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# Being Old and Obvious: Apotex v. Sanofi SCC

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# OSGOODE HALL REVIEW OF LAW AND POLICY

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COMMENT

BEING OLD AND OBVIOUS: *APOTEX V. SANOFI-SYNTHELABO* IN THE  
SUPREME COURT\*

David Vaver<sup>\*</sup>

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*In Apotex Inc v Sanofi-Synthelabo Canada Inc 2008 SCC 61, the Supreme Court held, affirming the lower courts, that allegations that Sanofi's patent for a blood anti-coagulant was invalid for obviousness and lack of novelty were unjustified. In doing so, the Court modified the criteria of anticipation and obviousness found in Beloit Canada Ltd v Valmet OY (1986), 8 CPR(3d) 289 (Fed CA), to align them more closely with European and American practice. The Court found that the lower courts had erred in not recognizing that anticipation requires both disclosure and enablement, and that obviousness may require an investigation into whether or not it was "more or less self-evident" to try the course that led to the invention. The English 5-step method of analyzing obviousness was adopted. The decision, while based on a pre-1989 patent, seems to apply equally to post-1989 ones. The paper takes the opportunity of discussing other statements in Beloit that have sometimes been misunderstood. It concludes by applauding the lack of discussion about the invention's commercial success on the issue of unobviousness.*

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<sup>\*</sup> This paper is a slightly revised version of one delivered at the Federal Court Judges' Annual Seminar held in Montreal on 7-8 October 2009. My thanks to Rothstein J and Hughes J for helpful comments on an earlier draft. Remaining errors and infelicities are mine alone.

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In *Apotex Inc v. Sanofi-Synthelabo Canada Inc*, the Supreme Court held that allegations that Sanofi's patent for the blood anti-coagulant Plavix® (clopidogrel bilsulphate) was invalid, because the invention was old or obvious, were unjustified. Apotex, which had made those allegations when seeking a notice of compliance from Health Canada to market a generic version of the drug, therefore had to wait to until Sanofi's patent expired to market it.

The trial judge (Shore J) had reached the same result as the Supreme Court, and was affirmed in fact and law by the Federal Court of Appeal (Noël JA, Richard CJ and Evans JA concurring).<sup>1</sup> In reaffirming, the Supreme Court, in a unanimous judgment delivered by Rothstein J, subtly but significantly tightened the standards of novelty and unobviousness that inventions must meet in Canada, aligning them more closely with European and American practice.<sup>2</sup>

This paper is a comment on this decision.

## I

To be considered old or obvious is not always a bad thing. We talk of the good old days, good old wine, even good old academics and (I dare say) good old judges; and making things seem obvious is what many a lecturer aspires to, though less often realizes.

Elsewhere, being old or obvious can be a less positive attribute. The good old days were not always that good; old wine can turn sour, as indeed can old academics. Being obvious is not always good either; the speaker who belabours the obvious risks losing his audience. So does the one who recycles stuff the audience already knows.

Patent law is categorical on the subject of oldness and obviousness: they are vices. If perchance the patent office does grant a

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<sup>1</sup> *Apotex Inc v. Sanofi-Synthelabo Canada Inc*, 2008 SCC 61, [2008] 3 SCR 265, aff'ing 2006 FCA 421, 59 CPR (4th) 46, aff'ing 2005 FC 390, 39 CPR (4th) 202 [*Sanofi*]. The Supreme Court also affirmed on conventional grounds both courts' holding that Apotex's allegation of double patenting was unjustified; this paper omits discussion of that aspect.

<sup>2</sup> Decisions already interpreting and applying *Sanofi* include *Apotex Inc v. Pfizer Canada Inc*, 2009 FCA 8 at 22ff (Noël JA, Létourneau & Blais JJA concurring); *Ratiopharm Inc v. Pfizer Ltd*, 2009 FC 711 at 158ff (Hughes J); *Lundbeck Canada Inc v. Canada (Health)*, 2009 FC 146 at 53ff (Harrington J).

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patent for an old or obvious invention, the grant is void from the start and may be struck off the register, on re-examination by the patent office or in impeachment proceedings before the federal court. Patent law aims to encourage the production of new and different technologies and processes for the overall benefit of society and the economy: whatever is already known or achievable by anybody without much thought or difficulty deserves no monopoly or social reward beyond the usual chance to compete in the marketplace. It is in the public interest that anyone be entitled to do, make or deal with the old or the obvious as and when he or she likes, without hindrance or payment.

By “old”, patent law does not mean “ancient”; it means “not new”, something different from what previously existed. The need to be “new” was central right from the first patent laws. Venice’s *Law of 1474* provided for a 10-year grant of monopoly for “any new and ingenious device, not previously made in our jurisdiction,” and England’s *Statute of Monopolies of 1624* also gave the “true and first inventor” of “any manner of new manufactures within the realm” the right to a 14-year monopoly. But even words like “new” need defining, and their meaning can change over time. In referring to things “not previously made” in Venice, the Venetian statute implied that something well known outside the city state could qualify for a Venetian patent if it was unknown locally. That was true under the English *Act of 1624* too: what was old in France could be new in England, and the first importer of a new manufacture was treated as the “true and first inventor” under English law. The idea was to encourage new industry, and the first importer certainly qualified there.

Today, of course, novelty is looked at globally, and first importers are no longer considered inventors, nor are they entitled to patents. Nor even is the innovator who toils to produce something that, unbeknownst to him, has already been sold in Kazakhstan or published in some obscure journal in some obscure language. Prior sale or publication of the invention anywhere in the world, however isolated and inaccessible, is fatal to any later claim of novelty for it in other jurisdictions.

The need for a patentable invention to be unobvious came later. The criterion was absent from legislation through the 19th century, and indeed did not make it into the Canadian *Patent Act*

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until 1989. But it was part of most countries' law, including Canada's, well before then. Judges said that the very idea of invention implied inventive ingenuity, without which an advance was obvious and undeserving of a monopoly. Patents went to those who thought and acted outside the box of obviousness; obvious advances were patent-free zones.<sup>3</sup>

As with novelty, what obviousness meant – beyond “very plain” – was not itself obvious. In England, before trying patent cases became the monopoly of the chancery judges, juries often decided questions of obviousness, and still do in the United States. Quite apart from the added unpredictability of jury decisions, what qualifies as obvious has varied over time and place as knowledge has expanded, and attitudes on monopoly, innovation and international competitiveness have fluctuated. Abraham Lincoln said the patent system “added the fuel of interest to the fire of genius”,<sup>4</sup> and courts sometimes demanded that inventions show some spark of genius before calling them unobvious.

That viewpoint, however, waned as beneficial discoveries came less from lone geniuses working in basements than from corporate researchers experimenting methodically in modern well-equipped laboratories. The “patient searcher is as much entitled to the benefits of a monopoly as someone who hits upon an invention by some lucky chance or an inspiration”, said an English patents judge in the 1970s, and the Supreme Court of Canada agreed.<sup>5</sup> The basic issue may be whether or not the inventor had disclosed something “sufficiently inventive to deserve the grant of a monopoly”,<sup>6</sup> but what qualifies is a question of degree that may strike different minds differently. No wonder Learned Hand CJ found the whole concept of

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<sup>3</sup> Unobviousness is like the criterion of originality in copyright law. Originality was deduced as essential from language in early copyright statutes that referred to “authors” and “works”.

<sup>4</sup> A Lincoln, “Second Lecture on Discoveries and Inventions” (1859), in D Vaver, *Intellectual Property Rights: Critical Concepts in Law* (Routledge, 2006), vol. 3, 36.

<sup>5</sup> *American Cyanamid Co v. Berk Pharmaceuticals Ltd*, [1976] RPC 231, 257 (Ch), Whitford J, cited with approval in *Farbwerke Hoechst AG v. Halocarbon (Ont) Ltd*, [1979] 2 SCR 929, 944, Pigeon J [*Halocarbon*].

<sup>6</sup> *Société Technique de Pulverisation STEP v. Emson Europe Ltd*, [1993] RPC 513, 519 (CA), Hoffmann LJ; *Janssen-Ortho Inc v. Novopharm Ltd*, 2006 FC 1234 at 110, Hughes J [*Janssen-Ortho*], aff'd 2007 FCA 217 (Sharlow JA, Nadon & Malone JJA concurring).

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unobviousness elusive: “as fugitive, impalpable, wayward, and vague a phantom as exists in the whole paraphernalia of legal concepts,”<sup>7</sup> or as Frank J put it more poetically, “the adventures of judges’ souls among inventions”.<sup>8</sup> Reviewing the Canadian case law through to the 1950s, Harold Fox agreed, concluding that obviousness “in the end is what the judges say it is.”<sup>9</sup>

## II

What was in issue in *Apotex v. Sanofi*? Sanofi had a 1985 patent for a broad class of anti-coagulant compounds. The claims covered all versions of the compounds (250,000 or more in all), including the racemates and constituent isomers. Sanofi had not tested the whole class but its claims extended, as Canadian patent law permits, to the genus of compounds with predicted similar properties to those it had successfully tested.

After filing for the patent, Sanofi continued its research into improved coagulants. Some false leads later, a Sanofi chemist was asked to try to isolate the isomers of one of the compounds to see how they or their derivatives might perform. The research involved using known techniques and trial and error, with no guarantee that any experiment would likely yield the isomers or any better resulting compound. As it turned out, the isomers were able to be isolated and the bisulphate salt of one of the isomers (the enantiomer that right-rotated polarized light) proved a better and less toxic anti-coagulant than the rest of the patented compounds, including the other mirror-

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<sup>7</sup> *Harries v. Air King Products Co* (1950), 183 F 2d 158 at 162 (2d Cir).

<sup>8</sup> *Picard v. United Aircraft* (1942), 53 USPQ 563, 569 (2d Cir) concurring, cert den 317 US 651 (1942), cited at first instance in *Halocarbon* case n 5 above (1974), 15 CPR(2d) 105, 112 (Fed TD, Collier J), affd by the SCC, n 5 above. The full quotation reads: “Invention,” for patent purposes, has been difficult to define. Efforts to cage the concept in words have proved almost as unsuccessful as attempts verbally to imprison the concept “beautiful.” Indeed, when one reads most discussions of “invention,” one recalls Kipling’s, “It’s pretty, but is it Art?” and the aphorism that there is no sense in disputes about matters of taste. Anatole France once said that literary criticism is the adventure of the critic’s soul among masterpieces. To the casual observer, judicial patent decisions are the adventures of judges’ souls among inventions. For a decision as to whether or not a thing is an invention is a “value” judgment...

<sup>9</sup> H G Fox, “Copyright and Patent Protection: A Study in Contrasts” (1957), 12 U.T.L.J. 27 at 33.

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image isomer and the combined racemate from which the successful isomer was isolated.

In 1988, Sanofi filed for a patent on the isomer in its various forms, including clopidogrel bisulphate, the salt form of the effective ingredient of what became Plavix®. It was this patent,<sup>10</sup> eventually granted in 1995, that Apotex challenged. Apotex said the isomer and its salt were disclosed in Sanofi's 1985 patent and were therefore not new; or, at least, making that isomer or its salt was obvious, given what the 1985 patent revealed and what ordinary pharmacchemists working in the field would have done or surmised. Apotex also challenged the whole idea that one can get a fresh patent for a better singleton selected from an undifferentiated class. The technological equivalent of picking the class's gold medallist before the exams are sat and marked was, according to Apotex, not something the patent law was meant to cover or encourage.

Apotex's arguments failed before Shore J and the Federal Court of Appeal on conventional grounds. Both courts relied largely on language in a 1986 decision of the Federal Court of Appeal, *Beloit Canada Ltd v. Valmet OY*,<sup>11</sup> which was then the "landmark decision [that] defined" both anticipation and obviousness.<sup>12</sup> The courts noted that selection patents in the chemical field had long been upheld in Canadian law, and with them the concept that an item selected from a patented class that was shown to work better or differently from its classmates could be considered new. They agreed that Sanofi's first patent included claims on the isomer that was the focus of Sanofi's later patent; but simply being claimed as part of an undifferentiated group of compounds did not disclose the isomer as something different from, and better than, the mass. Being one individual in the crowd at a rugby match does not disclose this attender to the world unless the television camera happens to alight on him and broadcast

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<sup>10</sup> The use of chiral chemistry to patent isomers extracted from an earlier patented general compound is a popular strategy among pharmaceutical companies "to develop replacements for the pharmaceuticals which are about to lose their patent protection": B. Domeij, *Pharmaceutical Patents in Europe* (2000), 149. Sanofi filed similar patents worldwide. Its US patent was upheld (*Sanofi-Synthelabo v. Apotex Inc* (2008), 550 F 3d 1075 (Fed Cir), aff'ing 492 F Supp 353 (SDNY 2007)), but its Australian patent was not (*Apotex Pty Ltd v. Sanofi-Aventis*, [2008] FCA 1194). The Supreme Court of Canada mentioned neither case in its *Sanofi* judgment.

<sup>11</sup> *Beloit Canada Ltd v. Valmet OY* (1986), 8 CPR (3d) 289 (Hugessen JA) [*Beloit*].

<sup>12</sup> *Sanofi*, supra note 1.

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his image. More specifically, nothing in the first patent taught the skilled reader “in every case and without possibility of error” to produce the second isomer, nor were its special properties mentioned; therefore the isomer had not been anticipated by the prior patent.

The obviousness argument was rejected because isolating the isomer was not an obvious step to take in the quest for a better coagulant, in light of what the prior patent and the common general knowledge available to the ordinary skilled pharmacist.

The Supreme Court dismissed Apotex’s appeal, but changed previous understandings of the law of novelty and unobviousness as expressed in *Beloit*. It made the following points:

1. It reaffirmed that the Canadian law of patents was statutory: there is no common law of patents.<sup>13</sup>

2. It confirmed that the grant of selection patents was consistent with the *Patent Act* and acceptable in principle. The criteria applied in Commonwealth (and until recently British) courts were helpful guides.<sup>14</sup> Although chemical inventions were the main candidates, other inventions could also qualify.<sup>15</sup> Whether the first patent was held by the second patentee or a third party did not matter.<sup>16</sup>

3. To find that an invention was anticipated by the prior art and so was already “known or used” or “described” in a prior patent or publication,<sup>17</sup> the Supreme Court confirmed that the prior art not only had to: (a) disclose the invention, but also – and this was novel – (b) enable the skilled worker to produce it.

4. Under requirement (a), the disclosure must give directions that, inevitably, would produce the claimed invention, or must for all

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<sup>13</sup> *Supra* note 1 at 12, citing *Comm’r of Patents v. Farbwerke Hoechst AG*, [1964] SCR 49, 57, as well as recent House of Lords authority

<sup>14</sup> *Supra* note 1 at 9 & 19, calling Maugham J’s decision in *Re I G Farbenindustrie AG’s Patents* (1930), 47 RPC 289 (Ch) the “locus classicus”; similarly under the *Patents Act 1977 (UK)*: Selection patents are analysed differently in the UK and EU, which no longer follows the *I G Farbenindustrie* case: *Dr Reddy’s Laboratories (UK) Ltd v Eli Lilly & Co Ltd*, [2009] EWCA Civ 1362.

<sup>15</sup> *Supra* note 1 at 99.

<sup>16</sup> *Ibid* at 98.

<sup>17</sup> *Patent Act*, s.27(1) (pre-1989). Cf present *Patent Act*, s 28.2(1)(b), applicable to post-1989 patents: subject-matter that is “disclosed...in such a manner” that it “became available to the public” anywhere is anticipated.



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practical purposes be equal to that in the patent.<sup>18</sup> If the skilled worker can discover the invention only after undertaking experiments, it is not disclosed. Rothstein J cited an 1862 English case, *Hill v. Evans*,<sup>19</sup> that continued as “unquestionable authority” in the UK and that he plainly considered equally authoritative in Canada. The passage in question, which Rothstein J did not cite at length, includes the following:

[K]nowledge, and the means of obtaining knowledge, are [not] the same. There is a great difference between them. To carry me to the place at which I wish to arrive is very different from merely putting me on the road that leads to it. There may be a latent truth in the words of a former writer, not known even to the writer himself; and it would be unreasonable to say that there is no merit in discovering and unfolding it to the world.<sup>20</sup>

That was the position in *Sanofi*. The isomer was certainly referred to and included within the claims in the first patent, but its special advantages were nowhere mentioned because they were then unknown. The lower courts rightly rejected the anticipation attack on this ground.

5. Under requirement (b) – enablement – the disclosure must contain enough information to allow the later invention to be performed without undue burden. Routine trial and error that is not “prolonged or arduous” is acceptable.<sup>21</sup> Just disclosing the theoretical formula of a compound may not disclose the compound itself unless the compound has actually been prepared or the skilled worker would know, from the given directions or his ordinary knowledge, how to go about making it.<sup>22</sup> On this theory, a disclosure may be a prior publication even though wrong directions on how to work the

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<sup>18</sup> *Free World Trust v. Électro Santé Inc.*, [2000] 2 SCR 1024 at 25-27, Binnie J; *Reeves Brothers Inc v. Toronto Quilting & Embroidery Ltd* (1978), 43 CPR (2d) 145, 157 (Fed TD), Gibson J.

<sup>19</sup> (1862), 4 De G F & J 288.

<sup>20</sup> *Ibid* at 301-2, by Westbury LC; approved in *Synthon BV v. Smithkline Beecham plc*, [2005] UKHL 59 at 20, Hoffmann L [*Synthon*].

<sup>21</sup> *Supra* note 1 at 37, #3.

<sup>22</sup> *Beecham Group Ltd's New Zealand (Amoxycillin) App'n*, [1982] FSR 181 (NZCA); *Boehringer Mannheim GmbH v. Enzyme Ltd*, [1993] FSR 716, 725-6 (Pat Ct).

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invention are given, if the skilled worker would easily detect and correct the mistake by routine trial and error.<sup>23</sup>

Rothstein J said the lower courts had overlooked this aspect of anticipation, which he took from recent House of Lords authority<sup>24</sup> and which is of long standing in the US.<sup>25</sup> The error was nonetheless harmless because the anticipation attack had already failed under requirement (a). He indicated however, *obiter*, that there was probably no enablement, given Shore J's findings under (a) that it had taken the inventor 6 months of trial and error to isolate the isomer: this effort was probably an "undue burden".<sup>26</sup>

6. The Court concluded that the lower courts had rightly, as far as they went, found that the invention was unobvious, but had wrongly not considered whether or not it was "obvious to try" to isolate the isomer. Prior Canadian caselaw categorically rejecting the "obvious to try" test<sup>27</sup> was inconsistent with modern UK and US authority and is now implicitly overruled. In fields where experimentation was common, it may be appropriate to ask whether or not it was "more or less self-evident" to try the course that led to the invention.<sup>28</sup> All the relevant facts must be considered, including such things as the history of the invention, the motive to find a solution to a known problem, and the number and extent of avenues of research.<sup>29</sup>

7. Without saying such an approach was compulsory, the Supreme Court thought the structured approach to analyzing obviousness that English courts had pioneered and refined could usefully be adopted in Canada, namely by following these five steps:

- First, identify the notional person skilled in the art to whom the claim is addressed at the priority date.
- Second, identify the common general knowledge of that person.

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<sup>23</sup> *Supra* note 1 at 37, #4; *Synthon*, *supra* note 20, at 20.

<sup>24</sup> *Viz.*, *Synthon*, *ibid.*

<sup>25</sup> *Seymour v. Osborne* (1870), 78 US 516.

<sup>26</sup> *Supra* note 1 at 47-48.

<sup>27</sup> Eg, *Bayer AG v. Apotex Inc* (1995), 60 CPR (3d) 58, 77-82 (Ont GD), Lederman J, *aff'd* (1998), 82 CPR (3d) 526 (Ont CA), leave to appeal denied [1998] SCCA No 563 [*Bayer*].

<sup>28</sup> *Supra* note 1 at 69.

<sup>29</sup> *Ibid.* at 59 & 69.

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- Third, construe the claim and identify its inventive concept.
  - Fourth, identify the differences between the claimed invention and the state of the art.
  - Fifth, set aside any knowledge of the claimed invention, and decide whether those differences involve steps that would have been very plain to the skilled person, or would require some invention.<sup>30</sup>

Having gone through the first four steps, Rothstein J thought it would not have been obvious for the skilled pharmacchemist to try the course that led to the isolation of the claimed isomer. It was not self-evident: (a) which of the thousands of compounds in the 1985 patent should be selected for further research; (b) that the research should comprise isolating the isomers of the racemate of that compound; and (c) that the claimed isomer would be better and less toxic than the other isomer or the racemate in which it was found. The Court was impressed by the fact that Sanofi chemists, who had at least the skill of the average pharmacchemist in the field (and probably a lot more), had spent some years and millions of dollars taking the racemate through to clinical trials without thinking to isolate the isomer and develop its bisulphate salt. If *they* had not thought it obvious to try that course, it would not have been obvious to the notional skilled pharmacchemist.<sup>31</sup>

### III

The following points are among those suggested by the *Sanofi* opinion:

1. The law on unobviousness as stated by the Court applies equally to pre-1989 and post-1989 patents.<sup>32</sup> Rothstein J noted that he was applying judge-made law on obviousness to the Sanofi pre-1989 patent but, in doing so, he drew on much English case law under the *Patents Act 1977* (UK). The 1977 *Act*'s provisions on obviousness are very close to those of the Canadian post-1989 *Act*,<sup>33</sup> so English case

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<sup>30</sup> *Ibid.* at 67, adopting the approach in *Pozzoli SPA v. BDMO SA*, [2007] EWCA Civ 588 at 23.

<sup>31</sup> *Ibid.* at 92.

<sup>32</sup> *Janssen-Ortho*, *supra* note 6 at 109.

<sup>33</sup> Under *Patents Act 1977* (UK), ss 3 and 2(2), an invention must not be "obvious to a person skilled in the art", having regard to anything "made available to the public"

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law will be equally useful guidance where no Canadian authority is on point. The same holds broadly true for the law of novelty on pre-1989 and post-1989 patents.

2. Rothstein J approved both UK and US authority that deplored the use of formulaic language and “rigid rules” on questions of obviousness.<sup>34</sup> His judgment itself should therefore not be read as substituting a new set of formulae in place of *Beloit*’s. He plainly regarded obviousness as a question involving “a value judgment which takes into account a variety of factors” some “purely technical, others not”.<sup>35</sup> His decision highlights some of the factors and the sort of evidence that will help demonstrate their presence, and echoes the approach already taken in decisions of the federal court.<sup>36</sup>

3. *Beloit* has been battered as an authority on both anticipation and obviousness and deserves a couple of extra jabs for other statements on obviousness that it makes and that have a habit of reappearing.<sup>37</sup> The dicta are: (a) “[e]very invention is obvious after it has been made, and to no one more so than an expert in the field,” and (b) obviousness is “a very difficult test to satisfy.”<sup>38</sup>

Those statements, while no doubt appropriate to the facts of *Beloit*, should not be pressed to imply more than they say. The first, that “[e]very invention is obvious after it has been made, and to no one more so than an expert in the field”, fairly emphasizes the need for tribunals to stand in the position of the ordinary skilled worker at the priority date, knowing only what he knew then, and to judge obviousness without hindsight. But it is sometimes pushed to imply,

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anywhere in any way before the invention’s priority date. For post-1989 Canadian patents, s 28.3(1)(b) of the Canadian *Patent Act* requires the “subject-matter defined by a claim” [i.e., the invention] not to “have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to information disclosed before the claim date ... in such a manner that the information became available to the public” anywhere.

<sup>34</sup> *Supra* note 1 at 61 & 63.

<sup>35</sup> *Nichia Corp v. Argos Ltd*, [2007] EWCA Civ 741 at 21-22, Jacob LJ (dissenting on other grounds).

<sup>36</sup> Eg, *Janssen-Ortho*, *supra* note 6 at 113, listing factors that the FCA on appeal called “helpful to guide the required factual inquiry, and as a framework for the factual analysis that must be undertaken” (at 25).

<sup>37</sup> It may be significant that Rothstein J mentioned neither statement in his comprehensive opinion.

<sup>38</sup> *Beloit*, *supra* note 11 at 295 & 294.

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wrongly, that most applications are for unobvious inventions or that most challenged patents are unobvious. No reliable data exist on either of these points.

The second comment – obviousness, “a very difficult test to satisfy” – may be useful as a warning not to set the bar too high before inventions may qualify as patentable, but it should not be taken to mean that obviousness is always very difficult to establish. How difficult it is to prove anything always depends on the facts of the case. Some inventions will withstand all obviousness attacks; to judge and expert alike, they may seem miraculous when first patented, and may seem miraculous even now. Others are immediately exposed once a piece of prior art is produced. Yet others become obvious only gradually as the evidence and arguments unfold. What looked clever to a patent office examiner may later look trite to a court with fuller material before it. Rothstein J’s statements are in line with this view. He said that courts should approach the “obvious to try” test “cautiously”: it was not “a panacea for alleged infringers”, just one factor to consider.<sup>39</sup> But he made it equally clear that the usual balance of probability standard of proof applies,<sup>40</sup> as it does to all civil cases.<sup>41</sup>

4. In the *Harvard Mouse* case, in arguing for the patentability of genetically modified animals, Binnie J said: “The mobility of capital and technology makes it desirable that comparable jurisdictions with comparable intellectual property legislation arrive (to the extent permitted by the specifics of their own laws) at similar legal results”.<sup>42</sup> *Sanofi* continues the harmonization trend through its reliance on modern UK and US precedents over earlier Canadian caselaw that had got stuck in a rut. Nothing in the *Patent Act* suggests that anticipation or obviousness should be any harder or easier to find in Canada than in any other major developed country. So cases where a Canadian patent on a foreign invention is held unobvious after a court abroad

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<sup>39</sup> *Supra* note 1 at 64.

<sup>40</sup> *Ibid.* at 66.

<sup>41</sup> *FH v. McDougall*, 2008 SCC 53 at 40 & 45, Rothstein J: “I think it is time to say, once and for all in Canada, that there is only one civil standard of proof at common law and that is proof on a balance of probabilities. ... I think it is inappropriate to say that there are legally recognized different levels of scrutiny of the evidence depending upon the seriousness of the case. There is only one legal rule and that is that in all cases, evidence must be scrutinized with care by the trial judge.”

<sup>42</sup> *Harvard College v. Canada (Comm’r of Patents)*, 2002 SCC 76 at 13, dissent [*Harvard Mouse*].

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rules the corresponding patent obvious<sup>43</sup> should become marginally rarer now. Conflicting decisions will of course never be entirely eliminated for national laws vary subtly, judges view and weigh facts differently, and evidence may differ from one jurisdiction to another.<sup>44</sup>

5. The Court left open the question of when the “obvious to try” test will be appropriate to apply. Much will depend on common practice in the art to which the invention belongs: “[i]n areas of endeavour where advances are often won by experimentation, an ‘obvious to try’ test might be appropriate.”<sup>45</sup> Presumably the expert evidence will indicate whether a particular field of technology qualifies as an area where the skilled worker is prone to search for improvements through experimenting.

6. In asking what courses are obvious to try, Rothstein J suggested putting the following questions:

(1) Is it more or less self-evident that what is being tried ought to work? Are there a finite number of identified predictable solutions known to persons skilled in the art?

(2) What is the extent, nature and amount of effort required to achieve the invention? Are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine?

(3) Is there a motive provided in the prior art to find the solution the patent addresses?<sup>46</sup>

He added that “a possibility of finding the invention is not enough.”<sup>47</sup> Jacob LJ from the Court of Appeal in an English case questioned: “Is it more or less self-evident that what is being tried ought to work?”<sup>48</sup> Jacob LJ himself had equated this formula with options that have “at least a fair expectation of success,”<sup>49</sup> although the

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<sup>43</sup> The leading example is from *Bayer*, *supra* note 27, where a Canadian patent for a German invention was found valid over a prior contrary ruling in Britain on the corresponding UK patent.

<sup>44</sup> *Sanofi* is itself an example of the phenomenon, if the Australian decision to invalidate the patent in *Apotex Pty Ltd v. Sanofi-Aventis*, *supra* note 10, stands.

<sup>45</sup> *Supra* note 1 at 68.

<sup>46</sup> *Ibid.* at 69.

<sup>47</sup> *Ibid.* at 85.

<sup>48</sup> *Saint-Gobain PAM SA v. Fusion Provida Ltd*, [2005] EWCA Civ 177 at 35.

<sup>49</sup> *Generics (UK) Ltd v. Daiichi Pharmaceutical Co Ltd*, [2009] EWCA Civ 646 at 22.

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House of Lords later qualified the adjective “fair” by saying: “How much of an expectation would be needed depend[s] upon the particular facts of the case.”<sup>50</sup>

One hopes Canadian courts will avoid the trap that English courts seem close to falling into again: using verbal formulae apt for one case as apt for all. Just as *Beloit* provided no “statutory prescription” on obviousness,<sup>51</sup> nor does English caselaw, nor does *Sanofi* itself. Since 1989, obviousness is a statutory criterion in Canada, and the court ultimately must construe its meaning in the light of the history and purpose of the *Patent Act* as a whole,<sup>52</sup> rather than finding apt universal paraphrases for the word.

The point was usefully made in the Federal Court of Appeal the year before the Supreme Court’s decision in *Sanofi*. Sharlow JA for the court agreed with the first instance judge (Hughes J) that “catch phrases ... from the jurisprudence” were “not to be treated as though they are rules of law.” Any list of factors, however useful, is:

...not a list of legal rules to be slavishly followed; nor is it an exhaustive list of the relevant factors. The task of the trial judge in each case is to determine, on the basis of the evidence, sound judgment and reason, the weight (if any) to be given to the listed factors and any additional factors that may be presented.”<sup>53</sup>

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<sup>50</sup> *Conor Medsystems Inc v. Angiotech Pharmaceuticals Inc*, [2008] UKHL 49 at 42, Hoffmann L. In *Intervet UK Ltd v Merial*, [2010] EWHC 294 at [241] (Pat Ct) Arnold J interpreted this to mean whether the skilled team “would have had a reasonable expectation of success and ... would have been likely to succeed.”

<sup>51</sup> *Supra* note 1 at 61.

<sup>52</sup> Cf Binnie J in *Harvard Mouse*, *supra* note 42 at 11:

I accept, as does my colleague [Bastarache J], that the proper approach to interpretation of this statute is to read the words “in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament”: E. A. Driedger, *Construction of Statutes* (2nd ed. 1983), at p. 87. ... The intent that can properly be attributed to Parliament, based on the language it used and the context of patent legislation generally, is that it considered it to be in the public interest to encourage new and useful inventions without knowing what such inventions would turn out to be and to that end inventors who disclosed their work should be rewarded for their ingenuity.

<sup>53</sup> *Janssen-Ortho*, *supra* note 6 at 27-28.

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7. On obviousness, the *Sanofi* judgments are remarkable by what is not mentioned: namely, the commercial success of Plavix® as a factor favouring unobviousness. Presumably, as in the companion US litigation,<sup>54</sup> the parties presented no evidence on the point.

One may hope, but, alas, with no conviction, that this conduct signals a trend against the use of this element as a relevant factor.<sup>55</sup> In NOC cases, reliance on it is anyway superfluous: why else would a generic company want to copy a medicine unless it was commercially successful? The same logic also applies to infringement litigation: a patentee would only very rarely spend money enforcing its rights unless the patent was for a winner. To allow commercial success to diminish an obviousness defence may deter the raising of legitimate cases where the attack is warranted on the technical evidence.

Giving weight to commercial success seems to reflect a natural desire to reward merit and deter free-riders. It is patent law's counterpart to copyright law's vacuous "rough practical test" that what is worth copying is *prima facie* worth protecting.<sup>56</sup> In a competitive market, what sells well may be *prima facie* worth protecting from the seller's viewpoint. In public policy terms, it should *prima facie* be worth leaving open to competition. Someone has to be first to market with a winner: being that someone does not make the outcome an invention, for a product may be new and attractive, yet obvious.

Commercial success nonetheless crops up constantly as a reason to hold a patent unobvious or otherwise valid, especially in borderline cases.<sup>57</sup> In Canadian litigation, it tends to surface too early and effectively shapes the eventual trial. Once a defendant pleads unobviousness, the parties inevitably reveal during pre-trial discovery how their products are faring on the market.<sup>58</sup> At trial, each side feels

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<sup>54</sup> *Sanofi-Synthelabo v. Apotex Inc*, *supra* note 10 at 392.

<sup>55</sup> See, eg *Janssen-Ortho*, *supra* note 6 at 113 & 114 #7, on appeal FCA at 25, #7.

<sup>56</sup> *University of London Press Ltd v. University Tutorial Press Ltd*, [1916] 2 Ch 601, 610 (Peterson J), discredited as a "misleading ... rhetorical device" in *Baigent v. Random House Group Ltd*, [2007] EWCA Civ 247 at [97], Lloyd LJ.

<sup>57</sup> *Haberman v. Jackel Inc*, [1999] FSR 683 (Pat Ct, Laddie J), where the evidence tipped a close case of a very simple advance – a baby's spill-proof training cup – towards a finding of validity and infringement.

<sup>58</sup> *Dimplex North America Ltd v. CFM Majestic Inc* (2003), 28 CPR (4th) 266 (Fed TD, Henaghan J). At trial, the court held that the commercial success of both parties' products was evidence of non-obviousness: 2006 FC 586 at 101 (Mosley J).



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it has to make something of the commercial success or failure of the products or processes, or risk adverse comment.

By contrast, current British practice disfavors pre-trial disclosure of commercial success, and the evidence may altogether be excluded at trial if it would prove little.<sup>59</sup> A leading British case states that, if admitted, the evidence “must be kept firmly in place”; its weight “will vary from case to case”; it “must not be permitted, by reason of its volume and complexity, to obscure the fact that it is no more than an aid in assessing the primary evidence.”<sup>60</sup> Yet still the idea keeps popping up. Even judges who avoid citing commercial success as a formal reason to support unobviousness nevertheless cannot seem to avoid mentioning it elsewhere as an implicit reason for upholding a patent.<sup>61</sup>

One is left with the uncomfortable feeling that the factor is, at best, a costly distraction or, at worst, a short-cut to the wrong destination.<sup>62</sup> One can only applaud the parties’ decision in *Sanofi* not to raise it.

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<sup>59</sup> *Supra* note 35 at 6; *Alan Nuttall Ltd v. Fri-Jado UK Ltd*, [2008] EWHC 1311 at 5-6 (Pat Ct), (Prescott QC).

<sup>60</sup> *Mölnlycke AB v. Proctor & Gamble Ltd*, [1994] RPC 49, 112 (CA), (Nicholls VC).

<sup>61</sup> Eg, *Supra* note 50 at 12.

<sup>62</sup> Cf *Supra* note 35, questioning whether discovery of an inventor’s notes and experiments was proportionate to the stakes involved in the case.