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**WHAT'S SO OBVIOUS? -
THE SEVERAL FACETS OF OBVIOUSNESS IN PATENT LAW**

by Robert H. Barrigar, Q.C., Barrigar Intellectual Property Law

1 Summary of this Paper

This paper deals with the concept of obviousness and tests for it in various contexts within Canadian patent law, identifies some flaws or gaps in the law, and in some instances suggests possible remedies. The present law is presented in some detail having regard to the expectation that some readers will not be Canadian patent practitioners. The sequence of topics is as follows:

2 The Several Meanings of and Tests for “Obviousness” Under the Present Law

2.1 Is an Invention Obvious?

2.2 What Does “Obvious” Mean in a Selection Patent Context?

2.3 In Obviousness-Type Double Patenting, What Does "Obvious" Mean?

2.4 What Does “Obvious” Mean in the Context of Purposive Construction?

2.5 What Is an Obvious Equivalent?

2.6 What Is so Obvious that It Need not Be Described in a Specification?

2.7 What Essential Element Is so Obvious that It Need not Be Recited in a Claim?

2.8 What Is so Obviously Useless that It Cannot Be Within the Claimed Invention?

2.9 What Kind of Error is so Obvious that It May Be Corrected via Section 8?

2.10 Is it Obvious that a Given Prediction is Sound?

3 Flaws and Unsettled Issues in the Existing Obviousness Law

3.1 Obviousness of Claimed Subject-Matter

3.2 Obviousness-Type Double Patenting

3.3 “Obvious” in the Context of Purposive Construction

3.4 Obvious Equivalence

3.5 Obvious Omissions

3.6 Sound Prediction

4 Where Do We Go from Here?

2 The Several Meanings of and Tests for “Obviousness” Under the Present Law

The concept of obviousness is pervasive in patent law, arising in several different contexts. The existence or non-existence of obviousness is usually determined by a defined test. The test is almost always a comparative test, although not always mentioned as such; the usual generic form of the test is this: is Fact Z obvious in view of Facts X, Y, etc.? (This generic form does not neatly fit all obviousness questions, such as whether a given element or combination is obviously useless.) The test must be performed by a hypothetical individual, usually in patent law the person skilled in the art or science to which Facts X, Y, Z relate. The qualities and qualifications of the individual are implied by the context; *e.g.* a statutory reference or reference in claims to an “obvious chemical equivalent” implies that the hypothetical individual has a suitable knowledge of chemistry; a patent for cellular telephony requires that the person skilled in that art be the hypothetical reader of the patent. The test frequently must be made at a prescribed time, *e.g.* as of the claim date of a given claim under review. Sometimes, one or more of Facts X, Y, etc. are implied – for example, they may include facts arising out of the general education, experience, expertise and general knowledge of the hypothetical person performing the test; sometimes the foregoing qualifications are supplemented by specific published literature or the like. The law relating to a number of the contexts in which the concept of obviousness is tested is briefly reviewed below, followed by a discussion of flaws in various aspects of the law.

2.1 *Is an Invention Obvious?*

To be patentable, an invention must be unobvious pursuant to §28.3 of the *Patent Act*, reading as follows:

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.

The claim date for each claim in a patent is defined in §28.1 of the *Act*.¹

A classic Canadian test for obviousness of an alleged invention, following generally the wording of the “Cripps question” in U.K. jurisprudence, is frequently cited, recently by the Federal Court of Appeal in *Halford v. Seed Hawk Inc.*², as follows:

The undisputed test for obviousness is whether at the date of invention, 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 the invention.

The currently most frequently quoted Canadian test is the following, pronounced by Hugessen J. in *Beloit Canada Ltd. v. Valmet Oy*³, and oftentimes repeated in the Federal Court of Appeal, e.g. in *Sanofi-Synthelabo Canada Inc. v. Apotex Inc.*⁴ at ¶38:

The test for obviousness is not to ask what competent inventors did or would have done to solve the problem. Inventors are by definition inventive. The classical touchstone for obviousness is the technician skilled in the art but having no scintilla of inventiveness or imagination; a paragon of deduction and dexterity, wholly devoid of intuition; a triumph of the left hemisphere over the right. The question to

be asked is whether this mythical creature (the man in the Clapham omnibus of patent law) would, in the light of the state of the art and of common general knowledge as at the claimed date of invention, have come directly and without difficulty to the solution taught by the patent. It is a very difficult test to satisfy.

Embellishments of the foregoing tests take into account the suitable qualifications of the hypothetical person skilled in the art, whether that person would have regard to all of the published literature or only a select subset of the literature, etc. and warn against the use of hindsight in analyzing allegations of obviousness. Related facts such as commercial success, failure of others to reach the invention, etc. may also be taken into account. A recent detailed analysis of the foregoing and other factors to be considered is that of Hughes J. in *Janssen-Ortho Inc. v. Novopharm Ltd.*⁵ In affirming this judgment, the FCA commented favourably on the factors listed by Hughes J., but provided an edited list reading as follows:⁶

1. The invention:

What is in issue is the patent claim as construed by the Court.

2. The hypothetical skilled person referred to in the *Beloit* quotation:

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

3. The body of knowledge of the person of ordinary skill in the art:

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 (*Whirlpool* at paragraph 74). 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.

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.

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.

Secondary factors

These factors may be relevant but generally bear less weight because they relate to facts arising after the date of the alleged invention.

7. Commercial success:

Was the subject of the invention quickly and anxiously received by relevant consumers? This may reflect a fact that many persons were motivated to fill the commercial market, which may suggest inventive ingenuity. However, it may also reflect things other than inventive ingenuity such as marketing skills, market power and features other than the invention.

8. Meritorious awards:

Awards directed to the alleged invention may be recognition that the appropriate community of persons skilled in the art believed that activity to be something of merit. That may or may not say anything about inventive ingenuity.

Canadian courts have sometimes said that an invention must be the result of an “inventive step”. In most cases, the phrase appears to have been casually used simply as the antithesis of obviousness. Per Binnie J. in *Whirlpool Corp. v. Camco Inc.*, quoting British authority:

The notional skilled addressee is the ordinary man who may not have the advantages that some employees of large companies may have. The information in a patent specification is addressed to such a man and must contain sufficient details for him to understand and apply the invention. It will only lack an inventive step if it is obvious to such a man.⁷

Similarly, in at least some cases, this requirement has been equated to a need for some degree of creative ingenuity, as in *SmithKline Beecham Pharma Inc. v. Apotex Inc.* where Linden J.A. said:

...the Applications Judge found as a fact that “no inventive step or skill” was required to arrive at the '637 Patent. In other words, one could arrive at the '637 Patent “without the aid of inventive genius but purely by mechanical skill.”⁸

The more precise meaning given “inventive step” in the British law is discussed further below.

Some questions that were unsettled years ago have become more or less settled. The “old” *Patent Act* did not include a requirement that an invention be unobvious; it is appropriate that §28.3 of the present *Patent Act* governing this subject does so, but does not include any definition of nor test for what is obvious. The wording of the section enables courts to import the previous common law on the question, and to refine the law as future cases require.

A critical question that arose some years ago is whether the hypothetical person skilled in the technology may have regard to the totality of published information, or if not, what constraints apply. Recent cases suggest that in our age of information overload, the skilled person would not have recourse to all of it. For example, in *Illinois Tool Works Inc. v. Cobra Fixations Cie*, Pelletier J. said that

...common general knowledge may include knowledge of particular patents which are sufficiently well known to have passed into general knowledge but does not include knowledge of all patents in the domain of the invention, even though these are considered to be public knowledge... One is entitled to look at the patents which a skilled workman would discover in a reasonable and diligent search to determine whether the "mosaic" leads directly to the invention... What constitutes a reasonable and diligent search is a question of fact.⁹

Canadian courts have been saying more or less uniformly for some time that an indication in the prior art that a particular suggestion is “worth a try” does not render a claimed invention obvious. In *Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning v. Halocarbon (Ontario) Ltd.* the Supreme Court said:

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.¹⁰

More recent cases are generally in accord. Shore J. in *Sanofi-Synthelabo Canada Inc. v. Apotex Inc.*¹¹ construed the judgment of the Federal Court of Appeal in *AB Hassle v. Genpharm Inc.*¹² as

repudiating the “worth a try” test in Canada.

2.2 *What Does “Obvious” Mean in a Selection Patent Context?*

A novel selection of species or preferred items from a previously known class or genus is patentable if the selection is unobvious and advantageous: *Baker Petrolite Corp. v. Canwell Enviro-Industries Ltd.*¹³ Patents protecting such selection are frequently referred to as “selection patents”. In the *Baker Petrolite* case, Gibson J. quoted with apparent approval the following set of tests for the validity of a selection patent set forth by Dr. H.G. Fox¹⁴, who presumably derived the tests from the British case *Re I.G. Farbenindustrie A.G.’s Patents*¹⁵:

Three general propositions may be asserted: First, a selection patent to be valid must be based on some substantial advantage to be secured by the use of the selected members. (The phrase will be understood to include the case of a substantial disadvantage to be thereby avoided.) Secondly, the whole of the selected members must possess the advantage in question. Thirdly, the selection must be in respect of a quality of a special character that can fairly be said to be peculiar to the selected group.¹⁶

The foregoing understanding of a selection patent and the *I.G. Farbenindustrie* criteria have received the approval of the Federal Court of Appeal in *Sanofi-Synthelabo Canada Inc. v. Apotex Inc.*¹⁷ and in *Pfizer Canada Inc. v. Canada (Minister of Health)*¹⁸.

Apart from the *I.G. Farbenindustrie* criteria, it appears that at least in recent cases, the courts treat the question of obviousness of an ostensible selection invention in essentially the same manner as for any other invention. See e.g. *Eli Lilly Canada Inc. v. Apotex Inc.*¹⁹, and *Eli Lilly Canada Inc. v. Novopharm Ltd.*²⁰

2.3 *In Obviousness-Type Double Patenting, What Does “Obvious” Mean?*

So-called obviousness double patenting is one of two types of double patenting, the other being “conterminous” or “coterminous” double patenting, the adjective “coterminous” indicating

that at least one claim of a second patent maps substantially identically on a claim of a first patent. The leading case on obviousness double patenting is *Whirlpool Corp. v. Camco Inc.* in which Binnie J. delivering the judgment of the Court said:

A patentee who can “evergreen” a single invention through successive patents by the expedient of obvious or uninventive additions prolongs its monopoly beyond what the public has agreed to pay.

* * *

66 There is, however, a second branch of the [double-patenting] prohibition which is sometimes called “obviousness” double patenting. This is a more flexible and less literal test that prohibits the issuance of a second patent with claims that are not “patentably distinct” from those of the earlier patent. In *Commissioner of Patents v. Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning*, [1964] S.C.R. 49, the issue was whether Farbwerke Hoechst could obtain a patent for a medicine that was a diluted version of a medicine for which it had already obtained a patent. The claims were neither identical nor conterminous. Judson J. nevertheless held the subsequent patent to be invalid, explaining at p. 53:

A person is entitled to a patent for a new, useful and inventive medicinal substance but to dilute that new substance once its medical uses are established does not result in further invention. The diluted and undiluted substance are but two aspects of exactly the same invention. In this case, the addition of an inert carrier, which is a common expedient to increase bulk, and so facilitate measurement and administration, is nothing more than dilution and does not result in a further invention over and above that of the medicinal itself.

67 In *Consolboard* [*Consolboard v. MacMillan Bloedel (Saskatchewan)* (1981) 56 C.P.R. (2d) 145, 160 (S.C.C.)] Dickson J. referred to *Farbwerke Hoechst* as “the main authority on double patenting” (p. 536) which stood for the proposition that a second patent could not be justified unless the claims exhibited “novelty or ingenuity” over the first.²¹

The references by the Supreme Court above to “patentably distinct” and “novelty or ingenuity” (note the alternative) suggest that either obviousness double patenting may be misnamed, or that obviousness in the usual sense relating to obviousness of an invention is the wrong test to apply, or is at least an incomplete test, in a double-patenting context. Judges in some later cases have ignored the “or” in the “novelty or ingenuity” criterion; it can be argued that the overall effect of the Supreme Court rulings is that the claims in issue meet both criteria. Per Phelan J. in *Bayer AG v. Novopharm Ltd.*: “To maintain the defence against the allegation of obviousness double-patenting, the claims must exhibit novelty and ingenuity”²².

The *Whirlpool* case is important if only to make clear that the principle applied in *Farbwerke Hoechst* continues to apply today, even though the statutory regime respecting pharmaceutical patents in effect at the time *Hoechst* was decided has since fundamentally changed.

Since *Whirlpool* was decided, the Federal Court of Appeal has pronounced on this issue. In *Aventis Pharma Inc. v. Pharmascience Inc.*²³, the appellant generic pharmaceutical company Pharmascience alleged invalidity of the Aventis patent in issue based on obviousness double patenting. Before reviewing the FCA judgment, it is useful to examine the Federal Court judgment in the case.²⁴ In the lower Court, after pointing out that the Supreme Court in *Whirlpool* did not resolve the question whether same or different inventorship governed the outcome of a double-patenting attack, Snider J. cautioned as to this issue:

If an invention is not new, the patentee would receive a term of protection for which he has not paid the "hard coinage of new, ingenious, useful and unobvious disclosures"; ...he would have received "something for nothing". The public, in such a situation, receives no consideration for the bargain. This would be true regardless of whether the inventors or the patentees are different or the same. If the claims of the two patents are not patentably distinct, the effect would be an extension of the original patent as was considered by the Supreme Court in [*Farbwerke Hoechst*]...

[59] Thus, I would not limit the operation of the concept of obviousness double patenting to the same patentees or inventors. In reviewing the facts of each case,

the focus must be the claims that form the invention and not the persons or parties that advance them. If the claims to one patent are not patentably distinct over those in another patent, an allegation of invalidity may have merit.²⁵

Snider J. analyzed the “patentably distinct” issue on the facts of the case and held that there was no double patenting. In so holding, her Ladyship took into account the following factors, finding most of them parallel to those governing a holding of unobviousness of the invention in issue in *Pfizer Canada Inc. v. Apotex Inc.*²⁶:

- One patent is an originating patent while the other patent relates to a selection. The former claims the genus; the latter claims the species. The claimed species have unexpected and valuable properties not possessed by the structurally closest compounds disclosed in the genus patent.
- The inventorship of the two patents is different.
- The second patent adds “something of a substantial character to existing knowledge” (quoting from the *I.G. Farbenindustrie* case discussed above in relation to selection patents).²⁷

It would appear from the judgment that the fact that one of the patents was for a patentable selection from the genus protected by the other patent was, in the view of Snider J., in and of itself dispositive of the “patentably distinct” issue; a patentable selection is inherently patentably distinct from the genus of which it is a subset.²⁸ (The FCA on the appeal noted that Snider J. had applied the “established legal test for obviousness”²⁹, apparently taking the test from case law on obviousness of an invention, and finding against Pharmascience.) Another way of summarizing the point is that a selection patent whose subject-matter meets the non-obvious standard according to selection-patent criteria cannot be invalid for obviousness-type double patenting.

In the *Aventis Pharma* case, the date of invention and filing date of the last-to-issue '206 patent for the genus preceded the date of invention and filing date of the two earlier-issued selection patents. If the question of obviousness double patenting required merely an answer to the question whether the subject-matter of the later of two patents to issue was obvious over that of the earlier, then the answer was straightforward in this case, since the last patent to issue was the earliest filed with the earliest date of invention. However, Snider J. ruled that in assessing the question of obviousness double patenting, the obviousness of the subject-matter of each of the two

patents in question relative to that of the other patent had to be examined.³⁰

Snider J. also held that the fact that Aventis had the benefit of a royalty income on the species from a licence under the first patent to issue did not compel a finding of “evergreening” (see the quotation above from the *Whirlpool* case), as the disparity between the issue dates of the two patents arose out of the statutory scheme applicable to “old *Act*” patents through no fault of the patentee.³¹ Her Ladyship observed:

[70] I also note that there was, in 1986, no certainty that the [second] patent would ever issue. The conflict proceedings were still in the future and could have had a different outcome. There was significant risk to Schering, at that time, that the 206 patent might never issue.³²

Snider J. held that the date for determining the issue of obviousness double patenting is, for old *Act* patents, the date of invention and not the issue date of the patent. In so doing, her Ladyship expanded on the evergreening conundrum presented by old *Act* patents in the judgment, finding that such evergreening as subsisted was inherent in the old *Act* and attributable to a large extent to the occurrence of conflict proceedings in the case before the Court:

[86] As the *Patent Act* now operates, the problem before me would not arise. However, that is not the scheme under which these patents are operating and I must consider whether there is any argument that would warrant varying the logical unfolding of events.

[87] The most significant of these arguments is that Schering's protection under the 206 patent extends well beyond 17 years after the date of the invention. Assessing the issue of obviousness double patenting as of the date of invention does appear to result in an inequity. As I noted earlier, had the 206 patent issued on or close to the date of invention, it would have expired long ago and Pharmascience would not need to allege non-infringement of the 206 patent.

[88] While recognizing this apparent inequity, I must also consider the situation of Schering in the event that I determine that the correct reference date is 2001. In

that case, Schering would not have had the benefit of a patent during the period 1981 to 2001 and would also be stripped of its side of the "bargain" as of 2001. The result would be that the patentee would receive nothing for its invention in respect of the claims that cover ramipril. This would be unfair, particularly when the delays in the issuance of the patent cannot, in any significant way, be attributed to Schering. Schering, unfortunately, was caught by an application of the old rules governing conflict procedures.³³

In upholding the judgment of Snider J., the FCA paraphrased the *Whirlpool* criteria applicable to obviousness double patenting as follows:

In obviousness double patenting, the claims of the patents are not identical or conterminous, but the later patent has claims that are not patentably distinct from the other patent, or involve no novelty or ingenuity.³⁴

The Court also quoted Judson J. in the *Farbwerke Hoechst* case³⁵:

A person is entitled to a patent for a new, useful and inventive medicinal substance but to dilute that new substance once its medical uses are established does not result in further invention. The diluted and undiluted substance are but two aspects of exactly the same invention. In this case, the addition of an inert carrier, which is a common expedient to increase bulk, and so facilitate measurement and administration, is nothing more than dilution and does not result in a further invention over and above that of the medicinal itself.³⁶

The Court further analyzed the Pharmascience submission as follows:

[70] Aventis and Schering argue that the doctrine of double patenting cannot apply unless there are multiple patents issued to the same inventor. In this case, the inventor of the '206 patent is not the same as the inventor of the '087 or '457 patents. They also argue that it would be wrong to extend the doctrine of double patenting to this case, because the result would be inconsistent with the scheme of the *Patent Act* as it read when the application for the '206 patent was filed.

[71] I agree with Aventis and Schering that in this case, applying the doctrine of double patenting would be inconsistent with the relevant statutory scheme. The issues relating to the validity of the '206 patent are governed by the *Patent Act* as it read prior to 1989 (the old *Patent Act*). Under paragraph 27(1)(a) [as am. by R.S.C., 1985 (3rd Supp.), c. 33, s. 8] of the old Patent Act, the first inventor of an invention was entitled to a patent regardless of the date upon which the application was filed, and the term of the patent began when the patent was issued and ran for a term of 17 years from that date. Delays in the commencement of the term could and often did result from conflict proceedings. Such delays were inherent in the statutory scheme.

[72] The inventions disclosed in the '087 patent and the '457 patent are not only narrower in scope than the inventions disclosed in the '206 patent, but are later in time (based on their respective application dates). Given that the inventors of the '087 and '457 patents were working independently of the inventor of the '206 patent, it cannot reasonably be found in this case that the filing of the application for the '206 patent was an attempt to extend unduly the term of the '087 patent and the '457 patent. On the contrary, to apply the doctrine of double patenting to the '206 patent in the circumstances of this case would deprive Schering unfairly of the patent rights to which it became entitled as a result of the disclosure of the '206 patent, and that outcome would be caused merely by the delay in the issuance of the '206 patent.

[73] That is not to say that I would be prepared at this point to adopt the proposition that double patenting can never apply unless there is a single inventor. Although it is difficult at this point to envisage a case involving more than one inventor that is or should be vulnerable to a claim of double patenting, I see no reason to foreclose such a possibility. In my view the doctrine of double patenting, as a set of judge-made rules, should be left to evolve on a case-by-case basis.³⁷

The reference to “a single inventor” in the foregoing passage is a simplification; presumably what the FCA intended to say was that if the inventorship of the two patents in question is identical, double patenting may arise, but if the inventorship is different, obviousness double patenting, at least in cases like the one before the Court, would not be likely to be found.

In *Sanofi-Synthelabo Canada Inc. v. Apotex Inc.*, the FCA held that if two patents claim different and distinct compounds, there cannot be double patenting.³⁸

The FCA had occasion to consider obviousness double patenting again in *Pfizer Canada Inc. v. Canada (Minister of Health)*.³⁹ The Court summarized the issue from the trial judgment to be considered as follows:

[22] Finally, Heneghan J. considered whether the '330 patent was invalid on the basis of obvious-type double patenting because it was not patently distinct from the '615 patent. Heneghan J. rejected this allegation. She was persuaded by the fact that the '615 patent had not been involved in the conflict proceedings to which the '330 patent was subject.

* * *

[143] The Trial Judge considered the rule against obviousness double patenting, according to which the question to be answered is whether the claims of one patent are patently distinct from those of the other patent(s). She found persuasive the fact that the '330 and '615 patents were not placed into conflict. She also noted that it was the Commissioner of Patents who suggested that a divisional application be made in respect of the '615 patent. On this basis, she concluded that Pfizer had met its burden of disproving the allegations of invalidity for double patenting.

[144] Apotex argues that the Judge should not have taken into account the fact that the '615 had not been involved in the conflict proceedings with the Hoechst patent. It further argues that she should not have been persuaded by evidence that the Commissioner had suggested that divisional application be made in respect of the '615 patent because, in its view, it was the patentee who had requested the division. Finally, Apotex argues that it submitted uncontroverted evidence that the compounds claimed in the '615 patent did not constitute inventive selection over the '330 patent.⁴⁰

The Court rejected the argument presented by Apotex for the following reasons:

[145] With respect to Apotex's first argument, it was reasonable, in my view, for Heneghan J. to consider whether the '615 patent had been involved in the conflict proceedings in determining whether there was double patenting. This fact lends some support to the conclusion that the '615 and '330 patents do not have the same scope, at least with respect to the scope of the invention disclosed in the Hoechst patent. I also find it unlikely that such evidence alone could dispose of the issue, unless it was shown that all of the subject matter covered by the Hoechst patent and the '330 patent was the same, such that if the '615 patent covered the same subject matter as the '330 patent, it would almost certainly have been involved in the conflict proceedings.

[146] Of some persuasiveness is a fact which Apotex points to in its Memorandum of Fact of Law. At paragraph 87 thereof, in attempting to explain its basis for stating that the Commissioner did not request the division of the '615 patent, Apotex states:

87. ... The Commissioner initially rejected the issuance of the '330 patent on the basis of double patenting over the '615 patent. The Commissioner, however, accepted Pfizer's representation that double patenting did not apply as there was a species/genus relationship between the two patents and thus removed his double patenting objection.

[147] This, in my view, demonstrates that the Commissioner specifically considered the possibility of double patenting, but was convinced that that was not the case.

[148] With respect to Apotex's allegation that it was the patentee, not the Commissioner, who requested the division, Apotex points to no evidence supporting that view. Heneghan J.'s finding that the Commissioner requested the division should therefore stand.

[149] In the end, the application of the test for double patenting to the facts of the case is a question of mixed fact and law, subject to the overriding and palpable error standard. Heneghan J. committed no such error. It was reasonable for her, in my view, to rely on the fact that there were no conflict proceedings involving the

'615 patent and that the Commissioner of Patents suggested that the '615 patent be filed as a divisional application. This appears to be the only evidence which was put before the Judge. Thus, in my opinion, these facts do not only indicate that the inventions claimed in both patents were patentably distinct, but also that the '615 patent was a valid selection patent.⁴¹ [The wording of the final sentence has been edited to reflect the Court's presumed intention.]

On the strength of *Whirlpool* and the two FCA cases discussed above, the following rules or guidelines appear to apply to obviousness double patenting, assuming throughout that both patents in question are owned by the same entity (or possibly by a related entity):

1. To avoid a finding of double patenting, the subject-matter of the later patent must be “patentably distinct” from the subject-matter of the earlier patent.
2. If the subject-matter of the later-filed patent manifests no novelty or ingenuity relative to the subject-matter of the earlier-filed patent, the later patent is invalid for double patenting.
3. The addition of an inert or otherwise inactive component to a patented active component involves no ingenuity; a patent granted for such addition is invalid by reason of double patenting.
4. If the inventorship of the two patents is not identical, this fact weighs against a finding of double patenting.
5. If the inventors of the second patent were working independently of the inventors of the first patent, this fact weighs against a finding of double patenting.
6. For “old *Act*” patents, the fact that the later-issued patent is directed to the earlier invention does not weigh in favour of a finding of double patenting.
7. If the Commissioner did not place two “old *Act*” patents in conflict, (presumably especially if the Patent Office has specifically considered the possibility), this fact weighs against a finding of double patenting.

8. If the two patents are a parent and a divisional, and have a genus/species relationship, this fact weighs against a finding of double patenting.
9. If the Commissioner has suggested that the application leading to the first patent be divided, this fact weighs against a finding of double patenting in respect of the parent and divisional patents.
10. If two patents claim different and distinct compounds, there cannot be double patenting. (Otherwise, if the distinction between what is claimed in one patent relative to what is claimed in the other is a distinction relating to inactive or inert components of the claimed invention, in which case the *Farbwerke Hoechst* principle comes into play.)

Other Federal Court decisions appear to be in accord with the foregoing and to add few significant qualifications or elaborations. The following are of some interest.

Per Hughes J. in *Merck & Co. Inc. v. Apotex Inc.*:

[213] I have already found that lisinopril and enalapril are separate inventions. A fortiori lisinopril and enalapril plus a diuretic are separate inventions, they are “patentably distinct” they are not “identical or coterminous”. Being different inventions, one is not “obvious” in view of the other in the sense of *Bayer* [*Bayer Inc. v. Canada (Minister of Health and Welfare)*, (1998), 82 C.P.R. (3d) 359 (F.C.)] or *Hoechst, supra*, where the same compound was simply diluted or formulated.⁴²

Also of interest relative to the “evergreening” point is the judgment of the FCA⁴³ in the *Merck v. Apotex* case on appeal from the judgment of Hughes J. On the appeal, double-patenting was not in issue. The Court noted in the context of the “improper divisional” issue:

[49] From a global perspective, when considering the harm that may result from an improper divisional, it becomes clear that the principle of double patenting provides a sufficient remedy. The harm is that two patents might issue for the same invention, giving the patentee differing monopolies. Where, as in the present case, the various divisional applications and the parent have no overlapping claims,

there is no risk that a patentee will be able to extend its patent monopoly by having two patents for the same invention.⁴⁴

The cases taken as a whole indicate that the “patentably distinct” issue may be decided with reference to one or more criteria or tests, and if according to any one or more of those criteria or tests the court has been persuaded that the claimed inventions of the two patents in question are patentably distinct, it apparently is not necessary to have resort to any of the other criteria or tests. Frequently, the courts approach the “patentably distinct” issue as an ordinary question of obviousness using “obviousness of an invention” case law for guidance, as in the judgment of Snider J. in *Aventis Pharma Inc. v. Pharmascience Inc.*⁴⁵, or as in the judgment of Phelan J. in *Bayer AG v. Novopharm Ltd.*:

[62] The fact that Bayer would take two years of research and development to solve the problems created by the '547 patent strongly suggests that something more than what was taught in the '547 patent was needed to address the issues of physiological intolerance. To conclude otherwise is to suggest that Bayer was virtually incompetent by missing a solution which was so apparent.

[63] The preponderance of the evidence confirms that Novopharm cannot establish the traditional definition of obviousness (although a claim of anticipation in respect of the '006 patent is not in issue) that its POSITA would come "directly and without difficulty to the solution taught by the patent" (*Beloit Canada* above). If that were the case, it is difficult to understand why Bayer did not immediately, directly and without difficulty come to the '006 patent solution.⁴⁶

In *Aventis Pharma Inc. v. Apotex Inc.*, Tremblay-Lamer J. ruled that a finding of obviousness over the prior art does not compel a finding of obviousness double patenting, and so found on the facts of the case.⁴⁷

2.4 What Does “Obvious” Mean in the Context of Purposive Construction?

The preferred approach to claim construction in Canada is purposive construction, whose origins can be traced to *Catnic Components Ltd. v. Hill & Smith Ltd.*⁴⁸ This doctrine, along with

the policy underlying same, were reviewed by the Supreme Court of Canada in *Free World Trust v. Électro Santé Inc.*⁴⁹ and in *Whirlpool Corp. v. Camco Inc.*⁵⁰ Per Binnie J. in *Free World Trust*:

A purely literal application of the text of the claims would allow a person skilled in the art to make minor and inconsequential variations in the device and thereby to appropriate the substance of the invention with a copycat device while staying just outside the monopoly. A broader interpretation, on the other hand, risks conferring on the patentee the benefit of inventions that he had not in fact made but which could be deemed with hindsight to be “equivalent” to what in fact was invented. This would be unfair to the public and unfair to competitors. It is important that the patent system be fair as well as predictable in its operation.⁵¹

Binnie J. set forth the following principles:

- (a) The *Patent Act* promotes adherence to the language of the claims.
- (b) Adherence to the language of the claims in turn promotes both fairness and predictability.
- (c) The claim language must, however, be read in an informed and purposive way.
- (d) 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.
- (e) The claims language will, on a purposive construction, show that some elements of the claimed invention are essential while others are non-essential. The identification of elements as essential or non-essential is made:
 - (i) on the basis of the common knowledge of the worker skilled in the art to which the patent relates;
 - (ii) as of the date the patent is published;
 - (iii) having regard to whether or not it was obvious to the skilled reader

at the time the patent was published that a variant of a particular element would not make a difference to the way in which the invention works; or

(iv) according to the intent of the inventor, expressed or inferred from the claims, that a particular element is essential irrespective of its practical effect;

(v) without, however, resort to extrinsic evidence of the inventor's intention.

(f) There is no infringement if an essential element is different or omitted. There may still be infringement, however, if non-essential elements are substituted or omitted.⁵²

Of interest for present purposes is the cited principle (e)(iii). To determine whether or not an element of a claim is essential, one must enquire whether at the time that the patent application is laid open to public inspection it was obvious to a skilled reader that a variant of that element would not make a difference to the way in which the invention works. In this regard, in *Canamould Extrusions Ltd. v. Driangle Inc.*, Stone J.A. repeated these words of Lord Diplock from pages 242-43 of the *Catnic* case, *supra*:

The question in each case is: whether persons with practical knowledge and experience of the kind of work in which the invention was intended to be used, would understand that strict compliance with a particular descriptive word or phrase appearing in a claim was intended by the patentee to be an essential requirement of the invention so that any variant would fall outside the monopoly claimed, even though it could have no material effect upon the way the invention worked.

The question, of course, does not arise where the variant would in fact have a material effect upon the way the invention worked. Nor does it arise unless at the date of publication of the specification it would be obvious to the informed reader that this was so. Where it is not obvious, in the light of then-existing knowledge, the reader is entitled to assume that the patentee thought at the time of the specification that he had good reason for limiting his monopoly so strictly and had

intended to do so, even though subsequent work by him or others in the field of the invention might show the limitation to have been unnecessary. It is to be answered in the negative only when it would be apparent to any reader skilled in the art that a particular descriptive word or phrase used in a claim cannot have been intended by a patentee, who was also skilled in the art, to exclude minor variants which, to the knowledge of both him and the readers to whom the patent was addressed, could have no material effect upon the way in which the invention worked.⁵³

Binnie J. expanded on the point in *Free World Trust*:

It would be unfair to allow a patent monopoly to be breached with impunity by a copycat device that simply switched bells and whistles, to escape the literal claims of the patent. Thus the elements of the invention are identified as either essential elements (where substitution of another element or omission takes the device outside the monopoly), or non-essential elements (where substitution or omission is not necessarily fatal to an allegation of infringement). For an element to be considered non-essential and thus substitutable, it must be shown either (i) that on a purposive construction of the words of the claim it was clearly not intended to be essential, or (ii) that at the date of publication of the patent, the skilled addressees would have appreciated that a particular element could be substituted without affecting the working of the invention, *i.e.*, had the skilled worker at that time been told of both the element specified in the claim and the variant and “asked whether the variant would obviously work in the same way”, the answer would be yes: *Improver Corp. v. Remington* [1990] F.S.R. 181 at p. 192. In this context, I think “work in the same way” should be taken for our purposes as meaning that the variant (or component) would perform substantially the same function in substantially the same way to obtain substantially the same result. In *Improver Corp. v. Remington*, Hoffmann J. attempted to reduce the essence of the *Catnic* analysis to a series of concise questions, at p. 182:

- (i) Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim. If no: –
- (ii) Would this (*i.e.*: that the variant had no material effect) have been obvious at the date of publication of the patent to a reader skilled in the art?

If no, the variant is outside the claim. If yes: –

(iii) Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention? If yes, the variant is outside the claim.⁵⁴

Binnie J. held the following as to substitutability of an element in the claim by a variant, according to the foregoing test:

In my view, *Catnic, supra*, and *Eli Lilly & Co. v. O'Hara Manufacturing Ltd.* (1989), 26 C.P.R. (3d) 1 (F.C.A.); were correct to put the onus on the patentee to establish known and obvious substitutability at the date of publication of the patent. If the patentee fails to discharge that onus, the descriptive word or expression in the claim is to be considered essential unless the context of the claims language otherwise dictates.⁵⁵

The “obvious substitutability” issue has been treated essentially as an “obvious equivalent” issue in the post-*Free World Trust* case law, as for example in *Janssen Pharmaceutica Inc. v. Apotex Inc.*⁵⁶, quoted below. Otherwise, the question of obviousness of a variant has not received explanatory comment in the case law.

2.5 *What Is an Obvious Equivalent?*

The term “obvious equivalent” appears in a variety of contexts. As noted above, it arises in the context of purposive construction in the question whether a variant of an element in a claim would obviously work in the same way as the claimed element. The term may appear in a claim, as for example one of the claims under review in *Aventis Pharma Inc. v. Pharmascience Inc.*⁵⁷, or in *Novartis AG v. Apotex Inc.*⁵⁸, or in *Bayer AG v. Apotex Inc.*⁵⁹ The term “obvious chemical equivalent” appears in the definition of “claim for the medicinal ingredient” in §2 and also in §6(6) of the *Patented Medicine (Notice of Compliance) Regulations*, and previously appeared in repealed §39(1) of the “old *Act*” (sometimes, depending upon the time frame, §39 was numbered as §41), reading as follows:

39. (1) In the case of inventions relating to substances prepared or produced by chemical processes and intended for food or medicine, the specification shall not include claims for the substance itself, except when prepared or produced by the methods or processes of manufacture particularly described and claimed or by their obvious chemical equivalents.

An improvement patent may be granted pursuant to §32 of the present *Patent Act*: “Any person who has invented any improvement on any patented invention may obtain a patent for the improvement...”, it has been held that the improvement cannot be an obvious equivalent of the original invention: *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)*⁶⁰.

As noted above, the doctrine of equivalents as applied in an infringement context presents a similar problem of interpretation of the phrase “obvious equivalent”. Now that the claim-interpretation doctrine of purposive construction has largely superseded the older doctrine of equivalents (the older doctrine relating to analysis of the scope of claims in an infringement context), the pertinent question in the newer doctrine is whether a given variant of the literally claimed invention would be considered by a person skilled in the art to be an obvious variant, or whether a given variant of an element of the claim would serve as well as what was literally recited in the claim. More precisely, the question stated in *Free World Trust* is whether it was obvious to the skilled reader at the time the patent was published that a variant of a particular claimed element would not make a difference to the way in which the invention works.⁶¹

As to this last question, Linden J.A. cautioned in *Janssen Pharmaceutica Inc. v. Apotex Inc.*:

[48] Specifically, the question of equivalence supposes that the person skilled in the art is told of both the invention and the variant and asked whether the variant would obviously work in the same way (*Improver* at page 192, *Free World Trust* at paragraph 55). Apotex has ignored the particulars of this test in order to argue that the skilled person must view the variant as being obvious without being told of the variant's existence. This is not the correct approach but approximates the analysis for determining the obviousness of an invention in order to decide the issue of patent validity. However, the Motions Judge was not concerned with the

inventiveness or validity of the Janssen Patent. He was concerned with deciding the issue of infringement, and he applied the correct notion of obviousness for the purpose of determining equivalence.⁶²

With the foregoing caution of Linden J.A. in mind, we may tentatively conclude on the case law that obviousness in the context of equivalence or non-equivalence of constituents, facts or propositions appears to be treated in essentially the same way as obviousness of subject-matter of a patent claim, with the qualification that the comparison to be made is not, in most if not all of these other contexts, a comparison with prior art. For example, a determination of whether two substances are “obvious chemical equivalents” is clearly not premised on one of them constituting prior art relative to the other. The post-*Free World Trust* case law has for the most part treated the question in a purposive-construction context as relating to substitutability, and consequently to equivalence of one or more variants of what has been literally claimed.

In the context of alleged obvious chemical equivalence allegedly constituting infringement in §55.2 prohibition proceedings, Campbell J. in *Bayer AG v. Apotex Inc.*⁶³ applied the thinking of Binnie J. quoted below from *Free World Trust*:

It would be unfair to allow a patent monopoly to be breached with impunity by a copycat device that simply switched bells and whistles to escape the literal claims of the patent. Thus the elements of the invention are identified as either essential elements (where substitution of another element or omission takes the device outside the monopoly), or non-essential elements (where substitution or omission is not necessarily fatal to an allegation of infringement). For an element to be considered non-essential and thus substitutable, it must be shown either (i) that on a purposive construction of the words of the claim it was clearly not intended to be essential, or (ii) that at the date of publication of the patent, the skilled addressees would have appreciated that a particular element could be substituted without affecting the working of the invention, i.e., had the skilled worker at that time been told of both the element specified in the claim and the variant and “asked whether the variant would obviously work in the same way”, the answer would be yes: *Improver Corp. v. Remington*, (1989) 17 F.S.R. 181 (Pat. Ct.) at p. 192. In this context, I think “work in the same way” should be taken for our purposes as

meaning that the variant (or component) would perform substantially the same function in substantially the same way to obtain substantially the same result.⁶⁴

In other words, two different substances are obvious chemical equivalents if one can be substituted for the other without affecting the working of the invention; *i.e.* if they both perform substantially the same function in substantially the same way to obtain substantially the same result, and if this would have been recognized at the relevant time by a person skilled in the technology. That hypothetical person, having been told of both the substance specified in the claim and the variant (*i.e.*, the alleged obvious equivalent), would have had to appreciate that the variant would obviously work in the same way as the claimed substance.

2.6 *What Is so Obvious that It Need not Be Described in a Specification?*

The question is not usually phrased this way in the decided cases. Rather, the question is whether the person skilled in the art, upon a reading of the specification, is able to practise the claimed invention to advantage. If the answer is yes, the specification is sufficient. If no, then the patent fails by reason of insufficiency of disclosure. By inference, that which is obvious to a person skilled in the art, either directly within the common knowledge of the art or else requiring no creativity or inventiveness to implement, need not be specifically described in the specification. For example, in the case of an electrical appliance invention, one need not describe the characteristics of the electricity supplied by the electric utility company. Per Pigeon J. in *Burton Parsons Chemicals Inc. v. Hewlett-Packard (Canada) Ltd.*:

In the present case, there was admittedly a meritorious invention and Hewlett-Packard, after futile attempts to belittle its usefulness, brazenly appropriated it. It was in no way misled as to the true nature of the disclosure nor as to the proper methods of making a competing cream. The objections raised against the claims really are that, except those pertaining to some specific embodiments of the invention, the others are so framed as to cover every practical embodiment, leaving to the man skilled in the art, the task of avoiding unsuitable materials in the making of the mixture, a task which any man skilled in the art ought to be able to perform without having to be told because any unsuitability depends on well-known

properties.⁶⁵

A patent description is not insufficient merely because limited trial or experimentation would need to be conducted by a person skilled in the art; the patent is not invalid if the requisite information needed for the successful practice of the invention can be ascertained by trial-and-error experimentation not amounting to invention: *Mobil Oil Corp. v. Hercules Canada Inc.*⁶⁶

2.7 *What Essential Element Is so Obvious that It Need not Be Recited in a Claim?*

Following the line of reasoning expressed above, presumably everyday elements or constituents or constraints that would obviously be used by the person skilled in the art to place the invented apparatus (say) in its expected context, such everyday items including, *e.g.*, enclosures, prime movers, fluids under pressure, fasteners, supports, frames, *etc.*, need not be specifically recited in claims. Support for this view can be found in *Burton Parsons, supra*; see also *British Thomson-Houston v. Guildford*⁶⁷; *Metalliflex Ltd. v. Rodi & Wienenberger A.G.*⁶⁸; *Sandoz Patents Ltd. v. Gilcross Ltd.*⁶⁹; *Steel Co. of Canada Ltd. v. Sivaco Wire and Nail Co.*⁷⁰ But in *Feherguard Products Ltd. v. Rocky's of B.C. Leisure Ltd.*⁷¹, the omission from a claim of a suitable fastener for "securing" two elements together was found in the context of the particular patent to render the claim void for lack of utility; this finding may be doubted if intended to be of general applicability. In contrast, if the environmental element or constraint in question is not an "everyday" item and is essential to the operability of the invention, apparently such element must be recited in the claim: *Norac Systems International Inc. v. Prairie Systems and Equipment Ltd.*⁷²; *Mullard Radio Valve Co. Ltd. v. Philco Radio & Television Corp. of Great Britain Ltd.*⁷³; *cf. Leithiser v. Pengo Hydra-Pull of Canada Ltd.*⁷⁴

An exemplary approach to an allegation that an essential element is missing from a claim is found in the judgment of Addy J. in *Canadian Patent Scaffolding Co. Ltd. v. Delzotto Enterprises Ltd.*:

Although the claim does not mention cross-bracing of the trusses, I agree with the evidence of the witnesses who stated that such cross-bracing would be devised and installed normally on location or otherwise as a matter of course, by any person

skilled in the art of concrete forming; the omission of any mention of cross-bracing from the claim is not at all fatal to the claim on the grounds that, without cross-bracing, the forms would not function properly, as any person who erects forms would realize that.⁷⁵

2.8 *What Is so Obviously Useless that It Cannot Be Within the Claimed Invention?*

Again the *Burton Parsons* reasoning applies; the skilled workman will reject as outside the scope of the invention obviously useless elements, combinations, etc. Commenting on *Burton Parsons*, Binnie J. in *Whirlpool* observed:

Knowledge of purpose is one of the important attributes the skilled worker brings to the exercise, as was made clear in *Burton Parsons Chemicals, Inc. v. Hewlett-Packard (Canada) Ltd.* [1976] 1 S.C.R. 555, a case that concerned the validity of a chemical patent. The invention was a type of conductive cream to be smeared on bits of the human body for the purpose of making electro-cardiograms and the like. The mixture was of no fixed composition. The essential invention was “to combine a highly ionizable salt with an aqueous emulsion” (p. 564). It was put in evidence that hundreds, if not thousands, of substances would fit the description, including some that would be toxic or irritating to the skin. A toxic “conductive cream” would not be a useful therapeutic tool, and it was alleged on that account that the patent lacked utility and was invalid. These objections were swept away by Pigeon J. who held that the notional skilled workman would understand perfectly well the purpose of the combination and could therefore be expected to apply the teaching of the patent by sensibly choosing components suitable for that purpose (p. 563).⁷⁶

2.9 *What Kind of Error is so Obvious that It May Be Corrected via Section 8?*

The case law suggests that the foregoing question is the wrong question to ask. Rather, the courts require that if §8 is to be invoked, the error must be “clerical”. but the error need not be “obvious”. Per Mahoney J. in *Bayer Aktiengesellschaft v. Commissioner of Patents*:

I accept that a clerical error is an error that arises in the mechanical process of writing or transcribing and that its characteristic does not depend at all on its relative obviousness or the relative gravity or triviality of its consequences.⁷⁷

2.10 *Is it Obvious that a Given Prediction is Sound?*

As will be seen below, the foregoing question is probably not the right question to ask.

The utility of a claimed invention as of the critical date, *e.g.* the claim date pursuant to §28.1 of the *Patent Act*, need not have been proved by testing or the like, but may be established by sound prediction. So far, the question of what degree of “soundness” is necessary to support a finding of sound prediction does not seem to have been addressed as such. The courts in dealing with sound-prediction cases have tended rather to ask the question whether there is any credible and reasonably reliable evidence that the prediction in question is sound, and if there is, to rule that the sound-prediction basis for establishing utility has been made out. The recent case *Aventis Pharma Inc. v. Apotex Inc.*⁷⁸ is exemplary. But the question “how sound is sufficiently sound?” and the related question of what is obvious to the peers of the inventors, lurk beneath the surface.

In the course of developing technology for a given utility, suppose that the inventors conceive a potential candidate that they follow up by investigation and analysis. At the outset, the utility of the conceived new candidate cannot be immediately tested nor reliably predicted. At some later time, enough is known about the candidate that the inventors can confidently predict that the requisite utility will exist, and they file a patent application for it. Later testing confirms that the sought utility is present in the candidate. Peers of the inventors consider that their prediction prior to the filing of the patent application was sound. The patent is valid. This exemplifies one type of sound prediction.

The foregoing type of sound prediction arises frequently in relation to pharmaceutical and biotech inventions. The ultimate utility sought is usually treatment or prevention of disease or symptoms thereof or of some other undesirable body condition. But clinical testing may be years away, and given the competition in the industry, no pharmaceutical company can afford to wait until clinical testing has taken place before filing a patent application. The leading case of this type is

*Apotex Inc. v. Wellcome Foundation Ltd.*⁷⁹ In this case, Binnie J. explained:

...if the utility of AZT for the treatment of HIV/AIDS was unpredictable at the time of the patent application, then the inventors had not made an invention and had offered nothing to the public in exchange for a 17-year monopoly except wishful thinking.

Where the new use is the gravamen of the invention, the utility required for patentability (s. 2) must, as of the priority date, either be demonstrated or be a sound prediction based on the information and expertise then available.⁸⁰

In a second type of sound prediction, the inventors either conceive or learn from experiment that a genus, class or category of (say) substances is expected to be useful for an identified purpose. They are able to test a handful of species of the genus, and the tests confirm that these species have the requisite utility. Their peers agree that they have invented the genus, and not merely a plurality of tested substances, because their peers would predict, knowing what the inventors knew as of the critical date, that untested members of the genus would have the same utility. Examples of this type of sound prediction were analyzed in *Hoechst Pharmaceuticals of Canada Ltd. v. Gilbert & Co.*⁸¹ and *Monsanto Co. v. Commissioner of Patents*⁸², both in the context of a patentable selection.

The sound prediction tests for these two categories may be respectively stated as follows:

1. Did it appear reasonable (apparently the question is not “was it obvious”) to the peers of the inventors on the critical date that on the basis of known facts X, Y, that the utility of candidate Z for a particular purpose could be soundly predicted?
2. Did it appear reasonable to the peers of the inventors on the critical date that on the basis of known facts (*e.g.*, satisfactory testing) as to the utility of species X and Y, both being members of genus Z, that it could be soundly predicted that all (or substantially all) members of genus Z have that same utility?

The case law to date does not require that, given certain known facts, a given prediction must be “obviously” sound. If that were a criterion, presumably the obviousness of the soundness of the prediction would be scrutinized and tested by hypothetical peers of the inventors, and in a lawsuit, as an actuality, by experts in the technology in question. But the courts appear not to require that

the prediction be “obvious” to anyone. Rather, as mentioned, they are interested in the question whether the evidence in the case at bar establishes that on the critical date, the inventors, on the basis of known facts, had “an articulable and sound line of reasoning” leading to the prediction. This approach to the question of sound prediction is found in the *Wellcome Foundation* case, where Binnie J. said:

70 The doctrine of sound prediction has three components. Firstly, as here, there must be a factual basis for the prediction. In *Monsanto and Burton Parsons*, the factual basis was supplied by the tested compounds, but other factual underpinnings, depending on the nature of the invention, may suffice. Secondly, the inventor must have at the date of the patent application an articulable and “sound” line of reasoning from which the desired result can be inferred from the factual basis. In *Monsanto and Burton Parsons*, the line of reasoning was grounded in the known “architecture of chemical compounds” (*Monsanto*, at p. 1119), but other lines of reasoning, again depending on the subject matter, may be legitimate. Thirdly, there must be proper disclosure.⁸³

Binnie J. did not provide any guidelines for testing soundness, but his Lordship said briefly:

71 It bears repetition that the soundness (or otherwise) of the prediction is a question of fact. Evidence must be led about what was known or not known at the priority date, as was done here. Each case will turn on the particularities of the discipline to which it relates.⁸⁴

Harrington J. put the question this way in *Sanofi-Aventis Inc. v. Laboratoire Riva Inc.*:

Put another way, was the promise of the invention a reasonable inference from what the inventors knew, or should have known, or was it based on mere speculation?⁸⁵

This dichotomy was expressed slightly differently by Binnie J. in the *Wellcome Foundation* case as follows:

There is no doubt that care must be taken that the doctrine is not abused, and that

sound prediction is not diluted to include a lucky guess or mere speculation. The public is entitled to obtain a solid teaching in exchange for the patent rights.

The public is entitled to accurate and meaningful teaching in exchange for suffering the patent monopoly. The patent claims must be supported by the disclosure. Speculation, even if it afterwards proves justified, does not provide valid consideration.⁸⁶

If, as the cases reveal, the contrasting poles are “mere speculation” and “reasonable inference”, then it would seem unlikely that the courts will raise the bar on the latter and insist that the reasonable inference must also be obvious to the inventors’ peers, or to persons skilled in the art generally.

A possible variant on the basic sound-prediction question is whether it is obvious that a prediction is sound as to all members of a selected group, and not merely to some of them. This latter question has so far also lurked in the unspoken background, and appears to raise essentially the same issues as the basic question.

However, it is of interest that some litigants have introduced a somewhat parallel concept into evidence presented to the courts in sound-prediction cases. Per Nadon J.A. in *Pfizer Canada Inc. v. Canada (Health)*:

[154] The issue of sound prediction is a mixed question of fact and law, in respect of which there was evidence in the record. In particular, Dr. Wasley and Dr. Anderson testified that a person of ordinary skill would have a sound basis to predict that all compounds claimed would have utility, on the basis of the captopril patents, enalapril disclosure and application, Tanabe patent and the inventor’s knowledge regarding certain other compounds.⁸⁷

The evidence in the foregoing *Pfizer Canada* case was certainly a mosaic, and one presumes that hindsight played an important role in the selection of the information presented in evidence. We shall undoubtedly read more about the finer points of the sound-prediction doctrine in future cases.

3 Flaws and Unsettled Issues in the Existing Obviousness Law

3.1 *Obviousness of Claimed Subject-Matter*

There appear to be two significant related issues that need further attention:

1. Does the case-law requirement for “inventive step” mean the same thing in Canada as it does in Britain (in particular) and under the EPC?
2. To what extent is the Canadian law on obviousness out of harmony with the law in Britain, America, and the law of other countries whose law has helped shape that of Canada? Does any disharmony matter?

Pursuant to Article 52(1) of the European Patent Convention,

European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.

Article 56 reads in part

An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.

The UK *Patents Act 1977* reads in part in §1:

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

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

The “inventive step” requirement in British and European law presupposes a technical problem to be solved. Per Lord Hoffman in *Biogen Inc v Medeva plc*:

A proper statement of the inventive concept needs to include some express or implied reference to the problem which it required invention to overcome.⁸⁸

It is difficult to apply the foregoing requirement to some subject-matter traditionally considered patentable in Canada, such as board games. Even where the subject-matter is purely technical, how does one deal with the problem of serendipitous invention? Example: “We sought to make a better tasting marmalade, but we unexpectedly found that one of our compositions served as a surprisingly strong yet flexible glue”. The British sometimes seem to get around the foregoing problem by contriving *ex post facto* a technical problem suited to the invented solution.

Rule 80 of the *Patent Rules* appears to reflect an attempt by Canadian authorities to bring the Canadian law into closer harmony with the European law. Rule 80 provides in part as follows:

The description shall...

(b) specify the technical field to which the invention relates;...

(d) describe the invention in terms that allow the understanding of the technical problem, even if not expressly stated as such, and its solution...

Clause (d) of this Rule is not compelled by the *Patent Act* nor by the Canadian case law, and the wording of clause (b) is difficult to reconcile with the currently permitted patenting of board games, for example. The Rule or the categories of subject-matter permitted to be patented in Canada, or both, will probably have to be reconsidered.

In contrast, the American statute does not mention “inventive step” but rather in 35 U.S.C. § 103(a) specifies the following:

103. Conditions for patentability; non-obvious subject matter

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill

in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Further, American courts in their approach to obviousness issues appear primarily to be governed by the decision of the Supreme Court in *Graham v. John Deere Co.*⁸⁹ This case held that the factors to be weighed when determining obviousness issues, frequently referred to as the “Graham factors” are the following:

1. the scope and content of the prior art;
2. the level of ordinary skill in the prior art;
3. the differences between the claimed invention and the prior art; and
4. any objective evidence of nonobviousness, such as commercial success.

The U.S. Supreme Court recently reviewed the foregoing and competing criteria for testing obviousness in *KSR v. Teleflex*⁹⁰. The Court in *KSR* repudiated the so-called TSM test for obviousness as the governing test, although it left open the possibility (subject to the overriding *Graham* criteria) that the TSM test might be of some value in some cases. The TSM test (an abbreviation of the “teaching/suggestion/motivation” test) had required that to establish obviousness, there must be a suggestion or teaching in the prior art that elements known in the prior art might usefully be combined to generate the claimed invention. Under TSM, the critical inquiry was whether something in the prior art suggested the desirability or purpose, and consequently the obvious character, of a claimed combination of previously known elements. In practice, the TSM test often required that the person attacking the patent find in the prior art some indication that the ideas from two publications (say) should be combined so as to lead directly to the claimed invention in issue. The *KSR* Court warned that a rigid application of TSM as a litmus test for obviousness is an insufficient compliance with the *Graham* analysis.

Even if TSM plays a diminished role in future U.S. cases, the TSM requirement for a prior-art teaching, suggestion or motivation to combine two or more prior technical ideas is not far from the Canadian requirement that the person skilled in the art would, in the light of the state of the art and common general knowledge as of the critical date, have come directly and without difficulty to the solution taught by the patent.

On the basis of what is written above, there would appear to be no major inconsistency between the post-*KSR* U.S. law of obviousness and the Canadian law. However, two possible inconsistencies may be implicit in the following passage from the opinion of the *KSR Court* delivered by Kennedy J. [citations omitted, except for *Graham*]:

The second error of the Court of Appeals lay in its assumption that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem. The primary purpose of Asano was solving the constant ratio problem; so, the court concluded, an inventor considering how to put a sensor on an adjustable pedal would have no reason to consider putting it on the Asano pedal. Common sense teaches, however, that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle. Regardless of Asano's primary purpose, the design provided an obvious example of an adjustable pedal with a fixed pivot point; and the prior art was replete with patents indicating that a fixed pivot point was an ideal mount for a sensor. The idea that a designer hoping to make an adjustable electronic pedal would ignore Asano because Asano was designed to solve the constant ratio problem makes little sense. A person of ordinary skill is also a person of ordinary creativity, not an automaton.

The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." 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.

The Court of Appeals, finally, drew the wrong conclusion from the risk of courts and patent examiners falling prey to hindsight bias. A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning. See *Graham*, 383 U. S., at 36 (warning

against a “temptation to read into the prior art the teachings of the invention in issue” and instructing courts to “ ‘guard against slipping into the use of hindsight’ ”. Rigid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it.⁹¹

It appears from the above that the *KSR* Court has left open the possibility of using hindsight (sometimes referred to as *ex post facto* analysis) to guide the court in applying the Graham factors, in at least some circumstances. Further, it appears that the *KSR* Court supports the conclusion that “worth a try” suggestions may lead to a finding of obviousness in some cases. No doubt these issues will be given careful consideration in future U.S. cases, and perhaps in Canadian cases as well.

On the hindsight issue, the Federal Court of Appeal said the following in *Bayer AG v. Apotex Inc.*, which appears to be close to the *KSR* view:

...The traditional warning about hindsight is found in *Beloit Canada* (at page 295, per Hugessen J.A.):

Every invention is obvious after it has been made, and to no one more so than an expert in the field. Where the expert has been hired for the purpose of testifying, his infallible hindsight is even more suspect. It is so easy, once the teaching of a patent is known, to say, "I could have done that"; before the assertion can be given any weight, one must have a satisfactory answer to the question, "Why didn't you?"

[25] This does not mean that the trier of fact is required as a matter of law to reject an expert’s hindsight analysis. After all, the evidence of a party alleging invalidity for obviousness is necessarily based to some degree on hindsight because it is addressed to a hypothetical question about a point of time in the past. However, as a factual matter, 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.⁹²

The High Court of Australia in *Aktiebolaget Hassle v Alphapharm Pty Limited*⁹³ had occasion in a pre-*KSR* case to compare the Australian, American and British law on obviousness of a claimed invention, including an analysis of the degree to which “inventive step” may be equated with

“unobviousness”. An underlying theme of the analysis was that as the respective statutes are different on what constitutes an invention, with particular regard to obviousness, it is not surprising that the related case law also differs from country to country. Relative to the “worth a try” test, the *Hassle* court held that

The test is whether the hypothetical addressee faced with the same problem would have taken as a matter of routine whatever steps might have led from the prior art to the invention, whether they be the steps of the inventor or not.⁹³

The High Court added.:

That way of approaching the matter has an affinity with the reformulation of the “Cripps question” by Graham J in *Olin Mathieson Chemical Corporation v Biorex Laboratories Ltd.* [1970] RPC 157... Graham J had posed the question at 187-188:

“*Would the notional research group at the relevant date, in all the circumstances, which include a knowledge of all the relevant prior art and of the facts of the nature and success of chlorpromazine, directly be led as a matter of course to try the -CF₃ substitution in the '2' position in place of the -C₁ atom in chlorpromazine or in any other body which, apart from the -CF₃ substitution, has the other characteristics of the formula of claim 1, in the expectation that it might well produce a useful alternative to or better drug than chlorpromazine or a body useful for any other purpose?*”

That approach should be accepted.⁹⁴

The New Zealand Court of Appeal in *Ancare New Zealand Ltd. v. Cyanamid of NZ Ltd.*⁹⁵ has doubted the “worth a try” test, observing that “anything may be worth a try”, implying that the test, if it is ever to be accepted at all at least in New Zealand, requires some refinement.

In summary, the Canadian law on obviousness appears to be out of step with the European and British law (i) to the extent that the latter require as a premise to a finding of invention that there have been a technical problem to be solved and an inventive step of a technical character that solves the problem, and (ii) to the extent that the “worth a try” test is readily accepted in the British law as being of value in reaching a conclusion that the claimed invention was obvious. As

mentioned, the Canadian law on obviousness presumably should apply to all classes of subject-matter within the ambit of the Patent Act; but §1 of the British *Act* explicitly excludes from patentable inventions

(c) a scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer.

So it appears unlikely that Canadian courts will accept the need for an “inventive step” in the sense in which the term is used in Britain. As to “worth a try”, the *KSR* court’s approach to the topic appears on the surface to have been reasonable, so it is possible that Canadian courts may modify their present entirely negative approach to the “worth a try” foundation for a finding of obviousness.

It is less clear that the Canadian law is out of step with the American law; the critical issues are the hindsight question and again the “worth a try” question. The conclusions of the *KSR* Court on these last two issues are somewhat tentative and are not markedly inconsistent with a liberal interpretation of the Canadian case law, especially as it might reasonably be expected to develop in the future. Presumably Canadian courts will continue to take into account differences from the law of other countries in shaping that development.

It may be helpful when reviewing the case law to bear in mind the warning of Diplock L.J. (as he then was) commenting on the issue of obviousness in *Johns-Manville Corporation's Patent* [1967] RPC 479 at 493-494:

I have endeavoured to refrain from coining a definition of 'obviousness' which counsel may be tempted to cite in subsequent cases relating to different types of claims. Patent law can too easily be bedevilled by linguistics, and the citation of a plethora of cases about other inventions of different kinds. 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 in some particular verbal formula. I doubt whether there is any verbal formula which is appropriate to all classes of claims.⁹⁶

The Federal Court of Appeal agrees with at least the last sentence quoted above; in *Bayer AG v. Apotex Inc.* the Court observed

There is no single factual question or a set of questions that will determine every claim of obviousness.⁹⁷

In comparing the result that a Canadian court might reach as compared with the result that a foreign court might reach on a given fact situation, one has to keep in mind not only the law on obviousness but also an abundance of other considerations, including differences in the law of evidence (*e.g.*, whether patent application file histories are admissible or not); whether obviousness is treated as strictly a legal question, or a factual question, or a mixed question; differences in burden of proof; whether jury trials are available; and whether or not one and the same court will decide both validity and infringement issues. Compatibility of the substantive law is only one of the important factors in the mix.

3.2 *Obviousness-Type Double Patenting*

There is a fundamental problem with the present law on obviousness-type double patenting, but it has nothing to do with obviousness. The problem is that if any two given patents have identical expiry dates, *prima facie* there is no inherent “evil” to be remedied even if the claims of the two patents overlap or are not “patentably distinct” from one another. Consequently, there should be no finding of double patenting in such circumstances, or if double patenting is found, there is no need for any remedy, and none should be given by the courts. If this proposal were adopted, there would remain some problems or potential problems, and these should be addressed. But redress by invalidation of the second patent that expires concurrently with the first, or some of its claims, is the old story of swatting a fly with a sledgehammer.

In case after case, the courts point to unjustifiable extension of a so-called “monopoly” or “evergreening” as the problem to which invalidation of the later patent (or claims thereof) by reason of double patenting is the standard judicial remedy. By way of example, in *Whirlpool*, Binnie J. for the Supreme Court said the following:

37 It is common ground that the bargain between the patentee and the public is in the interest of both sides only if the patent owner acquires real protection in exchange for disclosure, and the public does not for its part surrender a more extended monopoly than the statutory 17 years from the date of the patent grant (now 20 years from the date of the filing of the patent application). A patentee who can "evergreen" a single invention through successive patents by the expedient of obvious or uninventive additions prolongs its monopoly beyond what the public has agreed to pay.

* * *

63 The prohibition against double patenting relates back to the "evergreen" problem mentioned at the outset. The inventor is only entitled to "a" patent for each invention: Patent Act, s. 36(1). If a subsequent patent issues with identical claims, there is an improper extension of the monopoly.⁹⁸

As another example, in *Aventis Pharma Inc. v. Mayne Pharma (Canada) Inc.*, Beaudry J., relying on *Whirlpool*, said:

[73] The principle behind the patent system is that of a bargain between the patentee and the public by which the patentee obtains full monopoly for a period of 20 years over the subject of the claims in exchange for a complete disclosure of how to perform the invention so that the public can freely use it on expiry of the patent term. As a consequence of such a bargain, a patentee cannot "evergreen" or prolong its monopoly beyond what the public has agreed to through successive obvious patents. The double patenting prohibition relates to this "evergreen" problem. A patentee is only entitled to one patent per invention.⁹⁹

Even where the two patents are parent and divisional with identical expiry dates, double patenting is seen to be an evil that must be remedied by an invalidity holding. In a post-*Whirlpool* case, *GlaxoSmithKline Inc. v. Apotex Inc.*¹⁰⁰, in the context of a parent patent and a divisional patent that had followed, it was argued that the post-1989 amendments of the *Patent Act* had removed the "sin of double patenting", that sin again being characterized as "evergreening". Kelen J. rejected the argument, pointing out that in connection with patents to which §55.2 applies, the existence of

additional patents would allow the patentee to bring multiple prohibition proceedings thereby to obtain multiple injunctive periods.¹⁰¹ Further, Kelen J. observed that in the case *Bayer Inc. v. Canada (Minister of National Health and Welfare)*¹⁰², the patentee had filed what his Lordship referred to as a “terminal disclaimer” that had brought the terms of the parent and divisional patent into coincidence, yet the *Bayer* court had affirmed the requirement that the divisional patent must claim an invention that manifested inventive ingenuity in its own right. Regardless of parent/divisional relationships, “two inventions are required to support two patents”.¹⁰³ On the facts of the case, Kelen J. held that there was obviousness-type double patenting. (The “terminal disclaimer” in the *Bayer* case was actually a Dedication to the Public of the excess patent term on the later patent. This was discussed at the trial level in some detail. The *Bayer* case will be discussed further below.)

The points made by Kelen J. are not trivial and need some thinking. The *Bayer* court did not mention double patenting as such. It held on the basis of the decision of the Supreme Court of Canada in *Commissioner of Patents v. Farbwerke Hoechst AG*¹⁰⁴ that “the element of inventive ingenuity is essential for patents based on a divisional application”¹⁰⁵ and that “the composition claims disclose no inventive ingenuity over and above that of the compound claims”.¹⁰⁶ But it must be remembered that the *Hoechst* case was decided under the “old *Act*” and that at that time, parent and divisional patents almost invariably had different expiry dates. It is noteworthy that Binnie J. also relied upon the *Hoechst* case in ruling as he did in *Whirlpool*.¹⁰⁷

Further, the *Hoechst* case was decided at a time when the *Patent Act* did not permit claims to a medicinal substance *per se*. This situation led to developments in pharmaceutical patent practice that were contrived to fence off new medicinal substances by indirect means, such as obtaining multiple patents for multiple processes for making the new substances. Equally, the courts contrived judicial remedies for such back-door attempts to defeat the intended medicinal-substances provisions of the *Act*. Distortions crept into the patent law and some of them remain to this day.

The Supreme Court in *Shell Oil Co. v. Commissioner of Patents* explained what had happened, but perpetuated the essential double-patenting doctrine established by the *Farbwerke Hoechst* case. The *Shell Oil* Court held that beginning with *Farbwerke Hoechst*, the double-

patenting line of cases

were all cases falling within [the medicinal substance control provisions of the *Patent Act*]... I do not think it is possible to read those cases without concluding that one of the reasons for the rejection of the composition claims in those cases was that to allow them would permit the applicants to avoid the impact of [the medicinal substance control provisions of *Patent Act*] in respect of substances clearly falling within [such provisions]. I agree with counsel for the appellant that these cases did not establish a broad principle that compositions containing new compounds mixed with an inert carrier were not patentable. They did establish, however, that no inventive ingenuity is involved in mixing a compound with a carrier. Accordingly if the compound is patented, there is no invention in the composition.¹⁰⁸

Let us go back in time to the early 1960's and suppose that there was no prohibition on the patenting of medicinal substances. Suppose also that at the time, terminal disclaimers were routinely used by applicants to preclude different expiry dates for patents whose inventive kernels were essentially identical. Would the *Hoechst* court have ruled as it did? In such circumstances, what “sin” or “evil” needed to be remedied? If two different patents issue, one for the basic active compound, the other for the compound diluted in a carrier, and they both expire at the same time, then where’s the harm, apart from the §55.2 problem mentioned by Kelen J. in *GlaxoSmithKline*, which problem did not exist in the 1960's?

Not to have acknowledged in *Whirlpool* the foregoing *Hoechst* history and context, and to have extended in *Whirlpool* the double-patenting invalidation remedy to the evergreening problem without any qualification that might apply, for example, to new-*Act* divisional patents, are deficiencies in the *Whirlpool* judgment. Although *Whirlpool* was decided in relation to the old-*Act* patents in issue in that case, there is nothing in *Whirlpool* that suggests that its holdings should be limited to patents granted under the old *Act*. Unfortunately, the *Whirlpool* judgment focuses more on historical development of double-patenting law than on current realities.

If two patents with claims to overlapping subject-matter are not parent/divisional patents but would normally expire on different dates, that problem could be remedied by terminal disclaimer.

The availability of a terminal disclaimer to avoid double patenting under Canadian patent practice is long overdue. The Intellectual Property Institute of Canada (IPIC) on 9 March, 2007 officially recommended to the Canadian Intellectual Property Office (CIPO) that Canadian law be amended to remedy the deficiency, possibly in conjunction with the availability of continuation patent applications along the lines of U.S. practice.

Under American law, a second patent is not invalid for double patenting if the patentee holder forfeits the period of additional protection by making a terminal disclaimer: see, *e.g.*, *In re Bowers*¹⁰⁹; *In re Plank*¹¹⁰, and *In re Kaplan*¹¹¹. Conceivably if terminal disclaimers were to become effectively available in Canada to avoid double patenting, there should be some penalty short of invalidity if the applicant has failed to seek the terminal disclaimer prospectively to be effective as of the issue date of the second patent.

Returning to *Bayer Inc. v. Canada (Minister of National Health and Welfare)*¹¹², this time at the trial level, the patentee had filed a “Dedication to the Public” for the remaining term of the second patent, and argued that “the Dedication to the Public is a complete answer to any harm suggested by Apotex in connection with the 3334 patent because of its expiration on the same day as the 3067 patent expires”, but Lutfy J. ruled that this manoeuvre was ineffective to avoid double patenting and its consequences. In so doing, Lutfy J. relied not only upon the decision of the Supreme Court of Canada in *Farbwerke Hoechst, supra*, but also upon that court’s decision in *Shell Oil, supra*, in which latter the Supreme Court had ruled that independently of the medicinal substances provisions of the old *Act*,

... no inventive ingenuity is involved in mixing a compound with a carrier. Accordingly, if the compound is patented, there is no invention in the composition. That proposition, in my view, makes eminent good sense whether the substance is covered by s. 41 or not ...¹¹³

The judgment of Lutfy J. was upheld by the Federal Court of Appeal without analysis of the s.41-related issue nor of the terminal-dedication issue, but with a holding that “there is no error in the reasons or decision of the Motions Judge that would warrant our intervention”.¹¹⁴ Without mentioning *Shell Oil*, the FCA relied upon the *Farbwerke Hoechst SCC* decision, *supra*, for its

holding that inventive ingenuity is essential for patents based on a divisional application. This is the state of the present law, which apparently can be remedied only by amendment of the *Patent Act*.

As for the §55.2 problem mentioned by Kelen J., it should be easy enough to amend the *Patent Act* and/or the *Patented Medicine (NOC) Regulations* to preclude the multiple prohibition proceedings and multiple injunctive periods about which Kelen J. was worried.

With the abolition of the double-patenting doctrine and the foregoing remedial measures in place, there might remain some problems, if other case law remains intact and authoritative. For example, current case law confirms that a genus invention is not the same invention as, and therefore is patentably distinct from, a selection of species within the genus that satisfy selection-patent criteria. So conventional double-patenting law does not apply to selections. But it can happen that the respective patents for the genus and species have different expiry dates. In such a case, evergreening may be a problem insofar as the selected species are concerned. Should a terminal disclaimer be compulsory in such cases in order to avoid invalidity of the second patent?

As an example of another residual problem or quasi-problem, Beaudry J. in *Aventis Pharma Inc. v. Mayne Pharma (Canada) Inc.* pointed out:

[74] It is trite law that different types of claims exist in the pharmaceutical industry, namely product claims and process claims. Once a patent is obtained for a substance *per se*, no additional protection may be obtained for the same substance. However, it is nevertheless possible to obtain a patent for the process by which the substance is made independently of the patent on the substance *per se*. This type of patent is a valid patent and does not extend the statutory monopoly of the patent on the substance *per se*.¹¹⁵

The trouble is, in some cases the patentee may prolong *de facto* an exclusive right in the substance if the newly patented process for making the substance is sufficiently economically significant. However, this situation is analogous to the parallel problem with improvement patents - sometimes by the time that the basic patent has expired, the more recent improvement patent prolongs the exclusive right on the commercially viable successor to the originally patented product (say).

Perhaps there is no useful remedy to the foregoing residual problems, if they are perceived as being real problems. The counterargument of course is that the patent system promotes innovation, and innovation can take the form of patentable improvements (including selections) or freshly patentable technology that supersedes previously patented technology, so on this view there really is no residual problem.

The chances are that any identifiable residual problem that would continue to exist if double patenting (and its remedies) were abolished altogether, could be solved and remedied without resort to the potentially severe remedy of invalidation. And abolition of the doctrine would save a lot of court time.

If we confine attention to the “obviousness” issue in relation to obviousness-type double patenting, recall that in *Aventis Pharma Inc. v. Pharmascience Inc.*), the Court appears to have accepted without analysis the proposition that the obviousness test to be used for double patenting is identical to “the established legal test for obviousness”.¹¹⁶ The point probably remains open, as the “established” test governing the interpretation of s.28.3 requires a comparison between what is claimed and the applicable prior art, whereas in obviousness-type double patenting analysis, the focus is on that an earlier patent claims, not on what it teaches; further, the earlier patent may not be “prior art” as against the later, in the usual sense of “prior art”.

3.3 “Obvious” in the Context of Purposive Construction

Recall that the obviousness question relating to the doctrine of purposive construction of claims is whether the fact that a given variant of an element recited in a claim has no material effect on how the invention works would have been obvious at the date of publication of the patent to a reader skilled in the art. If the answer is no, the variant is outside the claim. The very limited guidance provided by the case law is that this reduces to a question of obvious substitutability, requiring the patentee to show that the variant of the claimed element or component would perform substantially the same function in substantially the same way to obtain substantially the same result. The question of obvious substitutability is essentially identical to the question of obvious equivalence, discussed next.

There is some concern as to the date on which the test of obvious substitutability should be applied. In *AT & T Technologies v. Mitel*, Reed J. derived a presumption of patent infringement if the “variant had no material effect”, as per the second of the *Improver* questions quoted above, as follows:

If a variant of an aspect of a claim has no material effect on the way the invention works, there is a presumption that the patent is infringed and that the patentee intended that that variant falls within the scope of the claim.¹¹⁷

Commenting on the foregoing, Binnie J. in the *Free World Trust* case, *supra*, said:

The desirability of such a presumption is supported by some commentators (see, e.g., J.-C. Boudreau, "AT&T Technologies: A Contribution to the Purposive Construction Approach for Patent Infringement Analysis in Canada" (1998-99), 15 C.I.P.R. 323). If this proposition is taken to mean that a presumption of non-essentiality will arise if it is established in light of the knowledge of substitutability existing *at the date of the infringement* (*AT & T Technologies, supra*, at p. 262) that a variant would have no material effect on the way the invention works then, with respect, I disagree with it. The effect would be that the ambit of the monopoly would grow over the life of the patent as new substitutes are developed and absorbed into the common knowledge of the skilled worker. The inventor cannot be thought to have the necessary "intent" in relation to after-created knowledge except in the irrelevant sense of intending to reap the benefit of the maximum coverage available. In my view, *Catnic, supra*, and *O'Hara* (1989), 26 C.P.R. (3d) 1, were correct to put the onus on the patentee to establish known and obvious substitutability at the date of publication of the patent. If the patentee fails to discharge that onus, the descriptive word or expression in the claim is to be considered essential unless the context of the claims language otherwise dictates.¹¹⁸

The foregoing ruling may prove to have been unfortunate. Suppose that in the context of an automobile engine, the creativity in a claimed novel carburetor lies in the configuration of the conduits for fluid flow therethrough, but the carburetor claim recites as part of the structure an “air filtering diaphragm” through which incoming air must pass, the preferred filter described being of

a type known at the time to be effective for use in carburetors, comprising parallel coarsely porous membranes between which are placed dust-trapping fibres. Suppose that five years after the patent issues, such filters for the carburetors have been universally superseded by spaced parallel plates between which the air passes, the static electric charge on the plates attracting dust particles. Should the patentee suddenly have a valueless patent merely because of evolution in the technology relating to a subordinate element in the claim having nothing to do with the creativity underlying the invention?

We may expect future cases to refine the foregoing concepts and tests and others giving rise to perceived problems. In the meantime, the doctrine of purposive construction otherwise appears to be serving its objectives reasonably well.

3.4 *Obvious Equivalence*

The question of obvious equivalence has surfaced for the most part in a purposive-construction context. Recall that Linden J.A. in *Janssen Pharmaceutica Inc. v. Apotex Inc.* cautioned that a variant must be identified to a skilled person before the skilled person answers whether the variant is obviously substitutable for a claimed combination or element.¹¹⁹ We know that in a purposive-construction context, the variant must perform substantially the same function in substantially the same way to obtain substantially the same result. We see in the cases that experts in their evidence frequently express conclusions as to whether variants are obvious equivalents. The courts weigh the evidence and reach a conclusion based on their evaluation of it. So far, no tests of obviousness have emerged from these cases. The *ad hoc* approach taken by the courts seems not to have generated any problems more serious than those that tend to emerge in any case in which experts disagree.

3.5 *Obvious Omissions*

The discussion earlier in this paper identified three types of omission, *viz* omission of obvious facts from descriptions, omission from claims of elements obviously required, and the need for the skilled reader to omit from the literal wording of claims those definitions that include

obviously unsuitable or useless items.

The question what date should be used to test the obviousness of an omission appears to have been given little attention but presumably the courts would look for guidance to the approved dates on which other obviousness tests are to be applied. Otherwise, where the issues are governed by black or white facts, no serious problems seem to have emerged in these areas. It is the grey facts that are troublesome.

In *Burton Parsons*, recall that Pigeon J. said

The objections raised against the claims really are that, except those pertaining to some specific embodiments of the invention, the others are so framed as to cover every practical embodiment, leaving to the man skilled in the art, the task of avoiding unsuitable materials in the making of the mixture, a task which any man skilled in the art ought to be able to perform without having to be told because any unsuitability depends on well-known properties.¹²⁰

Claim 17 in issue in that case reads

17. An electrocardiograph cream for use with skin contact electrodes and compatible with normal skin, comprising a stable aqueous emulsion that is anionic, cationic or non-ionic and, containing sufficient highly ionizable salt to provide good electrical conductivity.

The difficulty with the claim is that phrases such as “compatible with normal skin” and “sufficient highly ionizable salt to provide good electrical conductivity” are imprecise. What is “normal skin”? What is “good electrical conductivity”? Suppose that a competitor sells a cream that causes irritation to redheads and blondes but not to brunettes, and labels the competing cream with a warning to this effect. Does the competitor infringe or not? Suppose that the patentee’s described electrical conductivity is several times higher than that obtained by use of the competitor’s cream. Does the competitor infringe or not?

Sometimes a patent claim explicitly or implicitly requires a test to be performed to determine its scope. There is a suggestion in *AlliedSignal v. Du Pont Canada* that if the specification defines an element in terms requiring the performance of a test, and there is disagreement among the experts as to the preferred test or whether the patentee's test is reliable, it appears that the specification will nevertheless be upheld as sufficient if at least some segment of reputable expert opinion endorses the patentee's test.¹²¹ This case holds further that if the quantification of a parameter used in a claim can be tested according to at least one accepted industry test, yet the disclosure does not unambiguously teach how the test is to be performed, then the claim is valid, notwithstanding a possible difficulty in addressing the question of infringement. But if an infringer after a careful reading of the description and claims cannot with reasonable certainty determine whether or not there is infringement, does not that suggest that the specification is insufficient, or perhaps that the claims are void for ambiguity (as the trial judge had held)? It is somewhat difficult to reconcile cases such as the foregoing with other cases, especially older cases such as *Minerals Separation North American Corp. v. Noranda Mines, Ltd.*, in which Thorson P. put the matter as follows:

By his claims the inventor puts fences around the fields of his monopoly and warns the public against trespassing on his property. His fences must be clearly placed in order to give the necessary warning and he must not fence in any property that is not his own. The terms of a claim must be free from avoidable ambiguity or obscurity and must not be flexible; they must be clear and precise so that the public will be able to know not only where it must not trespass but also where it may safely go.¹²²

In *Free World Trust*, Binnie J. quoted the above passage¹²³ and then cautioned that claim construction is a more nuanced task than Thorson P. had suggested:

15 In reality, the “fences” often consist of complex layers of definitions of different elements (or “components” or “features” or “integers”) of differing complexity, substitutability and ingenuity. A matrix of descriptive words and phrases defines the monopoly, warns the public and ensnares the infringer. In some instances, the precise elements of the “fence” may be crucial or “essential” to the working of the invention as claimed; in others the inventor may contemplate, and the reader skilled in the art appreciate, that variants could easily be used or substituted without

making any material difference to the working of the invention. The interpretative task of the court in claims construction is to separate the one from the other, to distinguish the essential from the inessential, and to give to the “field” framed by the former the legal protection to which the holder of a valid patent is entitled.¹²⁴

It is undoubtedly too much to expect that Parliament could devise a formula for claim construction that, if followed faithfully, would provide a just result in every case. It is probably too much to expect that the courts will ever do so; all we may reasonably expect is a set of guidelines that from time to time become replaced or refined as the developing case law indicates. The doctrine of purposive construction affords us a good start.

3.6 *Sound prediction:*

A difficulty is that a very clever inventor may perceive that a given prediction is sound, but the inventor’s peers may not share that perception, having less insight than the inventor. So it is possible that in such a case, a court may hold that there is a lack of reliable evidence to support the alleged sound prediction, thereby penalizing the inventor who has superior insight. It may happen that some court some day may ask the question “was it obvious to the inventor’s peers that on the basis of the available data and the general knowledge and expertise in the technology, the prediction was sound?” (Note that there is a conceptual parallel between this question and the question whether a given selection can be justified as an invention.) Should that happen, it would not be the patent system’s finest hour; the patent system should not jeopardize the opportunity for the very clever inventor to file a valid patent application.

A variant on the basic sound-prediction question is whether it is obvious that a prediction is sound as to all members of a selected group. This latter question has so far also lurked in the unspoken background, and appears to raise essentially the same issues as the basic question.

4 Where Do We Go from Here?

Judges and counsel are aware of trends in case law and of flaws in the existing law. They will continue to do their part to shape the evolving case law constructively.

Where legislative change is needed, judges can say so and sometimes do. We must face the reality, however, that intellectual property law reform is not high on the list of Parliamentary priorities and is unlikely to become so in the foreseeable future.

IPIC has been persistent in its quest for remedial patent legislation, and from time to time has provided the Canadian Intellectual Property Office with a “wish list” of changes to the patent law. The most recent list of 10 topics requiring attention, dated August 2007, includes three of the topics discussed herein, *viz* sound prediction, double patenting, and terminal disclaimers.

FICPI Canada is well placed to compare the Canadian patent law with that of other countries, and its efforts may be expected to continue to complement those of IPIC.

Eventually, the squeaky wheel may receive some Parliamentary lubrication.

End Notes

1 References herein to the *Patent Act* or the *Act* are references to R.S.C. 1985, c. P-4, as amended, unless the context requires that the reference is to the “old *Act*”, in which case the reference is to R.S.C. 1985, c. P-4, as it stood prior to those amendments that took effect in 1989. Patents the applications for which were filed prior to 1 October 1989 are by and large governed by the “old *Act*”. A list of the amendments to the *Act* can be found in Barrigar, *Canadian Patent Act Annotated*, 2nd ed., Canada Law Book, at PA-1.

2 2006 FCA 275; 54 C.P.R. (4th) 130 at ¶40

3 (1986) 8 C.P.R. (3d) 289 at 294 (F.C.A.)

4 2006 FCA 421

5 2006 FC 1234, 57 C.P.R. (4th) 6, at ¶¶111ff

6 2007 FCA 217 at ¶25

7 (2001) 9 C.P.R. (4th) 129 (S.C.C.) at ¶70

8 (2003) 21 C.P.R. (4th) 129, 137 (F.C.A.)

9 2002 FCT 829, 20 C.P.R. (4th) 402(F.C.T.D.), *affd* 29 C.P.R. (4th) 417 (F.C.A.), beginning at ¶98

10 [1979] 2 S.C.R. 929 at 944, 42 C.P.R. (2d) 145 (S.C.C.)
11 (2005) 39 C.P.R. (4th) 202 (F.C.) at ¶78, affd 2006 FCA 421
12 (2005) 38 C.P.R. (4th) 17
13 (2001) 13 C.P.R. (4th) 193 at 226ff. (F.C.T.D.).
14 *Canadian Law and Practice Relating to Letters Patent for Inventions* (Carswell, 4th ed.,
1969) at 90
15 (1930) 47 R.P.C. 289 at 322
16 Note 13, at 227
17 Note 4, at ¶17
18 2006 FCA 214, 52 C.P.R. (4th) 241
19 2007 FC 455
20 2007 FC 596
21 Note 7, at ¶¶37, 66, 67
22 (2006), 48 C.P.R. (4th) 46 at ¶57
23 2006 FCA 229
24 2005 FC 340, 38 C.P.R. (4th) 441 (F.C.)
25 Note 24, at ¶¶57 - 59
26 (1997), 77 C.P.R. (3d) 547 (F.C.T.D.)
27 Note 24, at ¶¶62ff
28 Note 24, at ¶95
29 Note 23, at ¶63
30 Note 24, at ¶94
31 Note 24, at ¶¶68ff
32 Note 24, at ¶70
33 Note 24, at ¶¶86ff
34 Note 23, at ¶68
35 Note 10, at p.53
36 Note 23, at ¶69
37 Note 23, at ¶¶70-73
38 Note 4, at ¶46
39 2007 FCA 209

40 Note 39, at ¶¶22, 143 and 144
41 Note 39, at ¶¶145 - 149
42 2006 FC 524, 53 C.P.R. (4th) 1 at ¶213
43 2006 FCA 323, 55 C.P.R. (4th) 1
44 Note 43, at ¶49
45 Note 23
46 2006 FC 379, 48 C.P.R. (4th) 46 at ¶¶62, 63
47 2005 FC 1504, 44 C.P.R. (4th) 108
48 [1982] R.P.C. 183 (H.L.)
49 (2001) 9 C.P.R. (4th) 168 (S.C.C.)
50 Note 7
51 Note 49, at ¶29
52 Note 49, at ¶31
53 2004 FCA 63, 30 C.P.R. (4th) 129 at ¶21
54 Note 49, at ¶55
55 Note 49, at ¶57
56 2001 FCA 247, 13 C.P.R. (4th) 410 (F.C.A.) at ¶48
57 2005 FC 340
58 (2000) 6 C.P.R. (4th) 129 (F.C.)
59 (2004) 31 C.P.R. (4th) 46 (F.C.)
60 (1998) 80 C.P.R. (3d) 110 (F.C.) at ¶21ff
61 Note 49, at 184
62 2001 FCA 247, 13 C.P.R. (4th) 410 at ¶48
63 (2004) 31 C.P.R. (4th) 46 (F.C.) at ¶¶67 and 88
64 Note 49, at ¶55
65 (1974), 17 C.P.R. (2d) 97, 106 (S.C.C.)
66 (1995) 63 C.P.R. (3d) 473 (F.C.A.)
67 (1938), 55 R.P.C. 71 at p. 88
68 (1960), 35 C.P.R. 49, [1961] S.C.R. 117, 21 Fox Pat. C. 95
69 (1970), 64 C.P.R. 14 at p. 70 (Ex. Ct.), revd 8 C.P.R. (2d) 210, 33 D.L.R. (3d) 451 (S.C.C.)
70 (1973), 11 C.P.R. (2d) 153 at p. 196 (F.C.T.D.)

71 (1994) 53 C.P.R. (3d) 417, 425, affd (1995) 60 C.P.R. (3d) 512 (F.C.A.)
72 (2002) 19 C.P.R. (4th) 360 (F.C.T.D.), revd in part (2003) 25 C.P.R. (4th) 1 (F.C.A.) but
without comment on the principle under discussion
73 (1936), 53 R.P.C. 323 (H.L.)
74 (1974), 17 C.P.R. (2d) 110, [1974] 2 F.C. 954 (F.C.A.)
75 (1978), 42 C.P.R. (2d) 7, 16 (F.C.T.D.), affd 47 C.P.R. (2d) 77, 35 N.R. 424 (F.C.A.)
76 Note 7, at ¶53
77 (1980), 53 C.P.R. (2d) 70 at 73
78 2006 FCA 64, 46 C.P.R. (4th) 401
79 2002 SCC 77, [2002] 4 S.C.R. 153, 21 C.P.R. (4th) 499
80 Note 79, at 21 C.P.R. (4th) 521
81 [1966] S.C.R. 189, 50 C.P.R. 26
82 [1979] 2 S.C.R. 1108, 42 C.P.R. (2d) 161
83 Note 79, at ¶70
84 Note 79, at ¶71
85 2007 FC 532 at ¶47
86 Note 79, at ¶¶82, 83
87 2007 FCA 209 at ¶154
88 [1997] R.P.C. 1, 45 (H.L.)
89 383 U.S. 1 (1966)
90 127 S. Ct. 1727 (2007)
91 *Ibid.*
92 2007 FCA 243 at ¶¶24 - 25
93 [2002] HCA 59
94 *Ibid.* at ¶53
95 *Id.*
96 [2000] 3 N.Z.L.R. 299 at ¶85 (revd [2006] NZSC 20, without comment on this point)
97 2007 FCA 243 at ¶19
98 Note 7, at ¶¶ 37, 63
99 (2005) 42 C.P.R. (4th) 481 (F.C.) at ¶73
100 (2004) 27 C.P.R. (4th) 114 (F.C.T.D.), at ¶91

101 Note 100, at 146
102 (2000) 6 C.P.R. (4th) 285 (F.C.A.)
103 Note 100, at 146-7
104 [1964] S.C.R. 49, 41 C.P.R. 9
105 Note 102, at ¶2
106 Note 102, at ¶10
107 Note 21
108 (1982), 67 C.P.R. (2d) 1 at 13 (S.C.C.)
109 53 C.C.P.A. 15, 359 F.2d 886 (1966)
110 55 C.C.P.A. 1400, 399 F.2d 241 (1968)
111 789 F.2d 1574 (Fed. Cir. 1986)
112 (1998), 82 C.P.R. (3d) 359 (F.C.T.D.) (affd, Note 102)
113 Note 108, at 13
114 Note 102, at ¶1
115 (2005) 42 C.P.R. (4th) 481 (F.C.) at ¶74
116 Note 23, at ¶63
117 (1989) 26 C.P.R. (3d) 238 at 257 (F.C.)
118 Note 49, at 194
119 Note 62, at ¶48
120 Note 65
121 (1995) 61 C.P.R. (3d) 417 (F.C.A.)
122 [1947] Ex. C.R. 306 at 352
123 Note 49, at ¶14
124 Note 49, at ¶15