is not going to be very great, then it may well be that no patentable invention can result. Under U.S. obviousness law, all that is required is a reasonable expectation of success."

The phrases "sufficiently predictable" and "a reasonable expectation of success" appear to recognize the inherent inability to predict absolutely and require less than complete certainty for something to be obvious.

7.7.2.4 Measuring chemical characteristics

No man can have a patent merely for ascertaining the properties of a known substance. 148

Arguably, finding unexpected physical characteristics of a known compound could be patentable. Although a material would be known to have a characteristic (for example, some degree of efficacy), its quantum may be unknown until it is measured. As expressed by Purchas L.J. in his dissenting opinion in the *Genentech* case:

"The existence of the data was obvious but what it was was unknown." 149

7.8 The Cripps Question

The principal test for obviousness is named after the English barrister who suggested it in the 1920s: Sir Stafford Cripps:

"Was it obvious to any skilled chemist, in the state of chemical knowledge existing at the date of the Patent, that he could manufacture valuable therapeutic agents by making the higher alkyl resorcinols by the use of the condensation and

American Cyanamid v. Berk Pharmaceuticals [1976] R.P.C. 231 at p. 234 per Whitford J.; quoted in Xerox of Canada Ltd. et al v. IBM Canada Ltd. (1977) 33 C.P.R. (2d) 24 (F.C.T.D. per Collier, J.) at p. 54

In re O'Farrell 853 F.2d 894, 7 U.S.P.Q. (2d) 1673 at p. 1681(C.A.F.C. per Rich J.) 1988

I.G. Farbenindustrie A.G.'s Patent, [1930] 47 R.P.C. 289 (Ch. D per Maugham J.) at p. 322. The Court also said:

[&]quot;... if, for practical purposes it is not obvious to skilled chemists in the state of chemical knowledge existing at the date of a selection patent that the selected components possess a special property, there is then, or at least there may be, a sufficient "inventive step" to support the Patent."

Genentech Inc.'s Patent [1989] R.P.C. 147 (C.A. per Purchas L.J., dissenting) at p. 221, l. 28-29.

reduction process described? If the answer is "No" the Patent is valid as regards subject matter; if "Yes", the Patent is not valid." 150

The Cripps question still leaves open a further question: What is meant by "obvious"?

7.8.1 Led Directly and Without Difficulty to the Solution

The expression of the Cripp's Question as approved by the Supreme Court of Canada in *Hoescht*, ¹⁵¹ required that, in order for the invention to have been obvious, it must have been made from the prior art "directly and without difficulty". ¹⁵²

In order to be obvious, the route to the invention must be a flagstone path, plainly perceptible in either the dark or the light.¹⁵³ If a thing is obvious, you can go straight to it.

The Federal Court of Appeal deprecated the use of phrases such as "directly and without difficulty" cautioning their use:

"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*, [1972] R.P.C. 195 at pages 211-12."

Of course, the path cannot lead away from the invention. The prior art should not bias the notional worker away from exploring the chances of using the patented solution. If selected pieces of prior art lead to the invention, but the common general knowledge biased one away from the invention, then the invention is not obvious.¹⁵⁵

¹⁵⁰ Sharp and Dohme Inc. v. Boots Pure Drug Co. Ltd. (1928), 45 R.P.C. 153 at p. 173

Farbwerke Hoechst v. Halocarbon (Ontario) Limited et al (1979), 42 C.P.R. (2d) 145 (S.C.C.), 1979 CarswellNat 636 (S.C.C.) paras. 33-35.

Xerox of Canada Ltd. et al v. IBM Canada Ltd. (1977) 33 C.P.R. (2d) 24 (F.C.T.D. per Collier, J.) at p. 53; Beecham Canada Ltd. v. Procter & Gamble Co. (1982) 61 C.P.R. (2d) 1 (F.C.A. per Urie J.A.); at p. 27; Beloit Canada Ltd. v. Valmet Oy (1986), 8 C.P.R. (3d) 289 (F.C.A. per Hugessen J.A.) at p. 294

¹⁵³ Xerox of Canada Ltd. v. IBM Canada Ltd. (1977), 33 C.P.R. (2d) 24 at p. 62

Janssen-Ortho Inc. v. Novopharm Ltd. 2007 F.C.A. 217 (F.C.A. per Sharlow J.A., Malone and Nadon J.J.A., concurring) at para. 28.

General Tire & Rubber Co. v. Firestone Tyre & Rubber Co., Ltd., [1972] R.P.C. 457 at pp. 505-506

7.8.2 The Empirical evidence – the inventor's actual path

If the inventor did not arrive at the invention "directly and without difficulty", how then could an unimaginative, skilled worker arrived at it "directly and without difficulty"?

One of the questions asked by Justice Rothstein (in the circumstances of an invention resulting from expectation in the "obvious to try" test) was:

"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?¹⁵⁶

In *Novopharm Limited* v. *Janssen-Ortho Inc. and Daiichi Pharmaceutical Co., Ltd.*¹⁵⁷ Justice Sharlow considered that the actual path taken by the inventor was relevant to consider in determining obviousness:

"6. The time and effort involved in the invention

The length of time and expense involved in the invention may be indicators of inventive ingenuity, but they are not determinative because an invention may be the result of a lucky hit, or the uninventive application of routine techniques, however time consuming and expensive they may be. If the decisions made in arriving at the solution are few and commonplace, that may indicate that no inventive ingenuity was required 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."¹⁵⁸

Where a team experimented intensively over several months with many variables before arriving at the optimal combination, the court found there to be an invention. Where the trial judge found as a fact that the final product evolved after much work, both mental and physical, the Federal Court of Appeal found no reason to disturb that finding.

Apotex Inc. v. Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265, 2008 SCC 61, para. 69(2), H. Lundbeck A/S v. Generics (UK) Ltd., [2008] R.P.C. 19, [2008] EWCA Civ 311 at para. 24.

¹⁵⁷ 2007 FCA 217 (F.C.A. per Sharlow J.A, Nadon and Malone JJ.A. concurring) at para. 25

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

Dimplex North America Ltd. v. CFM Corporation 2006 FC 586 (F.C.).

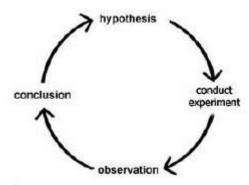
Tye-Sil Corp. v. Diversified Products Corp. (1991), 35 C.P.R. (3d) 350 at para. 42, 125 N.R. 218 (F.C.A.)

7.9 Obviousness in cases involving experimentation – Pre-Sanofi

7.9.1 Experimentation

Is something obvious if you have to do an experiment to find out whether your idea will work? How sure do you have to be that your invention will work: absolutely or with a high degree of predictability? If you'd have to play around with it a bit (experiment) to get it to work, is it non-obvious?

Experiments are part of the "Scientific Method" – the method by which scientific laws are tested and by which new discoveries and scientific laws are made. It can be an iterative process. The creation of a hypothesis precedes the experiment, anticipating (in a scientific rather than legal sense) what will occur when the experiment is done:



7.9.1.1 If trial and error are required, it can't be obvious

"Trial and error" suggests that research or experimentation has an unexpected, unsuccessful component. The "error" portion suggests that the skilled worker is going in the wrong direction, learning what didn't work rather than going in the plain and "obvious" direction of what would be expected to be a successful result. This type of experiment would, for the purposes of this analysis, be better described as "research" with an unpredictable outcome. If something requires this kind of research, then it is not obvious because it is not "plain as day" or "crystal clear". Furthermore, it is not directly leading to the solution; instead it leads to intermediate failures. Difficulties are encountered in the way of wasted effort and dead ends. Thus it is not "directly and without difficulty". Therefore, anything that requires "trial and error" cannot be obvious.

When you cannot predict the result of an experiment before you run it, the result is not obvious. Where it was impossible to predict the claimed advantages before the compounds were produced and tested, then a person would not be led directly and without difficulty to the solution taught by the patent. Where persons would not know, before separating a racemate into its two isomer and then testing the separated isomers, what the properties of the dextro-

rotary isomer would be, nor before trying different salts in combination with the isomer what the bisulfate salt's beneficial properties would be, the solution is not obvious.¹⁶¹

7.9.1.2 Experiments with unpredictable results

What then of experiments where the result is not known before the experiment is conducted? What happens to the freezing point of water when you add salt to the water? The water freezes at a lower temperature (hence salty slush on winter streets instead of ice). But what happens to the freezing point of water when you mix other things with it? For many substances, you don't know until you try – that kind of experimentation is called "research".

In some experiments, the result comes as an unanticipated outcome and a "Eureka" moment. For such result, a patent is usually available, subject to it meeting the other criteria of "an invention".

Research is usually done using current scientific knowledge to direct one to proceed in a direction that is most likely to provide a fruitful result. Typically however, one does not know, ahead of time, whether one will find success at all, or if one does, what form it will take. Hence science often proceeds through trial and error because if success was predictable, why would one bother to try and err. Instead, one would go straight to the obvious, predictably successful result.

There are lines of case law that say that:

- if any research is needed, the invention is not obvious
- "undue experimentation" renders a discovery non-obvious
- If the result of the experimental is highly predictable and the result expected (the experiment is confirmatory rather than exploratory), then the result is obvious.

These lines of cases are dealt with separately below.

7.9.1.3 If research was needed, the invention was not obvious

In the U.K case of *Osram Lamp Works* v. *Pope's Electric Lamp Co.*¹⁶³ Lord Parker stated that there is good subject matter for a patent, unless having regard to what was generally known at the date of the patent:

Sanofi-Synthelabo Canada Inc. v. Apotex Inc. 2006 F.C.A. 421, 358 N.R. 135 (F.C.A. per Noel J.A., Richard C.J. and Evans J.A. concurring) at paras. 42-44.

In 1896, French scientist Henri Becquerel left some uranium salts on top of a wrapped photographic plate in a drawer. Some time later, when he remove the plate, he discovered that the plate had an impression exposed on it, as if it had been exposed to light. The salts had emitted some form of rays so as to expose the photographic plate. Becquerel turned the matter over to one of his graduate students, Marie Curie, for further investigation. [Bryson, Bill; "A Short History of Nearly Everything"; Doubleday Canada 2003; p. 109.]

¹⁶³ (1917) 34 R.P.C. 369 Lord Parker

"... it was obvious without experimentation or research." 164

Since at least 1940's, Canadian patent law has provided that, for something to be obvious, experimentation or research is not permitted. In the J.R. Short $Milling^{165}$ case, Maclean J. stated that:

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

Fox, in his treatise on patent law *Canadian Law and Practice Relating to Letters Patent for Inventions*, cited the *J.R. Short Milling* case as authority for the proposition that:

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

This test is harmonic with the Supreme Court of Canada's endorsement of the *Pope Appliance* v. *Spanish River* concept endorsed in *Hoescht* (discussed above) that an invention is:

"... finding out something which has not been found out by other people."

The kind of experimentation referred to by Dr. Fox and the Courts must have been experiments where the results were not "sufficiently predictable" and non-confirmatory. The result of research is finding out what previously had not been known. If something has already been known, then it is "prior art" and is not patentable. If something was immediately apparent, it would be obvious and not inventive.

In 1995, in *Bayer* v. *Apotex*, ¹⁶⁷ Apotex contended that once it was known that Nifedipine (the prior art compound) could be used to treat acute angina when administered intravenously or orally, it was obvious to:

- put it in liquid form, and
- encase the solution in a soft gelatin capsule to deliver it perlingually (under the tongue)
- harden the shell. It was common knowledge how to harden the shell to permit it to be bitten; and

J.R. Short Milling Co. Ltd. v. Geo. Weston Bread & Cakes Ltd. [1940] 4 D.L.R. 579 (Maclean, J.)

ibid, at p. 396.

ibid, p. 598

Bayer v. Apotex Inc. (1995), 60 C.P.R. (3d) 58 at 80-81 (Ont. Gen Div. per Lederman J.) affd (1998), 82 C.P.R. (3d) 526 (Ont. C.A.)

 overcome problems with light sensitivity and insolubility. Problems such as light sensitivity and insolubility could easily be overcome through basic trial and error testing (routine workshop activity).

Counsel for Apotex suggested that a series of experiments, some of which might not be successful, rendered Bayer's alleged invention obvious:

"Along the way problems such as the light sensitivity and insolubility could be encountered, but given the prior art and common general knowledge they could easily be overcome through some basic trial and error testing. Such testing would be, according to Mr. Radomski, routine workshop activity and would have no ingenuity." 168

"Thus, Apotex's position is that the invention of the '582 was the product of mere workshop analysis, *i.e.*, you try one thing and if not successful you try a few other well-known tests to deal with the problem to arrive at the composition of an effective dosage form. This was all part of the expected skill of a formulation chemist in the pharmaceutical industry in 1968. "¹⁶⁹

Lederman J., rejected this argument setting out a "Would, not Could" test for whether the end result would have been "very plain" (and hence, obvious) to the notional technician:

"The test therefore is not whether anyone skilled in the art *could* have achieved the same result as the patentee's invention, but whether this particular drug dosage form of Nifedipine *would* have been very plain to the unimaginative technician in the drug formulation files: *Beecham Canada Ltd.* v. *Procter & Gamble* (1982), 61 C.P.R. (2d) 1 at p. 27, 40 N.R. 313 (F.C.A.)." 170

In describing the Canadian test of obviousness regarding experimentation, Lederman J. distinguished the Canadian law from the U.K. law stating that no inquiries, testing or experimentation is permitted, even if would have been "logical" to the notional technician to do that testing:

"There appears, however, to be a significant difference in the abilities of the English hypothetical skilled technician and the Canadian one. Indeed, making inquiries or testing, seems to be something outside the ken of the notional Canadian skilled technician. In *Cabot Corp.* v. 318602 Ontario Ltd. (1988), 20 C.P.R. (3d) 132 at p. 146, 19 C.I.P.R. 204, 9 A.C.W.S. (3d) 317 (F.C.T.D.), Rouleau J. quoted H.G. Fox in Canadian Law and Practice Relating to Letters Patent for Inventions at pp. 70-1, as stating in part:

"In order that a thing shall be 'obvious', it must be something that would directly occur to someone who was searching for something novel, a new manufacture, or whatever it might be, without the necessity of his having to do any

ibid, p. 76-77

ibid, p. 76-77

ibid, p. 79 d

experimenting or serious thought, or research, whether the research be in the laboratory or amongst literature."

(My emphasis.) Thus, although one would normally imagine that this mythical person's laboratory is filled with mythical test tubes and Petri dishes and that his or her daily life is spent in experimentation, for the purposes of this legal exercise, no research of any kind can be contemplated. So, although it may have been logical to an actual skilled person at the time, based on the state of the art, to conduct certain testing, that is not open to the mythical skilled technician. The mythical researcher cannot have an inquiring or thinking mind which ultimately would lead him or her to the answer but rather he or she is expected to instantly and spontaneously exclaim, without more, "I already know the answer and it is obvious". Nor is it appropriate to say that there were significant telltales which pointed the way for the mythical expert or that there were sufficient clues which made the invention "worth a try". In *Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning v. Halocarbon (Ontario) Ltd.* (1974), 15 C.P.R. (2d) 105 at p. 114, [1974] 2 F.C. 266 (T.D.), Collier J. in rejecting the "worth a try" test stated:

"Using the magnifying spectacles of hind-sight (a half borrowed phrase), it is easy to say that any experiment, if time and expense are unlimited... is or was worth a try."

On appeal, the Supreme Court of Canada affirmed this position (42 C.P.R. (2d) 145, 104 D.L.R. (3d) 51, [1979] 2 S.C.R. 929) and stated at p. 155:

Very few inventions are unexpected discoveries. Practically all research work is done by looking in directions where the "state of the art" points. On that basis and with hindsight, it could be said in most cases that there was no inventive ingenuity in the new development because everyone would then see how the previous accomplishments pointed that way.

Presumably, that is why Hugessen J. stated that the question he posed in *Beloit*, *supra*, about the mythical creature is a "very difficult test to satisfy".

The UK decisions which utilize the "worth a try" test, therefore, must be treated with great caution. The observations of Mustill L.J. in *Genentech, supra,* and the conclusion of Aldous J. in the *Bayer* case, *supra,* that the development of the nifedipine capsule was obvious rested on the "worth a try" test (as can be seen from those earlier quoted words of Aldous, J., which I have highlighted). Those U.K. decisions are, therefore, of little assistance in this case." ¹⁷¹

Lederman's decision was appealed to the Ontario Court of Appeal. The appeal was dismissed, with the appeal judge commenting that "I see no reason for interfering with Lederman's findings of fact or his conclusion that the patent is not invalid..." Leave to appeal to the Supreme Court of Canada was dismissed. 173

Bayer Aktiengesellschaft et al v. Apotex Inc. (1998) 82 C.P.R. (3d) 526 (Ont. C.A. per Cumming J. (ad hoc))

ibid at p. 80-81

¹⁷³ [1998] S.C.C.A. No. 563 (QL) [84 C.P.R. (3d) v]

7.9.1.4 Cases quoting and following Bayer v. Apotex

The *Bayer* case became a "wake-up call" for the "worth-a-try test" and many cases have since quoted from 174 and followed 175 Lederman's reasoning.

In *671905 Alberta Inc. et al* v. *Q'Max Solutions Inc.*¹⁷⁶, Gibson J. held the invention to be not obvious. In determining the issue of obviousness, Gibson J. noted as a point of consideration the fact that the inventor, Rick Smith, had to conduct "experimentation and literature research" in order to develop the invention. The Federal Court of Appeal dismissed the appeal on this point raising the issue of experiments but not deciding the case on that basis.

In *Procter & Gamble Pharmaceuticals Canada Inc.* v. *Canada (Minister of Health) and Genpharm,* ¹⁸⁰ Snider J. noted that it was not clear which factors of the relevant theory at the time were effective and which were not. Given this uncertainty, she concluded that it was not obvious what dosage would be effective or appropriate without the use of a bone cell activator and that the dosage would have to be tested to see if it was effective without an activator. ¹⁸¹

"...Since it was not clear which elements of the coherence theory were effective,. This moves Dr. Chambers skilled technician away from being one that applies mechanistic skill to one that innovates. Such a technician falls outside the scope of the legal test for obviousness." 182

"Genpharm points out, however, that the different potencies of these bisphosphonates are accounted for by using the Schenk model and the TPTX rat model, both of which are relied upon in the '376 patent, to determine the LED for each one. This argument, however, overlooks the fact that the mythical skilled technician does not conduct further

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Novartis AG v. Apotex Inc. (2001), 15 C.P.R. (4th) 417 (F.C.T.D. per Blais J.) online. The Federal Court of Appeal dismissed the appeal on the grounds of mootness, because an NOC had already been issued Novartis AG v. Apotex Inc. (2002), 22 C.P.R. (4th) 450 (F.C.A.)

Baker Petrolite Corp. et al v. Canwell Enviro-Industries Ltd. et al (2001) 13 C.P.R. (4th) 193 (F.C.T.D. per Gibson J.)¹⁷⁵ at p. 231, para. 96; 671905 Alberta Inc. et al v. Q'Max Solutions Inc. (2001), 14 C.P.R. (4th) 129 (F.C.T.D. per Gibson J.) Aug. 15, 2001 online; AB Hassle v. Genpharm Inc. [2003] F.C.J. No. 1910, 2003 FC 1443, (2003), 243 F.T.R. 6 (F.C.T.D. per Layden-Stevenson J.) online at para. 45; aff'd Genpharm Inc v. AB Hassle 2004 FCA 413 (F.C.A. per Rothstein J.A., Noël and Malone J.J.A. concurring) at para. 11.

⁶⁷¹⁹⁰⁵ Alberta Inc. et al v. Q'Max Solutions Inc. (2001), 14 C.P.R. (4th) 129 (F.C.T.D. per Gibson J.) Aug. 15, 2001 online

ibid, at para. 64, p. 152-153.

ibid, at para. 64, pp. 152-153.

¹⁷⁹ (2003) 27 C.P.R. (4th) 385 (F.C.A. Stone J.A., Noël and Sexton JJ.A. concurring) June 2, 2003

¹⁸⁰ (2004), 32 C.P.R. (4th) 224 (F.C.T.D. per Snider J.) online

ibid, at p. 245, paras. 64-65.

ibid, at p. 245, para. 65.

tests, serious thought or research to arrive at the invention claimed. To accept Genpharm's argument would expand the scope of the legal test for obviousness. This is because the mythical skilled technician, would, after reading Chesnut's study using clodronate and cognizant that it has a different potency than etidronate:

- Carry out tests using the Schenk and TPTX rat models to arrive at the range of etidronate dosages for rats; and,
- 2) Use this data to extrapolate the dosages for humans claimed by P & G in its '376 patent.

This, in my view, goes well beyond current legal understanding of obviousness." ¹⁸³

In *Pfizer Canada* v. *Apotex Inc.* (the <u>sertraline/Zoloft</u> case), ¹⁸⁴ Dawson J. applied the "no experimentation or serious thought" test. ¹⁸⁵ In *Bayer AG et al* v. *Apotex Inc. et al*, ¹⁸⁶ Gibson J. quoted from and adopted Dawson J.'s review of the law of obviousness from *Pfizer* v. *Apotex*, paras. 101-111 which includes the reference to Wetston J. and Lederman J.

7.9.1.5 The U.K. "Worth a try" test

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

The "worth a try" test provided that if the chances of success were enough to try, then it was obvious:

"It is enough that the person versed in the art would assess the likelihood of success as sufficient to warrant actual trial". 187

The "worth a try" test was, effectively, "If something is worth spending time and money looking into, then it is obvious." It created a very low bar for obviousness and hence resulted in a large number of UK patents being held to be obvious.

In the *Johns-Manville Corp's Patent*¹⁸⁸ case, the technology related to the use of flocculating agents in a process of manufacturing asbestos cement pipes. The flocculating agent, a water-soluble high molecular weight polyacrylamide, had only recently come on to the market but was sold and known to be a flocculating agent and was recommended for use as such by its manufacturers at the date of the patent, in the very proportions claimed by the patentees. The

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ibid, at p. 246, para. 68.

Pfizer Canada v. Apotex Inc. (2002), 22 C.P.R. (4th) 466 (F.C.T.D. per Dawson J.) the sertraline/Zoloft case

ibid, at para. 113,

¹⁸⁶ (2003), 29 C.P.R. (4th) 143 (F.C.T.D. per Gibson J.) at p. 167.

Johns-Manville Corporation's Patent [1967] RPC 479 (per Lord Diplock) at 495.

¹⁸⁸ [1967] R.P.C. 479 (C.A.)

trial judge, Whitford J. considered the invention to have been obvious because one would "see without difficulty that these newly-introduced polymers would be of advantage in his filtration step". In the House of Lords, Diplock L.J. considered that a threshold of certainty was too high:

"I think that 'would be' puts it too high if it postulates prior certainty of success before actually testing the polymers in the filtration process; it is enough that the person versed in the art would assess the likelihood of success as sufficient to warrant actual trial."

Diplock L.J. held that the flocculating agent was "well worth trying out" and that trying them out would have been obvious to those in the art (at p. 495):

"In so far as this witness obtained literature about flocculating agents used in other industries, and realised, as soon as he heard of them, that polyacrylaminades were well worth trying out as flocculating agents in his own industry of manufacturing asbestos cement pipes, his evidence confirms the opinion of the superintending examiner and the Patents Appeal Tribunal that the idea of trying out these newly-introduced flocculating agents in the filtration process in that industry would be obvious to persons 'versed in the art'."

"Sufficient to warrant actual trial" and "well worth trying out" became the "worth a try" test for obviousness.

Graham J. in *American Cyanamid Co.* v. *Ethicon Ltd.*¹⁸⁹ differentiated the *Johns-Manville* case from his own. Graham J. noted that, in the *Johns-Manville* case, the actual substance was already on the market and had been suggested by its makers as valuable for flocculating purposes, whereas in his case, no such facts existed.¹⁹⁰

"... it seems to me that to regard as obvious the choice of a starting material not then available on the market, which had only been suggested as one of thousands of other candidates for a research programme to find an end product with particular qualities, is a very far cry from suggesting the trial of a starting material available on the market, whose characteristics and capabilities are known, for use in a process where those capabilities are required." ¹⁹¹

In the U.K., the unimaginative skilled technician would be expected to try out all obvious modifications or combinations of the methods which seemed to him worth trying. 192

"In this case he would have been faced with a large variety of different methods, none of which had proved commercially useful. He would have had no assurance that any successful solution was possible, still less would have known in what direction to look for

¹⁸⁹ [1979] R.P.C. 215 at pp. 266-267

¹⁹⁰ [1979] R.P.C. 215 at p. 266.

¹⁹¹ [1979] R.P.C. 215 at p. 267.

Technograph Printed Circuits Ltd. v. Mills & Rockley (Electronics) Ltd. [1972] R.P.C. 346 (per Lord Reid) at p. 355:

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In the General Tire¹⁹³ decision, Sach L.J. of the House of Lords held that it would be obvious to do "a series of trial and error activities of a skilled compounder" but not obvious (inventive) to "the sort of experiments which can be ranked as of an inventive nature".

Thus, if there were only trial and error experiments (and no "inventive" ones) between the prior art and the claimed invention, it was deemed to be obvious under the "worth a try" test.

The "worth a try" test crept into some Canadian cases before Sanofi.

For example, Wetston J. in *Apotex Inc.* v. *Wellcome Foundation Ltd.*¹⁹⁴ Discussing obviousness, Wetston J. made the following statements at p. 269-270:

[243] There is no inventiveness in following an obvious and well-charted route using known techniques and processes involving known compositions unless the inventor encounters difficulties that could not have been reasonably expected by a person versed in the art or overcome by the application of ordinary skill: *Burns & Russell of Canada v. Day and Campbell Ltd.* (1965), 48 C.P.R. 207; *Genentech Inc.'s Patent*, [1989] R.P.C. 147 (C.A.).

[244] A & N submit that there can be no invention in pursuing an obvious line of research involving simple empirical experiments on compounds which are themselves neither novel nor inventive unless the idea prompting the research was not obvious or the research generated an otherwise unexpected result. In support of this position, A & N rely on the cases involving workshop improvement: *Leithiser et al. v. Pengo Hydra-Pull of Canada Ltd.* (1974), 17 C.P.R. (2d) 110 (F.C.A.); *Burns & Russell of Canada v. Day and Campbell Ltd., supra*; *Genentech Inc.'s Patent, supra*. Glaxo submits that inventions which are arrived at by methodical testing are valid and equally deserving of protection: *Farbwerke Hoechst A.G. v. Halocarbon (Ont.) Ltd., supra*.

[245] The general question to be resolved is whether or not the alleged invention required the exercise of inventive ingenuity: *Windsurfing International Inc. et al. v. Trilantic Corporation* (1985), 8 C.P.R. (3d) 241 (F.C.A.). That is, was the invention "plain as day" or "crystal clear" to a technician skilled in the art at the date of the invention: *Bayer v. Apotex Inc., supra*, at 79. Something is said to be obvious when it would occur directly to the ordinary person skilled in the relevant art searching for something novel without serious thought, research or experiment: G.F. Takach, *Patents: A Canadian compendium of law and practice*, (Edmonton: Juriliber, 1993). Where the alleged invention is the product of a collaborative research effort, the contribution of each notional member should be assessed separately, attributing to each the requisite level of skill required of a person fulfilling that function: *Genentech Inc.'s Patent, supra*, at page 278.

it. He would be expected to try out all obvious modifications or combinations of these methods which seemed to him worth trying."

General Tire & Rubber Company v. Firestone Tyre & Rubber Company Limited [1972] R.P.C. 457
 (H.L. per Sach L.J., Buckley and Orr concurring) at p. 497

^{(1998) 79} C.P.R. (3d) 193 (F.C.T.D. per Wetston J.)

Paragraph 243 appears to be a summary of the statement of law of Mustill J. from the *Genentech* case as quoted by Lederman J. in *Bayer* v. *Apotex* at p. 80:

"... Then, in a case like the present, which does not involve a simple leap from the prior art to the invention (as in the James Watt type of case) but rather entails a journey with numerous steps taken in sequence, the court must ask itself by what routes it would have been possible to proceed to the goal from the starting point. Then, the court must see what obstacles the skilled man would have faced on these routes, and must enquire how he could have overcome them, either in the way that the inventor himself overcame the obstacles on his chosen route or by circumventing or overcoming them in some other way, or by choosing another route from the outset, or by abandoning one route and choosing another.

Having identified these various expedients, the court must finally ask whether they could have been overcome by pertinacity, sound technique or trial and error, with no more, or whether there would have been required a spark of imagination beyond the imagination properly attributable to the man skilled in the art.

. . .

But where one is looking at the research team, one cannot treat them as dull plodders, for such people would not be members of the team at all, except as laboratory assistants. We have to envisage people who are skilled, and skilled in the art. Here we have a difficult art, in which the skill consists in a substantial degree of an ability to solve problems. It must, I consider, follow from this that the hypothetical skilled man must be credited with that particular ability in the appropriate degree."

Comparing Mustill J. and Wetston J. side-by-side it appears that Wetston J. improperly adopted the "worth-a-try" test:

Mustill J. in Genentech	Wetston
the court must ask itself	There is no inventiveness in following
by what routes it would have been possible to proceed to the goal from the starting point.	an obvious and well-charted route using known techniques and processes involving known compositions
Then, the court must see what obstacles the skilled man would have faced on these routes,	unless the inventor encounters difficulties that could not have been reasonably expected by a person versed in the art
and must enquire how he could have overcome them,	or overcome
either in the way that the inventor himself overcame the obstacles on his chosen route or by circumventing or overcoming them in some other way, or by choosing another	

Mustill J. in Genentech	Wetston
route from the outset, or by abandoning one route and choosing another.	
Having identified these various expedients, the court must finally ask whether they could have been overcome by pertinacity, sound technique or trial and error, with no more, or whether there would have been required a spark of imagination beyond the imagination properly attributable to the man skilled in the art.	by the application of ordinary skill

As cautioned by, Lederman J. in Bayer v. Apotex:

"The UK decisions which utilize the "worth a try" test, therefore, must be treated with great caution. The observations of Mustill L.J. in *Genentech, supra,* and the conclusion of Aldous J. in the *Bayer* case, *supra,* that the development of the nifedipine capsule was obvious rested on the "worth a try" test (as can be seen from those earlier quoted words of Aldous, J., which I have highlighted). Those U.K. decisions are, therefore, of little assistance in this case." ¹⁹⁵

7.9.1.6 Would not could: "Worth a Try" is not the test in Canada

For many years, Canadian pharmaceutical patent owners had, for the most part, fended off the Canadian generic pharmaceutical companies' attempts to make the U.K. "worth a try" or "obvious to try" test a part of the Canadian law of obviousness. The generics had argued that if something was "obvious to try", and was followed by standard, routine, trial and error experiments, there could be no invention. The "worth a try" test is not the law of obviousness in Canada.

The "worth a try" test was proffered in the *Hoescht* v. *Halocarbon* case at trial by Mr. Sim, counsel for the defendant Halocarbon. ¹⁹⁶ In the Supreme Court, ¹⁹⁷ Pigeon J. considered the test that had been applied by the Federal Court of Appeal in that case and found it to be too high a test for inventive ingenuity:

"Mr. Sim sparred at some length with Dr. Schmutzler, pressing and exploring the hypothesis that the liquid phase process was, to a skilled person, "worth a try". Using the magnifying spectacles of hind-sight (a half borrowed phrase), it is easy to say that any experiment, if time and expense are unlimited ... is or was worth a try."

^{(1995), 60} C.P.R. (3d) 58 (Ont. Ct. Gen. Div. per Lederman J.) at pp. 81-82; appeal dismissed, cross-appeal allowed on a different issue (1998), 82 C.P.R. (3d) 526 (Ont. C.A.); leave to appeal to the Supreme Court of Canada denied [1998] S.C.C.A. No. 563

¹⁹⁶ Farbwerke Hoescht v. Halocarbon (1974), 15 C.P.R. (2d) 105 at 114 (F.C.T.D. per Collier J.):

Farbwerke Hoechst v. Halocarbon (Ontario) Limited et al (1979), 42 C.P.R. (2d) 145 (S.C.C.), 1979 CarswellNat 636 (S.C.C.)

"On this point, the Federal Court of Appeal reached a different conclusion [from the trial judge], Jackett C.J. saying (at p. 471):

"The learned trial judge appears to have proceeded upon the assumption that the requirement of "inventive ingenuity", is satisfied unless the "state of the art" at the time of the alleged invention was such that it would have been obvious to any skilled chemist "that he would successfully produce isohalothane (assuming the monomer used here and hydrogen bromide) in the 'liquid phase'." (The italics are mine.) I do not think that the learned trial judge's assumption is correct as a universal rule. I would not hazard a definition of what is involved in the requirement of "inventive ingenuity: but, as it seems to me, the requirement of "inventive ingenuity", is not met in a the circumstances of the claim in question where the "state of the art" points to a process and all the alleged inventor has done is ascertain whether or not the process will work successfully."

In my view this statement of the requirement of inventive ingenuity puts it much too high. Very few inventions are unexpected discoveries. Practically all research work is done by looking in directions where the "state of the art" points. On that basis and with hindsight, it could be said in most cases that there was no inventive ingenuity in the new development because everyone would then see how the previous accomplishments pointed the way. The discovery of penicillin was, of course, a major development, a great invention. After that, a number of workers went looking for other antibiotics methodically testing whole families of various microorganisms other than penicillum noatum. This research work was rewarded by the discoveries a number of antibiotics such as chloromycetin obtained from streptomyces venezuelae as mentioned in Laboratoire Pentagone v. Parke, Davis & Co. [1968] R.C.S. 307, tetracycline as mentioned in American Cyanamid Co. v. Berk Pharmaceuticals Ltd. [1976] R.P.C. 231 where Whitford J. said (at p. 257):

"A patient searcher is as much entitled to the benefits of a monopoly as someone who hits upon an invention by some lucky chance or inspiration."

I cannot imagine patents obtained for antibiotics and for various processes for their production being successfully challenged on the basis that the discovery of penicillin pointed the way and there was no inventive ingenuity in the search for other antibiotics and in the testing and the development processes. In my view the true doctrine was clearly stated in *Pope Appliance Corporation* v. *Spanish River Pulp and Paper Mills* [1929] A.C. 269, where Viscount Dunedin said (at p. 280-1):

"... After all, what is invention? It is finding out something which has not been found out by other people. This Pope in the present patent did. He found out that the paper would so stick, and the practical problem was solved. The learned judges below say that all this might have been done by any one who experimented with "doctors" and air blasts already known. That is that some one else might have hit upon 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, ..."

The same result will be obtained by putting, as the trial judge did (at p. 274), the "Cripps question" as to what Viscount Simon said in *Martin and Biro Swan Ld.* V. *H. Millwood Ld.* [1956] R.P.C. 125, at pp. 133-4:

"... Your Lordships at least have the opportunity of affirming that the law on this matter is as stated by Jenkins, L.J. in *Allmanna Svenska Elektriska A/B* v. *Burntisland Ship Building Coy. Ld.* (1952) 69 R.P.C. 63, and that the proper question to ask is that which was formulated by Sir Stafford Cripps as counsel in *Sharp & Dohme Inc.* v. *Boots Pure Drug Coy. Ld.* (1928) 45 R.P.C. 153 at p. 163:

"Was it obvious to any skilled chemist in the state of chemical knowledge existing at the date of the patent that he could manufacture valuable therapeutic agents by making the higher resorcinols by the use of the condensation and reduction processes described. If the answer is 'No' then the patent is valid, if 'Yes' the patent is invalid." 198

The Cripps question applied by Collier J. in the *Hoescht*¹⁹⁹ case was:

"Using a paraphrase of the "Cripps question": Was it for all practical purposes obvious to any skilled chemist in the state of chemical knowledge existing at the

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Hoescht v. Halocarbon (Ont.) Ltd. [1974] 2 F.C.R. 266 (F.C.T.D. per Collier J.) at p. 274. The courts have sometimes tried to differentiate between "discoveries" and inventions" – the latter supposedly being patentable and the former not. In AB Hassle v. Genpharm Inc [2003] F.C.J. No. 1910, 2003 FC 1443, (2003), 243 F.T.R. 6 (F.C.T.D. per Layden-Stevenson J.) online, Justice Layden-Stevenson made this distinction at para. 51:

"Yet, there is a distinction between a "discovery" for which no patent can be given, and an "invention" for which a patent may be granted. A discovery is that which was previously unseen or dimly seen, yet lay on the path; an invention is that which lay outside the path to produce something new: Farbwerke Hoechst AG Vormals Meister Lucius & Bruning v. Halocarbon (Ontario) Ltd. (1979), 42 C.P.R. (2d) 145 (S.C.C.)"

Contrary to what was said by Layden-Stevenson J., the *Hoescht* case does not differentiate between "discoveries" and "inventions". The excerpt from the *Hoescht* case refers to "discoveries" throughout its discussion of inventiveness, quotes above. Nor does the *Hoescht* case refer to things "previously unseen or dimly lit, yet lay on the path." This sounds like a misquote of Collier J.'s borrowing from *General Tire* in the *Xerox* case (*Xerox of Canada Ltd. et al.* v. IBM Canada Ltd., (1977), 33 C.P.R. (2d) 24 (F.C.T.D. per Collier J.) at p. 62:

ibid, paras. 33-35.

[&]quot;... the route to obviousness must be a flagstone path, plainly perceptible in either the dark or the light."

date of the invention, which consists of the chemical literature available and his general knowledge, particularly in the field of fluorine chemistry, that he would successfully produce isohalothane (assuming the monomer used here and the hydrogen bromide) in the liquid phase? ...

... there was nothing in the prior publication to lead the skilled chemist to reasonably say it was plain the process could equally be carried out in the liquid phase..."

Therefore, the test in the Supreme Court decision in *Hoescht* endorsed Collier's requirement that in order for something to have been obvious, it must have been obvious that the solution would work <u>successfully</u>. Rather oddly, the Supreme Court made no reference whatsoever to *Hoechst* in *Sanofi*.

Interestingly, the quote cited above from the *Pope Appliance* case continues:

" ... for a patent represents a *quid pro quo*. The *quid* to the patentee is the monopoly; the *quo* is that he presents to the public the knowledge which they have not got. That knowledge the other inventor has kept sealed in his own breast, and he therefore cannot complain that his rival got the 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 than the present, when the objector does not say that he did discover, but only that if he had experimented he would have discovered." ²⁰⁰

Likewise, in *Beloit*, the test as articulated by Hugesson J.A. was "... whether this mythical creature (the man in the Clapman omnibus of patent law) **would**, in the light of the state of the art and common general knowledge as at the claimed date of invention, have come directly and without difficulty to the solution taught by the patent."²⁰¹ [emphasis added]

In *Bayer Aktiengesellschaft* v. *Apotex Inc.*, Lederman J. said the test of obviousness was whether the claimed invention <u>would</u> have been plain to the unimaginative technician, not whether he or she could have achieved the same result.²⁰² This is consistent with the

Pope Appliance Corporation v. Spanish River Pulp and Paper Mills [1929] A.C. 269 per Viscount Dunedin at p. 281

²⁰¹ Beloit Canada Ltd. v. Valmet Oy (1986), 8 C.P.R. (3d) 289 (F.C.A. per Hugessen J.A.) at p. 294

^{(1995), 60} C.P.R. (3d) 58 (Ont. Ct. Gen. Div. per Lederman J.); appeal dismissed, cross-appeal allowed on a different issue (1998), 82 C.P.R. (3d) 526 (Ont. C.A.); leave to appeal to the Supreme Court of Canada denied [1998] S.C.C.A. No. 563:

[&]quot;The test [of obviousness] therefore is not whether anyone skilled in the art *could* have achieved the same result as the patentee's invention, but whether this particular drug dosage form of Nifedipine *would* have been very plain to the unimaginative technician in the drug formulation field: *Beecham Canada Ltd.* v. *Procter & Gamble* (1982), 61 C.P.R. (2d) 1 at p. 27, 40 N.R.313 (F.C.A.)"

application of the Cripps Question by the Federal Court of Canada: Would the skilled worker be led to the claimed invention?²⁰³

Saying that scientists would have ultimately arrived at the invention is an expression of the "worth a try" test and does not render the claimed invention obvious. 204

7.9.2 The U.K. and U.S. "Obvious to try" tests

7.9.2.1 St. Gobain: U.K. "Obvious to try" test means it ought to work

In 2005, the U.K. law of obviousness underwent a sea change in Saint-Gobain PAM SA v. Fusion Provida Ltd. 205 ("St. Gobain"). Using logic similar to that expressed in the Canadian

203 For example, in Beecham Canada Ltd. v. Procter & Gamble Co. (1982), 61 C.P.R. (2d) 1 (F.C.A.):

> "The question to be answered is whether at the date of invention (August-September, 1964) an unimaginative skilled technician, in light of his general knowledge and the literature and information on the subject available to him on that date, would have been led directly and without difficulty to Gaiser's invention."

AB Hassle v. Genpharm Inc [2003] F.C.J. No. 1910, 2003 FC 1443, (2003), 243 F.T.R. 6 (F.C.T.D. per Layden-Stevenson J.) online The case involved an omeprazole tablet with three layers. Genpharm argued that scientists would have added alkaline material to the acid sensitive drug, not initially, but ultimately: some point the skilled worker would have done it (para. 109). Justice Layden-Stevenson characterized this argument as resembling the English "worth a try" test (para 112). She said (at para 113):

> "Dr. Rowe's position, in my view, constitutes an adoption of the English approach. In essence, his evidence is to the effect that, based on the prior art, adapting pH would be worth a try. I am not persuaded that Dr. Rowe, absent the "worth a try" approach, would go directly and without difficulty to the solution. Thus, in England he might succeed on this approach; in Canada he cannot. Astra (and Takeda) have satisfied me that Genpharm's allegation with respect to the '377 Takeda patent is not justified."

In Genpharm Inc v. AB Hassle 2004 FCA 413 (F.C.A. per Rothstein J.A., Noël and Malone J.J.A. concurring), the Federal Court of Appeal dismissed the appeal by Genpharm from the decision of Layden-Stevenson J. stating that the Genpharm obviousness test arguments were rejected in Genpharm v. Procter & Gamble 2004 FCA 393. With respect to her decision on obviousness, the Federal Court of Appeal said at para. 11:

"She [Layden-Stevenson] found that Genpharm's position regarding obviousness respecting the '377 Patent resembled the English "worth a try" test. Before this Court, Genpharm agreed that the English "worth a try" test is not applicable in Canada. At paragraph 113, Layden-Stevenson J. concluded that the solution of the '377 Patent would, absent the "worth a try" approach, not be arrived at directly and without difficulty. There was evidence to support that conclusion. Genpharm has not demonstrated any palpable and overriding error in Layden-Stevenson J.'s conclusion on this point."

Saint-Gobain PAM SA v. Fusion Provida Ltd., [2005] EWCA Civ 177; Tomos Shillingford of the UK 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, 2006, available at http://www.twobirds.com/English/News/Articles/Pages/Has the obvious to try test been buried .aspx)

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Hoechst 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":

"Mere 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."

206 [emphasis added]

Therefore, under this revised U.K. "obvious to try" test, the fact that the invention was "obvious to try" was not enough to meet the test. It had to be self-evident (or obvious) that it would work.

7.9.2.2 The "obvious to try" test in the U.S.A.

*In re O'Farrell*²⁰⁷, Rich J. emphasized that the "obvious to try" test is not the proper test for obviousness under US law:

"It is true that this court and its predecessors have repeatedly emphasized the "obvious to try" is not the standard under § 103." ²⁰⁸

Rich J. refers to two types of cases where something can be "obvious to try" but nevertheless be unobvious:

- "In some cases, what would have been "obvious to try" would have been to vary all
 parameters to try each of numerous possible choices until one possibly arrived at a
 successful result, where the prior art gave either no indication of which parameters
 were critical or no direction as to which of many possible choices is likely to be
 successful" 209 and
- "In others, what was obvious to try was to explore a new technology or general approach that seemed to be a promising filed of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it." 210

The U.S. test provides in its test for obviousness, not for absolute certainty but a "reasonable expectation of success":

ibid, at p. 1680

²⁰⁹ In re O'Farrell 853 F.2d 894, 7 U.S.P.Q. (2d) 1673 at p. 1681(C.A.F.C. per Rich J.) 1988

²¹⁰ In re O'Farrell 853 F.2d 894, 7 U.S.P.Q. (2d) 1673 at p. 1681(C.A.F.C. per Rich J.) 1988

Saint-Gobain PAM SA v. Fusion Provida Ltd., [2005] EWCA Civ 177 at para. 35.
 In re O'Farrell 853 F.2d 894, 7 U.S.P.Q. (2d) 1673 at p. 1681(C.A.F.C. per Rich J.) 1988

"Obviousness does not require absolute predictability of success. Indeed, for many inventions that seem quite obvious, there is no absolute predictability of success until the invention is reduced to practice. There is always at least a probability of unexpected results, that would then provide an objective basis for showing that the invention, although apparently obvious, was in law unobvious ... For obviousness under § 103 all that is required is a reasonable expectation of success."

The United States Supreme Court, in 2007, in *KSR International Co. v. Teleflex Inc. et al.*²¹² overturned "teaching, suggestion or motivation" ("TSM") test. In order to show a patent claim to be obvious under the TSM test, the prior art had to explicitly motivate or suggest the combination of the prior art's teaching. The U.S. Supreme Court found the TSM test to be too rigid. It cited the *Graham v. John Deere* case²¹³ as saying that secondary considerations, including commercial success and long felt but unsolved needs, might be used to give light to the circumstances surrounding the origin of the subject matter sought to be patented. Similar to the U.K. courts, the U.S. Supreme Court held that when the result is predictable, the fact that a combination was obvious to try might show that it was obvious:

"When there is a design need or market pressure to solve a problem and there are a finite number of identified, **predictable solutions**, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103."²¹⁴ [emphasis added]

7.10 The Sanofi "Obvious to try" test

In *Sanofi*, Justice Rothstein stated that the convergence of the U.S. and U.K. law on the issue of the "obvious to try" test suggested that the Canadian obviousness test should be reexamined.²¹⁵

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.²¹⁶

Not all cases involve experimentation of the sort in *Sanofi* and the "obvious to try" test should not be applied to them. ²¹⁷

²¹⁴ 127 S.Ct. 1727 (2007) at 1742.

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²¹¹ In re O'Farrell 853 F.2d 894, 7 U.S.P.Q. (2d) 1673 at p. 1681(C.A.F.C. per Rich J.) 1988

²¹² 127 S.Ct. 1727 (2007).

²¹³ 383 U.S. 1 (1966).

Apotex Inc. v. Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265, 2008 SCC 61, para. 60.

Apotex Inc. v. Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265, 2008 SCC 61, para. 68.

The "obvious to try" test was not applied in:

Sadly, the "obvious to try" test is a misnomer of sorts, because the question raised by the test is not whether it would be obvious to give the proposed invention a try, but rather, whether you can predict that the invention will work.

Sanofi clarified and articulated the applicability of the "obvious to try" test as part of the obviousness analysis. The new test requires predictability: in order for there to be a finding of obviousness, one must have been able to predict than the alleged invention would work. In this sense, the Canadian test is very similar to the American test of obviousness in KSR²¹⁸ and the U.K. obviousness test as articulated in *St. Gobain*.²¹⁹

7.10.1 Sanofi: Factors to consider for inventions borne by experimentation

The Canadian Supreme Court said in *Sanofi* that in cases where advances are often won by experimentation, ²²⁰ an "obvious to try" test might be appropriate to use in the fourth step of the *Windsurfing* obviousness approach.

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 is not true of chemical and pharmaceutical products. Their behaviours in the human body (and particularly their side-effects) are inherently unpredictable.

- UView Ultraviolet Systems Inc. v. Brasscorp Ltd., 2009 FC 58 (F.C. per O'Keefe J.), 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 at para. 189, the case was not the
 type of case where, as the Supreme Court suggested, the "obvious to try" test would be
 appropriate.
- Bristol-Myers Squibb Canada Co. v. Apotex Inc. 2009 FC 137 (F.C. per Hughes J.), 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 (paras. 157-159).
- Bridgeview Manufacturing Inc. et al v. 931409 Alberta Ltd. c.o.b.a. Central Alberta Hay Centre et al, 2010 FCA 188 (F.C.A. per Sharlow J.A., Nadon & Trudel JJ.A. concurring) at para. 42, a case involving a mechanical device, and although the "obvious to try" tests was appropriate where, in the relevant art, advances are won by experimentation, this was not a case where the Sanofi refinement had any application.
- KSR International Co. v. Teleflex Inc. et al. 127 S.Ct. 1727 (2007)
- Saint-Gobain PAM SA v. Fusion Provida Ltd., [2005] EWCA Civ 177. In contrast, the Federal Court of Australia in an action between the same parties relating to the corresponding Australian patent, held the alleged invention to be obvious, based on a legal test similar to the old U.K. "worth a try" test ([2009] FCAFC 134 at para. 177).
- Apotex Inc. v. Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265, 2008 SCC 61, para. 68; followed in *Eli Lilly Canada Inc. et al* v. *Novopharm Limited*, 2010 FCA 197 (Layden-Stevenson J.A., Nadon and Sharlow JJ.A. concurring) at paras. 54-64.

One cannot be sure how a pharmaceutical will behave with certainty until it is tested on a patient.

Borrowing from several U.K. decisions and the U.S. *KSR* decision, the Court indicated the following factors should be considered in applying the "obvious to try" test,²²¹ and approved the use of direct evidence from the invention team itself:²²²

- 1. Is it "very plain" or "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?²²³
- 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?²²⁴
- 3. Is there a motive provided in the prior art to find the solution the patent addresses?²²⁵

7.10.1.1 1. More or less self-evident it ought to work

The language "more or less self-evident" appears to be a synonym for "readily apparent", "predictable" or "plain as day", the latter being a synonym for "obvious". In other words, could one have predicted at the relevant date that what is claimed to be the invention would work? 227

In an apparent departure from the Supreme Court's direction that the four *Sanofi* factors "should be taken into consideration" in applying the "obvious to try" test (including where it was more or less self-evident that what is being tried ought to work), in *Lundbeck Canada Inc. v. Canada (Health), Genpharm and Apotex* 2009 FC 146 (F.C. per Harrington J.), the Court said at para. 56 that the four factors that Justice Rothstein had put forward were "non-mandatory". Relying heavily on the arduous research path taken by the inventors, Justice Harrington concluded that it was not self-evident that what was being tried ought to work (paras. 103 & 124.).

Apotex Inc. v. Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265, 2008 SCC 61, para. 70.

Apotex Inc. v. Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265, 2008 SCC 61, paras. 65 & 66 and 69(1).

²²⁴ Apotex Inc. v. Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265, 2008 SCC 61, para. 69(2); H. Lundbeck A/S v. Generics (UK) Ltd., [2008] R.P.C. 19, [2008] EWCA Civ 311 at para. 24

Apotex Inc. v. Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265, 2008 SCC 61, para. 69(3); Angiotech Pharmaceuticals & Anor v. Conor Medsystems Inc. [2007] EWCA Civ 5 at para. 45.

Bayer v. Apotex Inc., (1995), 60 C.P.R. (3d) 58 (Ont. Ct. Gen. Div. per Lederman J.) at 79; appeal dismissed, cross-appeal allowed on a different issue (1998), 82 C.P.R. (3d) 526 (Ont. C.A.); leave to appeal to the Supreme Court of Canada denied [1998] S.C.C.A. No. 563.

In Sanofi-Aventis Canada v. Apotex Inc.²²⁷, the Court was persuaded that it would have been obvious to try to substitute a 5,5 bicyclic ring for the proline ring on the (prior art) enalapril backbone.²²⁷ With respect to whether it "ought to work" based upon the patentee's evidence of sound prediction, the Court concluded that one could soundly predict that a 5,5 bicyclic ring on an enalapril backbone would work, and a skilled person would expect that compound to have activity.²²⁷ The alleged invention was held to be obvious.

The concept that the solution "ought to work" is analogous to the question asked in the *Hoescht* case: could one predict success for the solution? If it was predictable, then it was obvious. If success could not be predicted, then the solution was not obvious.

In what appears to have been a departure from the test elsewhere articulated, Justice Rothstein twice asked whether it would have been self-evident "to try" the racemate separation methods", 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." ²²⁸ [emphasis added]

and 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." [emphasis added]

This wording was unfortunate as it muddies the inquiry. It suggests that the question is whether it was obvious to try to obtain the invention rather than 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". Such approach was adopted, in my opinion, incorrectly by Justice Hughes' paraphrasing of the *Sanofi* test in the clarithromycin case:

"The question for obviousness purposes is that as stated by the Supreme Court of Canada in *Sanofi* at paragraph 66, was 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." [emphasis added]

The Supreme Court went on, however, 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." 231

Apotex Inc. v. Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265, 2008 SCC 61, para. 66. This language was repeated in *Eli Lilly Canada Inc. et al* v. Novopharm Limited, 2010 FCA 197 (Layden-Stevenson J.A., Nadon and Sharlow JJ.A. concurring) at paras. 55.

²²⁹ Apotex Inc. v. Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265, 2008 SCC 61, para. 92.

Abbott Laboratories v. Canada (Health) 2008 FC 1359 (F.C. per Hughes J.) at para. 96; aff'd but not discussed on appeal at Abbott Laboratories v. Canada (Health) 2009 FCA 94 (F.C.A. per Richard C.J., Pelletier and Layden-Stevenson JJ.A. concurring). The only issue was whether a particular crystal form was sufficiently soluble so as to provide therapeutic use [para. 97]. After having found the patent to be anticipated, the Court held that it was 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 [para. 99] and, if it were necessary to do so, it would find that claim 5 of the '527 patent was obvious [para. 100].

observing that the mere possibility of getting the invention was insufficient:

"Mere possibility that something might turn up is not enough." 232 ...

"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." ²³³

Sanofi marketed a medicine called Plavix, which keeps platelets from sticking together and forming clots, and which thereby protects against future heart attacks or strokes. Apotex sought approval to market a generic version but, it light of what it alleged, would not receive approval unless it had the court declare that Sanofi's patent on Plavix was invalid.

The active ingredient of Plavix was the right-handed version or enantiomer²³⁴ of a racemate.²³⁵ Research had shown that the right-handed version had better therapeutic properties and fewer detrimental effects than the left-handed version. Both versions were claimed in an earlier patent (the "genus patent"), amongst more than 250,000 possible compounds. The patent at issue claimed the right-handed version and a salt of it and, as such, was a "selection patent". A selection patent claims a species of compounds selected from a previously patented genus because of that species' superior or surprising qualities.

The obviousness question before the Supreme Court was whether the selection patent was obvious in view of the genus patent. The Federal Court application judge and the Federal Court of Appeal had rejected Apotex's arguments that the selection patent was obvious and, thereby, invalid.

The Supreme Court noted that the evidence in *Sanofi* showed that the skilled person would not have known:

before separating the racemate into the two isomers and testing them, that the
properties of the right-handed isomer would have properties advantageous over those of
the racemate or the left-handed isomer;²³⁶

- ²³¹ Apotex Inc. v. Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265, 2008 SCC 61, para. 85.
- ²³² Apotex Inc. v. Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265, 2008 SCC 61, para. 66.
- ²³³ Apotex Inc. v. Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265, 2008 SCC 61, para. 85.
- An enantiomer is one of two stereoisomer compounds, each of which has the same molecular formula but are structurally mirror images of one another, just as one's right hand is a mirror image of the left hand. That analogy is used in the scientific nomenclature for the two forms: dextro (right-handed) and levo (left-handed). Understandably, the right and left-handed forms sometimes have different functionality a right hand properly fits into a right-hand glove, whereas a left hand does not.
- A racemate is a mixture of equal amounts of two enantiomers.
- Apotex Inc. v. Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265, 2008 SCC 61, paras. 75 & 84.

- before trying the salts in combination with the right-handed isomer, what the bisulfate salt's beneficial properties would be;²³⁷ nor
- that the right-handed isomer ought to work.²³⁸

The Court accordingly concluded the invention was not obvious.

In *Abbott Laboratories* v. *Canada (Health) and Sandoz*,²³⁹ 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,²⁴⁰ and then observed that there was nothing in the prior art that would suggest that this formulation would be suitable.²⁴¹ She also referred to other prior art that taught away from the invention and the failure of other prior users to make the invention.

7.10.1.2 finite number of identified predictable solutions

This language was taken, without attribution, from the US KSR decision.²⁴²

See Chapter 7.1 Confirmatory and Predictable Experiments are not inventive, above.

7.10.1.3 nature and amount of effort required: routine trials or prolonged and arduous?

See Chapter 7.8.2 The Empirical evidence – the inventor's actual path above.

In *Ratiopharm Inc.* v. *Pfizer Limited*²⁴³ the court found the alleged invention to be obvious. 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. 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. While besylate would not be everyones' first choice, it was not an

²³⁷ Apotex Inc. v. Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265, 2008 SCC 61, para. 92.

²³⁸ Apotex Inc. v. Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265, 2008 SCC 61, para. 92.

²⁰⁰⁹ FC 648 (F.C. per Heneghan J.)

²⁴⁰ 2009 FC 648 (F.C. per Heneghan J.) at paras. 123-134.

²⁴¹ 2009 FC 648 (F.C. per Heneghan J.) at para. 125.

Apotex Inc. v. Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265, 2008 SCC 61, para. 69(1); Saint-Gobain PAM SA v. Fusion Provida Ltd., [2005] EWCA Civ 177 at para. 35 and KSR International Co. v. Teleflex Inc. et al.. 127 S.Ct. 1727 (2007) at 1742.

Ratiopharm Inc. v. Pfizer Limited 2009 FC 711 (F.C. per Hughes J.)

unreasonable choice.²⁴⁴ In proceeding through a salt screen, the besylate as well as other sulphonates, seemed to work well enough so as to pass them along to others for final formulation and seek regulatory approval.²⁴⁵

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
- The type of experiments used by Pfizer's scientists to verify the physicochemical 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.²⁴⁶

7.10.1.4 Motivation in the prior art

See Chapter 7.6 above Motivation: The Climate of the invention, above.

7.10.2 Resolution of "obvious to try the invention" vs. obvious it "ought to work"

It appears that only part of the *Sanofi* obviousness test was applied in *Abbott Laboratories v. Canada (Health)*,²⁴⁷ 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 paragraph 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 if it would work.²⁴⁸ The applications judge concluded that testing for solubility was routine.²⁴⁹ 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 if it was soluble at a rate sufficient to give therapeutic utility²⁵⁰ 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 paragraph

Ratiopharm Inc. v. Pfizer Limited 2009 FC 711 (F.C. per Hughes J.) at para. 168.

Ratiopharm Inc. v. Pfizer Limited 2009 FC 711 (F.C. per Hughes J.) at para. 169.

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".

Abbott Laboratories v. Canada (Health), 2008 FC 1359 (F.C. per Hughes, J.)

²⁴⁸ *Ibid*, para. 96.

²⁴⁹ *Ibid*, para. 98.

²⁵⁰ *Ibid*, para. 99.

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.²⁵¹

7.11 Secondary Considerations

7.11.1 Commercial Success

Was the subject of the invention quickly and anxiously received by relevant consumers?²⁵² If it was, it may be inventive. Commercial success is a secondary factor when considering obviousness.²⁵³

Where there was a long-felt need and the invention met with commercial success and acceptance, it is difficult to argue that it was not an invention. If it was so obvious and others were seeking to solve the same problem, why was it not done earlier by someone else? The conclusion that a product was a commercial success may be reasonably drawn from facts in evidence which tend to show that:

- 1. The product had good sales. 254
- 2. The product was widely-adopted.²⁵⁵

The best question to ask in cross-examination of an expert witness who has stated that the invention would have been obvious, is: "If it was so obvious, then why didn't you think of it?" ²⁵⁶

Where something has become successful, so as to replace the item or method employed before, it is difficult to argue that it was obvious.²⁵⁷ For a contrary view to the need for a long-felt want, see the *Quantel* case.²⁵⁸

Abbott Laboratories v. Canada (Health), 2009 FCA 94.

Novopharm Limited v. Janssen-Ortho Inc. and Daiichi Pharmaceuticals Co., Ltd. 2007 FCA 217 (F.C.A per Sharlow J.A., Nadon and Malone JJ.A.) online at para. 25(7).

Novopharm Limited v. Janssen-Ortho Inc. and Daiichi Pharmaceuticals Co., Ltd. 2007 FCA 217 (F.C.A per Sharlow J.A., Nadon and Malone JJ.A.) online at para. 25(7).

Eli Lilly & Co. v. Marzone Chemicals Ltd. (1977), 37 C.P.R. (2d) 3 (F.C.T.D per Gibson J.) at p. 21 and 36

²⁵⁵ Beloit Canada Ltd. v. Valmet Oy, (1986) 8 C.P.R. (3d) 289 (F.C.A. per Hugessen J.A.) at p. 296

Beloit v. Valmet Oy (1986) 8 C.P.R. (3d) 289 (F.C.A. per Hugessen J.A.) at p. 295; posed in Corlac Inc. et al v. Weatherford Canada Ltd., 2011 FCA 228 (F.C.A. per Layden-Stevenson J.A., Nadon & Evans JJ.A. concurring) at para. 81.

Technograph Printed Circuits Ltd. v. Mills & Rockley (Electronics) Ltd. [1969] R.P.C. 395 (per Harman, L.J.) at p. 404; Mahurkar v. Vas-Cath of Canada Ltd. (1988), 18 C.P.R. (3d) 417 (F.C.T.D. per Strayer J.) at p. 436

Quantel Ltd. v. Spaceward Microsystems Ltd. [1990] R.P.C. 83 (Patents Court per Falconer J.) at p. 137, I. 50-52.

Marketplace success is not conclusive proof of ingenuity, for it may have been due to marketing or sales ingenuity rather than inventive ingenuity.²⁵⁹ Nevertheless, it is compelling evidence.²⁶⁰ At the very least, commercial success shows practical utility.²⁶¹

Commercial success around the world is relevant²⁶² and if the defendant's device or process is infringing, then its commercial success is relevant as well. Even if the issues of profits or damages have been severed from the trial issues of liability by, for example, a *Federal Courts Rule* 153 or 107 order, one can learn of the defendant's sales and gain an idea of the potential damages or profits available on discovery on the issues of liability.

In *Garford Pty Ltd.* v. *Dywidag Systems International, Canada, Ltd.*, ²⁶³ 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." This is likely wrong because, as pointed out by the Federal Court of Appeal in *Corlac*, ²⁶⁴ *Sanofi* said that an "expansive and flexible approach that would include 'any secondary considerations that [will] prove instructive' will be useful". ²⁶⁵

7.11.2 Awards to the Inventors

If directed to the alleged invention, meritorious awards may be recognition that the appropriate community of persons skilled in the art believed that activity to be something of merit.²⁶⁶

Corlac Inc. et al v. Weatherford Canada Ltd., 2011 FCA 228 (F.C.A. per Layden-Stevenson J.A., Nadon & Evans JJ.A. concurring) at para. 67 citing Sanofi at para. .

Janssen-Ortho Inc. and Daiichi Pharmaceuticals Co., Ltd. v. Novopharm Limited Federal Court per Hughes J., T-2175-04, October 17, 2006, 2006 FC 1234 at para. 113.7; Novopharm Limited v. Janssen-Ortho Inc. and Daiichi Pharmaceuticals Co., Ltd. 2007 FCA 217 (F.C.A per Sharlow J.A., Nadon and Malone JJ.A.) online at para. 25(7).

The King v. Uhlemann Optical Co. (1949), 10 Fox's Pat. C. 24 per Thorson P. at pp. 44 and 46; Teledyne Industries, Inc. et al. v. Lido Industrial Products Ltd. (1979) 45 C.P.R. (2d) 18 (F.C.T.D. per Addy, J.) at p. 32

Cutter (Canada) Ltd. v. Baxter Travenol Laboratories of Canada Ltd. et al. (1983) 68 C.P.R. (2d)
 179 at p. 191

²⁶² Kramer et al. v. Lawn Furniture Inc. (1974) 13 C.P.R. (2d) 231 (F.C.T.D. per Addy, J.) at p. 237.

²⁰¹⁰ FC 581 (F.C. per Zinn J.)

Apotex Inc. v. Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265, 2008 SCC 61, para. 63.

Janssen-Ortho Inc. and Daiichi Pharmaceutical Co., Ltd. v. Novopharm Limited, Federal Court per Hughes J., T-2175-04, October 17, 2006, 2006 FC 1234 at para. 113.9; Novopharm Limited v. Janssen-Ortho Inc. and Daiichi Pharmaceuticals Co., Ltd. 2007 FCA 217 (F.C.A per Sharlow J.A., Nadon and Malone JJ.A.) online at para. 25(8).

On the other hand, scientists and engineers do not measure inventions in the same way as does the court. Witness Edwin Howard Armstrong who was credited with inventing regeneration and FM radio by the U.S. Institute of Radio Engineers whereas Justice Cardozo of the US Supreme Court considered otherwise.²⁶⁷

7.12 Applying Sanofi under the "New" Patent Act

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*, ²⁶⁸ a proceeding under the *Patented Medicines (Notice of Compliance) Regulations (PMNOC Regulations)*.

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.

Although Justice Noël began his analysis by quoting Justice Rothstein's apparent misstatement,²⁷⁰ he then recognized that the Supreme Court's test required a very high predictability of success, without going so far as to say that it "ought to work":

"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."²⁷¹

"In so holding, the Federal Court Judge [in the *Apotex v. Pfizer* case] 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."²⁷²

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

Apotex Inc. v. Pfizer Canada Inc. et al, 2009 FCA 8, at para. 27:

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

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

Tom Lewis, "Empire of the Air, The Men Who Made Radio"; Edward Burlingame Books; 1991.

Apotex Inc. v. Pfizer Canada Inc. et al, 2009 FCA 8.

²⁶⁹ SOR/93-133.

Apotex Inc. v. Pfizer Canada Inc. et al, 2009 FCA 8, at para. 29.

Apotex Inc. v. Pfizer Canada Inc. et al, 2009 FCA 8, at para. 37.

"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." [emphasis added]

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.²⁷³

7.12.1 Determine obviousness with reference to the claims

In contrast to the U.K. *Patents Act 1977*, section 28.3 of the "New" *Patent Act* requires that "the subject-matter **defined by a claim**... [must] not have been obvious..." (emphasis added). Although *Sanofi* stated that the "inventive step" may be found elsewhere than in the claims, 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*²⁷⁴ 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.*,²⁷⁵ 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.²⁷⁶ 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.*, where Lord Hoffman stated that:

"... the 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." ²⁷⁷

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, at paragraph 67, that the second step is the need to "identify the inventive concept of the claim in question or if that cannot readily be done, construe it." The Court further found Justice Snider's obviousness determinations to be consistent with the *Sanofi* framework.²⁷⁹

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Apotex Inc. v. Pfizer Canada Inc. et al. 2009 FCA 8, at para. 46.

Apotex Inc. v. Pfizer Canada Inc. et al, 2009 FCA 8.

²⁰⁰⁹ FCA 222 (F.C.A. per Layden-Stevenson J.A., Linden and Evans JJ.A. concurring)

Apotex Inc. v. ADIR and Servier Canada Inc., 2009 FCA 222 (F.C.A. per Layden-Stevenson J.A., Linden and Evans JJ.A. concurring), para. 68.

²⁷⁷ [2008] UKHL 49 at para. 19

Apotex Inc. v. ADIR and Servier Canada Inc., 2009 FCA 222, para. 69.

²⁷⁹ *Ibid*, para. 90.

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*, 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 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., 2010 FCA 188, 87 C.P.R. (4th) 195, para. 51 (*Bridgeview*), leave to appeal dismissed, [2010] S.C.C.A. No. 346."

7.13 The Wrong Tests

7.13.1 Dissection of Combinations

It is not proper to dissect the combination into its parts and ask whether the use of each of the constituent elements was obvious. The invention claimed is the combination. Normally, it is the combination that is the inventive concept. Once that is created, the fact the constituent elements were obvious in suggesting themselves to the inventor cannot invalidate the patent.²⁸¹

Where the invention lies in a particular combination, it is not permissible to "mosaic in the matter of inventiveness", a dissection of constituent elements is not the proper approach.²⁸² An invention can be created, that when dissected, may consist of individual items all of which formed part of the public knowledge.²⁸³

The individual stages of conversion of one device to the other may, disaggregated, appear obvious, but it must be remembered that is the whole leap that is judged.²⁸⁴

Corlac Inc. et al v. Weatherford Canada Ltd., 2011 FCA 228 (F.C.A. per Layden-Stevenson J.A., Nadon & Evans JJ.A. concurring) at para. 69.

Albert Wood and Amcolite v. Gowshell, Ltd. (1937), 54 R.P.C. 37 at p. 40

Omark Industries (1960) Ltd. v. Gouger Saw Chain (1964), 45 C.P.R. 169 (Ex.Ct. per Noel J.) at pp. 218- 219

General Tire & Rubber Co. v. Firestone Tyre & Rubber Co., Ltd., [1972] R.P.C. 457 at p. 504

Van Der Lely (c.) N.V. v. Bamfords Ltd., [1960] 7 R.P.C. 169 (High Ct. Chancery per Lloyd-Jacob J.) at p. 19

7.13.2 Ex Post Facto – 20/20 Hindsight

Nothing is so easy to say after the fact that the thing was obvious and required no invention. ²⁸⁵ 20-20 hindsight is a common commodity. ²⁸⁶ It has been said that this is "the most dangerous of all the factors" to be considered in assessing obviousness and should be applied "only with the greatest of care". ²⁸⁸

It is somewhat unfair to fasten upon one or two of a large number of prior art documents, from which it is said the invention can be easily found, when you know exactly what you are looking for.²⁸⁹

Ex post facto analysis of an invention is not sound.²⁹⁰ This is particularly so where an expert in the field has been hired for the purpose of testifying. In that case, infallible hindsight is particularly suspect. Every invention is obvious after the fact, and to no one more so than to an expert in the field. Before weight can be given to an expert's assertion that, "I could have done that", the question, "Why didn't you?" must be satisfactorily answered.²⁹¹ An allegation of obviousness may be weakened if the evidence does not explain, directly or by inference why the claimed invention was not discovered by others.²⁹²

Reading & Bates Construction Co. v. Gaz InterCite Quebec Inc., (1988) 18 C.P.R. (3d) 180 (F.C.A.) per Stone J.A. at p. 188. T.H. Huxley, Charles Darwin's friend was heard to say after hearing of Darwin's theory of natural selection, "How incredibly stupid not to think of that." Peter Johnson, Where Good Ideas Come From – The Natural History of Innovation, Penguin Group US, October 2010, Chapter 3.

Eli Lilly and Co. et al. v. Marzone Chemicals Ltd. et al. (1977) 37 C.P.R. (2d) 3 (F.C.T.D., per Gibson, J.) at pp. 33-34

Janssen-Ortho Inc. and Daiichi Pharmaceutical Co., Ltd. v. Novopharm Limited Federal Court per Hughes J., T-2175-04, October 17, 2006, 2006 FC 1234 at para. 113.10

Janssen-Ortho Inc. and Daiichi Pharmaceutical Co., Ltd. v. Novopharm Limited Federal Court per Hughes J., T-2175-04, October 17, 2006, 2006 FC 1234 at para. 113.10

Keller and Richter's Patents [1975] R.P.C. 75 at pp. 90-91

The King v. Uhlemann Optical Company (1949) 10 Fox P.C. 24 (Ex.Ct. per Thorson, P.) at p. 43

²⁹¹ Beloit v. Valmet Oy (1986) 8 C.P.R. (3d) 289 (F.C.A. per Hugessen J.A.) at p. 295

Apotex Inc. v. Bayer Inc. 2007 FCA 243 (F.C.A. per Sharlow J.A., Malone and Sexton J.J.A. concurring) at para. 25. At para. 43, Justice Sharlow found the invention to be non-obvious because there was:

[&]quot;... there is no convincing explanation as to why the ciprofloxacin solution was found only by the claimed inventors of ciprofloxacin, and not by any of the other scientists engaged in the same or similar work Both parties presented the evidence of highly qualified experts, who gave full and cogent explanations as to why they believed that a person of ordinary skill in the art would or would not have been led directly and without difficulty from norfloxacin to ciprofloxacin. ... The weight of the evidence compels me to reject the submission of Apotex on this threshold question. That is a sufficient ground on which to find that Bayer has met its burden of establishing the allegations of invalidity based on obviousness are not justified."

7.13.3 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* 33 F. 2d 924 have placed weight upon subsequently discovered advantages that is not the law here. Little, if any, weight should be put on this factor.²⁹³

7.14 Evidence and expert witnesses

The Court's determination of obviousness must be guided by expert evidence about the relevant skills of the hypothetical person of ordinary skill in the art and he state of the art at the relevant time. ²⁹⁴

For a plaintiff trying to disprove obviousness (support inventiveness) the most convincing expert witness is not the notional worker who did not think of it but rather the inventive expert who did not think of it.²⁹⁵ If the invention was not obvious to a leading inventor at the critical date, it is hard to accept that an unimaginative skilled technician would see the solution "as clear as day".²⁹⁶

Experts help the Court understand what would have been available to the notional worker and what would have been obvious to that worker. However the issue of obviousness is a decision for the Court, and it cannot abdicate this responsibility to the witnesses. A witness cannot merely instruct the Court as to whether the invention is obvious or not.²⁹⁷

The issue is not whether it would be obvious to the witness, particularly if the witness is an expert in the area. After all, the test is what would have been obvious to a skilled addressee and not necessarily and expert with multiple patents of their own.²⁹⁸

Mr. Justice Muldoon of the Federal Court of Canada has expressed his frustration as a lay judge having to determine technical issues between debating experts.²⁹⁹ However, his complaint is

Janssen-Ortho Inc. and Daiichi Pharmaceutical Co., Ltd. v. Novopharm Limited Federal Court per Hughes J., T-2175-04, October 17, 2006, 2006 FC 1234 at para. 113.8;

Apotex Inc. v. Bayer Inc. 2007 FCA 243 (F.C.A. per Sharlow J.A., Malone and Sexton J.J.A. concurring) at para. 19.

See for example, Dr. Beal, the inventor's theses supervisor in *Control Data Canada Ltd.* v. Senstar Corp., (1989), 23 C.P.R. (3d) 449 (F.C.T.D. per Cullen, J.) at pp. 464-465; an Dr. Uldall in *Mahurkar* v. *Vas-Cath of Canada Ltd.* (1988), 18 C.P.R. (3d) 417 (F.C.T.D. per Strayer J.) at p. 432-433;

Procter & Gamble Pharmaceuticals Canada Inc. v. Canada (Minister of Health) and Genpharm (2004), 32 C.P.R. (4th) 224 (F.C.T.D. per Snider J.) online at para. 99

General Tire & Rubber Co. v. Firestone Tyre & Rubber Co., Ltd. [1972] R.P.C. 457 at pp.497-498

General Tire & Rubber Co. v. Firestone Tyre & Rubber Co., Ltd. [1972] R.P.C. 457 at p. 504

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based on the supposition that there is a 'scientific verity" or absolute truth, and therefore one expert who disagrees with another must not be telling the truth and the matter resolves itself to one of credibility. In fact, there is no such thing as a "scientific verity". There are only models or explanations of varying utility. When a model is useful, it is used; when it breaks down it is discarded and a better model is used. Most issues in patent cases revolve around the meaning of the terms in the patent rather than on what is happening with the technology – "pure technical issues" are quite rare. Compare Mr. Justice Muldoon's analysis with the approach of Madam Justice Barbara Reed:

"In my view, the best expert witnesses are good teachers. They are able to explain their opinion, and why they hold it in simple terms to somebody who has no expertise in the area.

I operate from the assumption that it doesn't matter how complex a matter may be, it can be made simple enough that I can understand it. It can be explained in terms without using jargon. If that doesn't happen, jump to the conclusion that the side that is putting forward the inarticulate expert is trying to snow me and doesn't have a good case."³⁰⁰

Unilever PLC et al. v. Procter & Gamble Inc. et al. (1993), 47 C.P.R. (3d) 479 (F.C.T.D. per Muldoon J.) at p. 488-9

[&]quot;Preparing to be an Expert Witness"; Canada Law Book video; 1996