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# Should Scientific Research in the Lead-up to Invention Vitate Obviousness under the Patented Medicines (Notice of Compliance) Regulations: To Test or Not To Test?

Ron A. Bouchard†

## I. Abstract

This article is an analysis of case law pertaining to whether scientific research in the lead-up to invention should vitiate a finding of obviousness in pharmaceutical litigation under the *Patented Medicines (Notice of Compliance) Regulations* (the “*NOC Regulations*”). The *NOC Regulations* belong to a class of legal instruments referred to as “linkage regulations” that tie patent protection for marketed pharmaceuticals to the Canadian drug approval process. Therefore, the *NOC Regulations* control entry of generic drugs into the market and access by the public to affordable medication. The issue of testing arises out of the complex and inverse relationship between inventiveness and obviousness in patent law such that the lower the threshold for inventive ingenuity in the patentability analysis, the higher the threshold for parties attacking patents on grounds of obviousness. The present analysis demonstrates there is substantial uncertainty in Canadian jurisprudence over what constitutes the accepted test for obviousness. Some cases stand for the proposition that no testing whatsoever is allowed, others for the opposite proposition that some testing is allowed, while still others purport to follow the former while actually applying the latter. Historical cases supporting the “no testing” line of cases were analysed and found to offer no strong legal precedent for this approach. It is suggested that courts adopt a “purposive test” for obviousness based on Canadian law requiring patents to be construed purposively rather than literally, federal policy underlying the *NOC Regulations* requiring application of regulations in a manner that is fair and balanced to all parties, and Supreme Court of Canada jurisprudence requiring fair, unequivocal, and predictable application of laws. The proposed test would be consistent with appellate court jurisprudence in other jurisdictions with analogous patent legislation and policy.

## II. Introduction

In Canada, the availability of generic drugs owes its pedigree to compulsory licensing.<sup>1</sup> As part of its perceived obligations under the North American Free Trade Agreement (NAFTA) and the World Trade Organization’s Agreement on Trade Related aspects of Intellectual Property (TRIPS), Canada repealed its compulsory licensing regime for pharmaceuticals in favour of “linkage regulations” referred to as the *Patented Medicines (Notice of Compliance) NOC Regulations* (the “*NOC Regulations*”).<sup>2</sup> The substance and procedure of the *NOC Regulations* were modelled on analogous legislation in the United States.<sup>3</sup> So-called linkage regulations tie patent protection for marketed pharmaceuticals to the drug approval process, and thus control both entry of generic drugs into the Canadian market and access by Canadians to affordable medication. Under the Canadian linkage regulation regime, the typical route for a generic pharmaceutical company to obtain market access for its product is to attack the relevant brand-name pharmaceutical company’s patents for being either invalid (on the grounds of, for example, obviousness, anticipation, double patenting, and claims broader than disclosure) or to claim that its product will not infringe listed patents. Given that a substantial percentage of the cases litigated under linkage regulations in Canada and the United States involve allegations of invalidity based on obviousness,<sup>4</sup> the test for obviousness determines, in part, the availability of generic medications in North America.

When assessing the issue of obviousness, courts are charged with addressing whether an invention is rendered obvious in light of previous disclosures.<sup>5</sup> This analysis involves a determination of whether the impugned invention represents an “inventive step” over previously disclosed inventions.<sup>6</sup> One problem that frequently comes up in the obviousness analysis is whether or not

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experimental research or testing conducted by the patentee in order to arrive at the invention constitutes this kind of inventive step. Under Canadian law, courts are obliged to carry out the analysis from the perspective of a person skilled in the relevant art casting their mind back to the claim date. The specific question addressed in this paper is: Should scientific research and testing conducted during the lead-up to invention *automatically* vitiate a finding of obviousness for a party attacking the patent on grounds of validity under the *NOC Regulations*?

The question is not an easy one. The concepts of obviousness and inventiveness in patent law are inversely related and linked through the inventive ingenuity of relevant persons skilled in the art. A lower standard for inventiveness in the patentability analysis equates to a higher standard for obviousness for parties attacking the patent on grounds of obviousness. Not surprisingly, brand-name and generic pharmaceutical companies seek differing standards for inventiveness and obviousness. Brand-name firms desire a relatively stringent standard for inventiveness such that any research or testing undertaken to arrive at an invention will result in a patent monopoly. Under this strict standard, a generic company faces the fact that if evidence of testing is adduced then its attack on patent validity must fail. By contrast, generic firms seek a more flexible standard for inventiveness, with the result that some testing is allowed without automatically vitiating a finding of obviousness. As will be discussed in detail below, it is perhaps not surprising that courts have had difficulty in grappling with this complex issue.

The present analysis is split up into five parts. In Part I, the case law on obviousness is canvassed with the objective of determining whether or not there is in fact a coherent legal approach to the issue of scientific testing under the *NOC Regulations*. It is concluded that there is substantial uncertainty in Canadian jurisprudence over what constitutes the accepted test for obviousness under the *NOC Regulations*. While many judges apply the leading decision in *Beloit v. Valmet*<sup>7</sup> to the effect that no testing is allowed, others judges have seen fit to allow some testing provided it is non-inventive in nature, while still others have expressly adopted the reasoning in *Beloit* as the accepted test, yet applied the more flexible standard to the evidence at hand. Thus, courts are delivering highly contradictory messages over what constitutes the degree of allowable testing under the obviousness rubric. Part II is an analysis of historical precedents cited in favour of the “no testing” approach. It is concluded that there is no strong jurisprudential or scholarly grounds on which to base a finding of no testing. Part III analyzes the implications of not having a fair, equivocal, or predictable test for obviousness, and the effects of this on potential litigants. It is concluded that the constitutional requirement for fairness, predictability, and certainty in law applies to the test for obviousness, and that this requirement is breached for two

reasons. First, because courts are releasing inconsistent opinions on the issue (no testing versus some testing) and the opinions themselves are internally inconsistent (courts say they are applying one standard but actually apply another). Secondly, because judicial reasoning on the inventive capacity of persons skilled in the art contravenes normative practices in the pharmaceutical industry, which in turn unfairly biases the legal test for obviousness in favour of patentees. Part IV contains recommendations for law reform. A purposive approach to obviousness is proposed which focuses not on binary notions of testing/no testing, but rather on the essence and context of inventive activity leading up to invention from the vantage point of the skilled technician. The decision of Justice Gibson in *Bristol Myers Squibb v. Novopharm*<sup>8</sup> is used as an example of how the central elements of a purposive construction might be applied to the test for obviousness. Finally, Part V discusses application of the purposive approach to pharmaceutical litigation conducted outside the umbrella of the *NOC Regulations*.

### III. Statutory Requirement and Classical Test

By 1996 amendment to the *Patent Act*<sup>9</sup> (the “Act”), a statutory requirement for obviousness came into force for patent applications after October 1, 1989.<sup>10</sup> Section 28.3 of the Act does not however provide a statutory definition of obviousness beyond reference to relevant persons skilled in the art. As noted by the courts<sup>11</sup> and practitioners,<sup>12</sup> the common law test prior to codification has continued to be applied.

The leading common law test for obviousness in Canada was articulated by Justice Hugessen in *Beloit v. Valmet*:

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. . .

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?”<sup>13</sup>

Thus, for Justice Hugessen, and the considerable corpus of patent law relating to the obviousness test relying on his judgment,<sup>14</sup> there are only two perspec-

tives from which to view a patent: that of an inventor, and that of a person skilled in the art. One is completely inventive while the other is not inventive at all. The obviousness test is to be gauged only by the latter. As we shall see below however, the lack of convergence between the judicial construction of persons skilled in the art and actual skilled technicians in the global pharmaceutical industry has led to considerable judicial manipulation of the case law in order to get around the restrictive language of *Beloit*.

## IV. Analysis

### Part I: NOC Case Law

A review of pharmaceutical case law demonstrates there is substantial confusion in Canadian courts regarding the amount of scientific research during the lead-up to invention allowed to be contemplated in the obviousness analysis by persons skilled in the art. On one hand, many judges have articulated a stringent standard of “no experimentation or serious thought” (“no testing” for shorthand) while others have taken a more flexible approach, allowing testing that is “due”, “mechanical”, or “routine” without vitiating the obviousness attack. Adding to the confusion is the fact that still other courts have articulated one standard while silently applying the other. Thus it is hardly surprising that one recent decision involved the application of a much less stringent test under anticipation than under obviousness, which is traditionally a much harder ground of attack to make out in patent litigation.<sup>15</sup> Part I of the analysis is therefore broken up into three sections: (a) decisions that apply the stringent standard, (b) decisions applying the more flexible standard, and (c) decisions that claim to follow the former approach but apply the latter.

#### (a) Stringent Standard

As noted above, the test articulated in *Beloit* does not refer explicitly to scientific research or testing, in the lead-up to invention or otherwise. The origin of the stringent standard can be traced back to two lines of historical cases.<sup>16</sup> The first comprises legal commentary by Professor Harold Fox to the effect that no testing whatsoever can be carried out in the context of the obviousness analysis:

In order that a thing shall be “obvious” it must be something that would directly occur to someone who was searching for some-thing novel, a new manufacture, or whatever it might be, without the necessity of his having to do any experimenting or serious thought, or research, whether the research be in the laboratory or amongst literature.<sup>17</sup>

In this formulation, the standard for scientific research or testing that vitiates the obviousness attack is very stringent. Not only is no experimenting, serious thought or research whatsoever allowed under the obviousness test, but this includes all research, whether it is

conducted in the laboratory or within the confines of a library or presumably even on the Internet. This passage has a substantial history in the judicial analysis of obviousness in Canada.<sup>18</sup> The second line of cases involve the notion that if more than a “mere scintilla” of inventiveness is exercised on the road to invention,<sup>19</sup> then the invention cannot be obvious. Both lines of cases are summarized in Table 1 *infra*. Applied together, they result in a high barrier for parties alleging invalidity based on obviousness, leading Justice Hugessen in *Beloit* to say “it is a very difficult test to satisfy”.<sup>20</sup>

The high watermark in pharmaceutical or chemical cases for the stringent standard is Justice Lederman’s trial decision in *Bayer v. Apotex*,<sup>21</sup> In *Bayer*, the obviousness analysis focused on three interrelated issues: the “no testing” approach to obviousness and the related “worth a try” obviousness formulation, and whether a person skilled in the art “would have” or “could have” arrived at the impugned invention. The case involved a compulsory license for nifedipine, a dihydropyridine Ca<sup>2+</sup> channel blocker used in the treatment of various cardiovascular disorders. The issue of validity revolved around nifedipine’s poor activity as a solid dosage form, poor solubility in water as a liquid form, and significant light sensitivity; all of which led to difficulties in arriving at a dosage form with good bioavailability and rapid onset of action.

Apotex argued that the invention set out in Canadian Patent No. 981,582 (the ‘582 patent) was obvious given the disclosure in a South African patent application that nifedipine could be used to treat acute angina when administered either intravenously or orally and that it worked like nitrates, e.g., nitroglycerin. Apotex contended it was obvious to put nifedipine in liquid form and then encase the solution in a soft gelatin capsule in order to deliver it perlingually, as had been previously done for nitroglycerin. Given the relevant prior art and common knowledge attributed to persons skilled in the art of pharmaceutical science, problems overcome by the ‘582 patent, such as light sensitivity and insolubility could easily be overcome through routine trial and error testing. Apotex argued that such testing would be routine workshop activity and therefore would involve no inventive ingenuity.<sup>22</sup>

Apotex made out its case based on the ground that testing conducted in the work-up phase to the invention by persons skilled in the art constituted non-inventive or obvious testing. However, Justice Lederman rejected this approach, citing the Federal Court’s decision in *Cabot Corp. v. 318062 Ont.*<sup>23</sup> (citing Fox) to the effect that no testing could be undertaken in the context of obviousness. This was true even under conditions where the impugned testing was both logical and reasonable in light of the prior art.<sup>24</sup> A second ground offered by Justice Lederman was based on his interpretation of the inventive capacity of relevant persons skilled in the art articulated in *Beloit*. In particular he relied on the pro-

position that persons skilled in the art are to be construed as having “no scintilla” of inventiveness, imagination, or intuition.<sup>25</sup> Such a person would, quite obviously, undertake no testing in order to arrive at an invention. The notion that even a mere scintilla of invention is sufficient to justify patentability in the context of a validity attack has a long history in Canada<sup>26</sup> and the United Kingdom.<sup>27</sup>

Rather than addressing the issue of testing directly,<sup>28</sup> Justice Lederman re-phrased Apotex’s argument as “worth a try” rather than the routine experimentation or workshop improvement approach advocated by Apotex.<sup>29</sup> As noted above, this formulation is a logical extension of the “no testing” approach; by definition the worth a try approach would allow some testing. Justice Lederman also expressed an abundance of caution relating to the issue of hindsight.<sup>30</sup> However, the worth a try approach to obviousness differs significantly from one addressing the issue of routine experimentation. While it minimizes hindsight error it does so at the cost of allowing a person skilled in the art to make an informed decision as to whether or not an invention is obvious based on the evidence before the court as of the claim date. As such, it minimizes the role of persons skilled in the art in the obviousness determination, which is then left in the hands of the presiding judge. As discussed more fully below, this contradicts the requirements of section 28.3 of the Act, which stipulates that persons skilled in the art are to provide the lens through which the judiciary must gaze when addressing the issue of obviousness.

A second important aspect of the decision in *Bayer* was the court’s distinction between whether a person skilled in the art “would have” or “could have” arrived at the invention based on prior art. As with the worth a try approach, favouring the term “would” over “could” can be seen as an extension of the no testing approach, as clearly one of these terms encompasses some testing while the other does not. The Federal Court of Appeal’s “cling free” case<sup>31</sup> was cited as authority for the could versus would distinction. However, this distinction was never made by Justice Urie in *Beecham*.<sup>32</sup> Indeed, not only was it not made, but it can be argued that *Beecham* is cited primarily in the case law for the proposition that to be obvious a person skilled in the art must come directly and without difficulty to the solution taught by the patent. The distinction by Justice Lederman between whether a person skilled in the art would *versus* could have arrived at the invention has been applied in many subsequent cases.<sup>33</sup>

In rejecting any allowances for testing, the court in effect marginalized the skilled technician in the obviousness analysis. As noted by Justice Martland writing in dissent in *Farbwerke v. Halocarbon*,<sup>34</sup> use of the term “would” in this context amounts to a rejection of the more flexible Cripps Question, where emphasis is placed on investigation into whether or not activity engaged in

by the inventor crossed the line from mere workshop activity into the realm of inventive ingenuity based on evidence before the court as interpreted by one skilled in the appropriate art.<sup>35</sup> The approach taken in *Bayer* unduly benefits patentees because it minimizes the legal burden of having to adduce evidence proving that testing undertaken by them to arrive at the invention would have been inventive in nature. Rather, under the *Bayer* test, it need only be proved that some testing was conducted in the lead-up to the invention, following which a finding of obviousness is *automatically* vitiated. Consequently, rejection of routine testing in favour of the no testing approach, substitution of the former with the worth a try approach, and reliance by the court on the distinction between could and would all marginalize persons skilled in the art in the obviousness analysis.

Table 1 (Appendix 1) below summarizes decisions to date where testing was not allowed in the obviousness analysis. As in Tables 2-3 *infra*, the tabulated decisions are split up into NOC and non-NOC cases. In Table 1, the cases are further split into the two lines of cases underpinning the “no testing” approach: cases traceable back to Fox’s explicit injunction against testing, and cases traceable to the injunction against the exercise of more than a “mere scintilla” of inventiveness.

### (b) Flexible Standard

Critical to understanding why and how a skilled formulator would (or could) contemplate testing a compound for its properties is the nature of the tacit and focal codified knowledge<sup>36</sup> possessed by the ordinary person skilled in the art in the pharmaceutical industry. As noted by Justice Snider in a recent case involving crystalline forms of azithromycin, pharmaceutical companies litigating under the *NOC Regulations* are sophisticated multinational firms, capable of rapidly and efficiently conducting all necessary research relating to the optimal design, medical chemistry, formulation, dosage forms, manufacturing, and storage of pharmaceutical products.<sup>37</sup> Indeed, once a pharmaceutical compound has been synthesized, it routinely undergoes considerable testing relating to each of these broad issues.<sup>38</sup> As pointed out by Wolfe and colleagues in the context of innovation clusters,<sup>39</sup> the life sciences industry is heavily dependent on both synthetic and analytical knowledge bases.<sup>40</sup> Unfortunately, while the identity and inventive capacity of relevant persons skilled in the art have been understood within the pharmaceutical industry for many years, very few judges have made an attempt to understand in detail the nature of the “persons”, “skills”, or “art” in the context of cases under the *NOC Regulations*. Indeed it can be argued that much of the confusion in Canadian courts over the issue of testing can be traced back to a fundamental misreading of this issue.<sup>41</sup>

Based on the above discussion, the relationship between inventiveness, obviousness and the inventive capacity of persons skilled in the art is crucial to a proper

understanding of the issue at hand, as it informs the normative context in which “routine” scientific research occurs in the pharmaceutical sector. One of the few decisions in recent years where the issue was addressed directly is Justice Reed’s decision in *Apotex v. Hoffmann-La Roche*.<sup>42</sup> The case offers a good example of the fact that a substantial amount of testing can be routinely undertaken by a skilled formulator (or team of skilled formulators) as part of the normal drug formulation exercise:

Once a compound such as trimethoprim has been synthesized there are various tests through which it must go before it becomes accepted as a new drug for treatment of disease in humans. Research typically begins, as it did in this case, with the synthesis of the new compound (or with the isolation of that compound if the compound is one naturally occurring in nature). If this is done rationally the biochemist will likely have some idea as to the potential properties of the compound. The compound once created is then sent to a research facility for testing both *in vitro* (in glass) and *in vivo* (in life). *In vitro* testing is that which occurs in a test tube or more precisely in small glass saucer shaped dishes (petrie dishes). The effectiveness of the new compound against various types of bacteria is tested. If the results are promising, *in vivo* tests are then conducted, often using mice because the behaviour of infectious diseases in mice parallels that in humans. Lastly the drug is tested in humans, a stage referred to as clinical trials or clinical testing.

In any event, once trimethoprim had been successfully synthesized by Drs. Hitchings and Roth it was sent in May of 1956 to Dr. Bushby at the Wellcome Research Laboratory in Beckenham, Kent, England for *in vitro* and *in vivo* testing ...

Testing was not without difficulty. Initially the batches of trimethoprim were of uneven purity. The most significant difficulty however arose from a report received in September 1960 that chronic toxicity studies carried out in dogs had found severe leucopenia, that is a severe drop in the white blood cell count. But, those results could not be reproduced. By December 1961 clinical trials had commenced at Hammersmith Hospital in London and Dr. Bushby was attempting to interest other medical centres in doing likewise.<sup>43</sup>

As to whether such significant and “difficult” testing should vitiate the obviousness attack, Justice Reed held that evidence before the court indicated that testing of sulphamethoxazole with trimethoprim was nothing other than an “entirely obvious routine, indeed, mechanical step to take”.<sup>44</sup> Sensibly, the amount of allowable testing is not without limitation. As noted by Justice Reed in a different decision, routine testing can only render a claim invalid where it involves no inventive step.<sup>45</sup> Central to the concept of allowable testing articulated by Justice Reed in both of these cases is that testing *outside* the bounds of obviousness involves an inventive step, whereas that *inside* the obviousness fence does not. Although grounded in Supreme Court of Canada and other appellate jurisprudence (cf. Table 2), this distinction has been largely ignored in cases where the more stringent standard is applied.

Many decisions under the *NOC Regulations* allowing some form of testing employ terms such as

“routine”, “workshop”, or “mechanical” testing. An understanding of these terms is therefore central to a pragmatic test for obviousness that is faithful to the tacit and focal knowledge bases and normative practices within the global pharmaceutical industry. For example, in an early case involving a method for coating moulded masonry, the Exchequer Court of Canada held that obviousness turns on the nature of the skills of the person skilled in the art as they are applied to the specific task at hand. In particular, an invention is patentable only where it is or not “beyond the expected skill of the calling” or “beyond the skill of the routineer”.<sup>46</sup> In other words, testing within the skill of the routineer is neither inventive nor supports the traditional patent bargain. The reasoning in *Burns & Russell* was relied on by Justice Wetston in the *Apotex v. Wellcome AZT* trial decision:

There is no inventiveness in following an obvious and well-charted route using known techniques and processes involving known compositions unless the inventor encounters difficulties that could not have been reasonably expected by a person versed in the art or overcome by the application of ordinary skill: *Burns & Russell of Canada v. Day and Campbell Ltd.* (1965), 48 C.P.R. 207; *Genentech Inc.’s Patent*, [1989] R.P.C. 147 (C.A.).<sup>47</sup>

This reasoning has been followed in later cases under the *NOC Regulations*. For example, in *SmithKline Beecham v. Apotex*, the first of two “pink hue”<sup>48</sup> cases, Justice Gibson, after citing Fox to the effect that a person skilled in the art should be “assumed to be a man who is going to try to achieve success and not one looking for difficulties or seeking failure”, stated:

Having determined that a wet formulation of paroxetine tablets gives rise to a “pink hue problem”, a problem of significant enough magnitude to cause a skilled person to seek out at least a partial solution to the problem, I am satisfied that a logical first step for a person skilled in the art would be to turn to the alternative formulation methods disclosed by the ’060 Patent and to determine whether each or any of those alternative formulation methods would solve, or at least partially solve, the problem. Such an enquiry would, I am satisfied, involve no inventive step or skill. It would simply involve application of the invention taught by the ’060 Patent.<sup>49</sup>

Thus, routine investigation of the matter at hand includes logical, rational, or incremental steps toward solving the problem at issue. As exemplified by the reasoning of Justice Reed in the trimethoprim decision, the question to be answered is whether or not such steps are inventive, e.g., nonobvious.

Similarly, in *Janssen-Ortho v. Novopharm*,<sup>50</sup> a case involving the l-isomer of the antibiotic levofloxacin, the court allowed non-inventive testing relating to a number of characteristics of the compound at issue, including the (i) solubility, (ii) toxicity, and (iii) degree of antimicrobial activity of levofloxacin compared to the previously disclosed racemic mixture of the same drug ofloxacin. Justice Mosley held that, given the previous patent on the racemic mixture, it would have been obvious to a person skilled in the art to conduct testing on the solubility,

toxicity, and the degree of antimicrobial activity of the l-isomer and that such testing was non-inventive. At various points in the judgment, the court described testing on these variables as mechanical, routine, involving simple analytical procedures that were uncomplicated and generally accepted, and that revealed no new uses, surprising results, or properties.<sup>51</sup> Therefore, even though the exact antimicrobial, solubility, and toxicity characteristics of levofloxacin could not have been predicted with absolute certainty without verification through testing, these characteristics would have been predictable or obvious to persons skilled in the art and thus amenable to verification using routine analytical tests available at the time of the claim date.

Table 2 in Appendix 1 below summarizes decisions supporting some type of research or testing without automatically vitiating a finding of obviousness. Together, the decisions stand for the proposition that acceptable testing is testing that falls short of inventiveness and which allows the skilled technician to come directly and without difficulty to the invention at issue. These cases are clearly at odds with those summarized in Table 1.

### (c) Cases That Cite Stringent Standard But Apply Flexible Standard

Confusing the case law even further is a third line of cases in which judges grappling with the complex evidence before them cite the stringent standard, yet, with varying degrees of silence, go on to apply the more flexible test. For example, in the *Apotex v. Wellcome AZT* trial decision, Justice Wetston specifically cited *Bayer* to the effect that for an invention to be obvious, no thought, research or experiment could be undertaken on the road to discovery.<sup>52</sup> However, the standard *actually* applied by the court was that of no “undue experimentation”:

There is no inventiveness in following an obvious and well-charted route using known techniques and processes involving known compositions unless the inventor encounters difficulties that could not be reasonably expected by a person versed in the art or overcome by the application of ordinary skill.<sup>53</sup>

Consequently, the court accepted that some testing could be allowed in the obviousness analysis without vitiating a finding of obviousness. As noted earlier, Justice Wetston’s reasoning on the issue parallels that of the Exchequer Court in *Burns & Russell* in this regard.<sup>54</sup> Nevertheless, the court held that the proffered evidence was overly speculative and would have entailed undue experimentation in order to arrive at the impugned invention.<sup>55</sup> Even so, Justice Wetston clearly left open the possibility that testing would not *per se* obviate a finding of obviousness. Thus, it is not surprising that many of the cases in Tables 2 and 3 refer to this decision.

Similarly, in a case involving the selective serotonin re-uptake inhibitor (SSRI) sertraline for panic and obsessive-compulsive disorder, the court stipulated that the

threshold for testing was “crystal clear and without the need for experimenting or serious thought”.<sup>56</sup> However, the court went on to find that no inventive ingenuity or “undue experimentation” was exercised in prescribing sertraline for panic disorder or obsessive compulsive disorder:

Those articles teach, prior to the effective date, that current research suggested that SSRIs were logical candidates for use with OCD patients, that sertraline was in clinical trials as a treatment for OCD, that the balance of the evidence suggested SSRIs are effective in PD and preliminary results warrant investigating sertraline for PD. On the basis of this literature no inventive ingenuity, or undue experimentation was required in order to prescribe sertraline for the treatment of PD or OCD. To paraphrase Mr. Justice Wetston in *Apotex Inc. v. Wellcome Foundation Ltd, supra*, there was no inventiveness in following an obvious and well-charted route using known techniques and known compositions unless unexpected difficulties were encountered.<sup>57</sup>

A similar result was obtained in the second of two cases involving the proton pump inhibitor omeprazole, *AB Hassle v. Genpharm*.<sup>58</sup> While Justice Layden-Stevenson stated clearly that for an invention to be obvious it must occur directly to the skilled person “without serious thought, research or experiment”,<sup>59</sup> the test she *actually* applied was that in the AZT trial decision to the effect that there is no inventiveness in following an obvious and well-charted route using known techniques and processes involving known compositions unless the inventor encounters difficulties that could not have been reasonably expected by a person versed in the art, or overcome by the application of ordinary skill. Justice Layden-Stevenson found that nothing in Apotex’s evidence indicated that testing conducted by Hassle was routine and, therefore, the invention was not obvious.<sup>60</sup> Thus, while the court was willing to apply a more liberal test than did Justice Campbell in the first omeprazole decision,<sup>61</sup> evidence adduced by Apotex was, as in that case, simply insufficient to demonstrate obviousness.

Another case on point is *Novartis v. Apotex*.<sup>62</sup> *Novartis* involved formulations of cyclosporin purported to solve the problem of poor bioavailability through the use of concentrated microemulsions. The ‘150 patent held by Novartis was invalid on grounds of anticipation, obviousness, and because the claims were deemed broader than the disclosure. The court dealt extensively with the issue of the skilled formulator and what would or would not be properly construed as part of the normal formulation exercise. Based on the facts before the court there were as many as four separate steps to go from the prior art to the invention. The main issue was phrased as follows:

... Apotex alleges that the technician skilled in the art with the teachings of the two ‘667 and ‘307 patents would understand that to improve the stability and the bioavailability produced by the delivery system of these patents, a microemulsion process would be needed so that a formulation of a high surface area of oil in contact with water which permits the cyclosporin to partition into the water and be

absorbed across intestinal mucosa into the bloodstream, would result.

The key question is whether the formulator skilled in the art would be aware that the smaller the droplets' size, the higher the surface area of contact between oil and water enhance, and thus, the better the drug blood levels that result.<sup>63</sup>

Laying the groundwork for his analysis, Justice Blais cited with approval the “worth a try” approach articulated in *Bayer* and Fox's statement that to be obvious an invention must be arrived at without any experimenting, serious thought or research. However, Justice Blais did not hold that testing engaged in by Novartis was *per se* inventive. Rather, he addressed several complex and lengthy aspects of the evidence that shed important light on what a person skilled in the art would have known and grappled with, presumably in the absence of inventive ingenuity.<sup>64</sup> The not-insignificant exercise the skilled formulator faced in attempting to solve the problem before the court involved several overlapping considerations, including that compositions of cyclosporin within the claimed patents would be in the form of a pre-concentrated microemulsion, that such emulsions increase the rate of mass transfer of cyclosporin from the oil to aqueous phase, that such an increase would be inversely related to emulsion droplet size, and in turn result in increased bioavailability of the drug in a patient's body:

Apotex suggests that in view of the teachings of the '667 and '307 patents and the literature available, a skilled formulator would understand that well formulated compositions within the scope of the '667 and '307 patents would be a microemulsion preconcentrate as claimed in claim 1 of the '150 patent and it follows that emulsion and microemulsion systems were developed as a means to increase the mass transfer rates of the drug to the aqueous phase. It was also well known that the rates of the mass transfer of the drug to the aqueous phase would increase as the size of the oil droplets decreased, e.g. the smaller the droplets' size, the higher the surface area of contact between oil and water enhance, and thus, the better the drug blood levels. The real question is whether every formulator skilled in the art should know that the higher [the] surface area of the dispersed phase (oil in water), that is a small particle size emulsion, the greater the absorption/bioavailability.

Apotex suggests that the emulsion and the microemulsion processes were commonly known in the industry and that the formulators skilled in the art were aware of these processes at the time of the patent.<sup>65</sup>

From this passage it can be gleaned that based on known art regarding (a) microemulsion systems and (b) the relationship between the size of emulsion droplets to mass transfer rates, the skilled formulator would have known that: (i) reducing droplet size would increase droplet surface area, and (ii) that this increase in surface area would result in an increase in bioavailability due to (iii) increased absorption, and that all of the above *might* (iv) solve known problems with cyclosporin bioavailability. Based on this and other evidence before the

court, the court held that testing engaged in by Novartis was not inventive and therefore that the invention was obvious.<sup>66</sup>

A similar result was obtained in two decisions involving the  $\beta$  adrenoceptor antagonist carvedilol for congestive heart failure<sup>67</sup> and the antibiotic azithromycin.<sup>68</sup> In the latter decision, Justice Mosley stated that no “experimentation or research” is permissible under the obviousness test.<sup>69</sup> However, later in his reasons he *actually* found that the testing by Pfizer in order to prove that its dosage form of azithromycin did not demonstrate a food effect was routine and did not constitute undue experimentation.<sup>70</sup> Consequently, the invention was obvious. Similarly, in *Glaxosmithkline*, Justice Noël cited *Bayer* and Fox to the effect that no research whatsoever could be undertaken in the obviousness test,<sup>71</sup> but *actually* found that testing undertaken by GSK constituted non-inventive testing, with the result that the invention was obvious.<sup>72</sup>

A summary of cases where judges cite the stringent standard as authority, but then go on to apply the more flexible standard is provided in Table 3 in the Appendix below. It is clear that a significant number of cases fall into this category.

#### (d) Summary

As can be seen from the data in Tables 1-3 and discussion thereof in the text, there are three divergent lines of case law pertaining to obviousness in Canada under the *NOC Regulations*: (i) those that adopt a stringent “no-testing” approach; (ii) those that adopt a flexible approach; and (iii) those that appear to adopt the former approach but actually apply the latter. The cases underpinning the no testing approach can themselves be split into two groups. The first can be traced back to Professor Fox's legal commentary on this topic, while the second can be traced back to the intersection of obviousness and inventiveness and the injunction against the exercise of even a mere scintilla of inventive ingenuity by persons skilled in the art. The remainder of this article will concentrate on the former line of cases; the second is dealt with in forthcoming work.<sup>73</sup> Together, they are often referred to in NOC jurisprudence as the “accepted approach” to obviousness. This seems to conflict however with the data in Tables 2 and 3, which indicate the presence of two other distinct (and growing) contrary lines of jurisprudence. The only conclusion one can draw from this analysis is that while Fox, *Beloit* and *Bayer* are routinely cited as leading authority on the issue of testing there is no single authoritative line of jurisprudence indicating whether or not scientific testing in the lead-up period to an invention should vitiate a finding of obviousness. As such, there is considerable confusion in Canadian courts on this issue.

## Part II: Harold Fox Was Wise But Wrong on the Issue of Testing

### (a) Case Law

From Part I of the analysis it is clear that the stringent or strict approach to obviousness in Canada owes its legitimacy in large part to legal commentary by Harold Fox. It is beyond question that Professor Fox was a leading figure of intellectual property law in Canada. His textbooks are mainstays of patent analysis<sup>74</sup> and, as reflected in the case law described above, he continues to be heavily cited to this day. As a reminder, Professor Fox's precedent-setting passage on obviousness is as follows:

In order that a thing shall be "obvious" it must be something that would directly occur to someone who was searching for something novel, a new manufacture, or whatever it might be, without the necessity of his having to do any experimenting or serious thought, or research, whether the research be in the laboratory or amongst literature.<sup>75</sup>

It is obvious that for Fox, no research whatsoever during the lead-up period to an invention can be permitted in order to arrive at a conclusion of obviousness. However, while it continues to be cited *verbatim* in both NOC and non-NOC decisions, there are serious problems with the issue of testing as dealt with by Professor Fox.

To begin with, the test for obviousness is not unlike that for anticipation even though the legal requirements for both otherwise differ significantly.<sup>76</sup> Indeed, obviousness and anticipation constitute separate and distinct legal requirements under Canadian, American, and British patent law. However, Fox's position on anticipation parallels his injunction against experimenting in the obviousness analysis: inventive ingenuity in an invention exists where experiments were necessary to show whether or not it could be usefully carried out.<sup>77</sup> In other words, experimentation trumps a finding of anticipation. Consequently, the test for obviousness can be conflated into that for anticipation. As noted by Justice Hughes in a recent NOC case involving levofloxacin, the lack of inventiveness attributed to persons skilled in the art in cases employing the stringent standard comes "perilously close" to that for anticipation, with the result that obviousness is "little different than a consideration of anticipation".<sup>78</sup> Ambiguity of this nature is likely responsible for the counter-intuitive (but not impossible) finding that a patent can be anticipated but not obvious over the prior art.<sup>79</sup>

A second caveat regarding Fox's obviousness analysis is the narrow scope of case law cited in support of the stringent standard. Indeed, three of the four cases cited by Fox were decided by a single judge, Justice Maclean of the Exchequer Court, and there are questionable elements of Justice Maclean's analysis in these cases that seem to have gone unnoticed. For example, paragraph 21 of *Short Milling v. Weston*,<sup>80</sup> reproduced in its entirety

below, represents all of Justice Maclean's analysis on obviousness. As is clear from the passage, no review of law applicable to obviousness was undertaken:

That there is invention in the bleaching agent disclosed by Haas, and his process or processes of producing the same, is not, I think, subject to any serious doubt, assuming for the moment that anticipation is not to be found in any of the prior art cited, and this will be considered presently. I think Haas undoubtedly made an important discovery, and as the result of substantial and original research and experimental work he has disclosed a process or processes, or means, for translating his discovery into practical and useful ends, something that was not, I think, done before. The bleaching of flour or dough, and the production of a white loaf of bread, was and is being successfully attained by the use of the bleaching agent prepared according to the process, and by the means, described by Haas. This was, I think, something novel and useful, particularly because of its adaptability for use in bakeries as already mentioned, and I do not think there is any fair ground upon which it should be denied the merit of a patentable invention, unless, as I have already stated, anticipation of it has been definitely established. There would not seem to be any room for saying that Haas was something obvious. In order that a thing shall be "obvious," it must be something that would directly occur to someone who was searching for something novel, a new manufacture or whatever it might be, without the necessity of his having to do any experimenting or research, whether the research be in the laboratory or amongst literature. Haas discovered the existence of a flour bleaching enzyme in the soy-bean, he disclosed a process, and the sequence of the various steps in that process, by which a bleaching agent could best be made therefrom for commerce, and the property that it will have when so made or manufactured, and none of these things can, I think, be said to have been obvious.<sup>81</sup>

The statement by Justice Maclean to the effect of "no experimenting or research" thus sits somewhat uncomfortably as a bald statement with no apparent precedent in Canadian law.

Neither of the two remaining decisions by Justice Maclean<sup>82</sup> entails a review of, or even mentions, previous case law pertaining to obviousness. Tellingly, these cases are never cited in later decisions supporting the stringent standard: only the passage by Professor Fox is quoted, minus any reference to the cases cited by him. Confusing elements of Justice Maclean's reasoning in *Short Milling* have not escaped judicial notice, as revealed by the following passage from the decision of Justice Collier of the Federal Court in *Xerox v. IBM*:

... Maclean, J., in *J.R. Short Milling Company (Canada) Ltd. v. Geo Weston Bread and Cakes Ltd., et al.*, [1941] Ex.C.R. 69, at 86, used this test:

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

I have some reservations about the phrase "whether the research be in the laboratory or amongst literature", having in mind the putting in evidence, in proof of this defence, of the so-called "prior art". Maclean, J's expression "directly occur" is, to my mind, a useful one. The form of question

occasionally used at this trial was to this effect: Would an ordinary skilled workman (at the relevant date) have been led directly and without difficulty to ... ? That inquiry, I think, embraces the essence of the test formulated by Maclean, J.<sup>83</sup>

Fortunately, the judiciary in Canada have not followed Justice Maclean's explicit disclaiming of researching the literature (also found in Fox<sup>84</sup>), as this would obviate persons skilled in the art having legitimate legal knowledge of the prior art, one of the pillars of the obviousness test even at the time of *Short Milling*. The "directly and without difficulty" element of Justice Maclean's test refers to the "Cripps Question" posed by Sir Stafford Cripps in *Sharp and Dohme v. Boots*.<sup>85</sup> It is submitted that Justice Collier was correct in highlighting this section of Justice Maclean's decision as the essence of the obviousness test as it was then known. It is further submitted that Justice Maclean's statement in *Short Milling*, namely that that no experimenting or research can be allowed under the Canadian obviousness test, should be overruled in favour of a more pragmatic and evidence-based test.

It is possible that the remaining case cited by Fox contains the seed of what may have led to the reasoning in *Short Milling*. In *Canadian Industries v. Sherwin-Williams*,<sup>86</sup> Justice Angers of the Exchequer Court quotes the following passage by Justice Rinfret in *Crosley Radio Corp. v. Canadian General Electric*<sup>87</sup> regarding the role of thought and experiment in the obviousness analysis:

The mere lack of obviousness is not sufficient to establish invention. There must be inventive ingenuity: see *Crosley Radio Corporation and Canadian General Electric Company Limited*, where the Honourable Mr. Justice Rinfret said (1936 SCR 551, at 555):

Notwithstanding the very ingenious and exhaustive argument of counsel for the appellant, we would hardly think, however, he would ask this Court to give a sacrosanct meaning to the use of the word "obvious" for the purpose of discriminating between the category of improvements which ought to be regarded as being properly inventions in the legal sense and the category of those not so regarded.

It has long been laid down in our courts that, in order validly to support a patent, it was, of course, necessary that the art, or the improvement thereon, should be new, that it must be useful and that it must not have been anticipated by prior knowledge or prior user by others within the meaning of sec. 7 of the Patent Act, in force at the time of the issuance of the patent in suit; but that something additional was also required. It was essential that there should be invention and that one did not hold a valid subject-matter of a patent unless he showed the exercise of the inventive faculties (See: *Halsbury's Laws of England*, vbis. Patents and Inventions, no. 288); and that is to say, in the words of Lord Watson (*Thomson v. American Braided Wire Company (1889)*, 6 R.P.C. 518 H.L.), "a degree of ingenuity ... which must have been the result of thought and experiment".<sup>88</sup>

It is clear from the passage at the bottom of the preceding paragraph that at no point in his decision did Justice Rinfret hold that "any experimenting or research, whether the research be in the laboratory or amongst

literature" vitiates an obviousness attack, just that some of either *must have been* involved in its opposite. Perhaps this is the logical trap that Justice Maclean fell into when providing his reasons in *Short Milling*.

More important however is the fact that Justice Angers in fact allowed a substantial degree of testing in the case before him in *Sherwin-Williams*. This case involved the validity of a patent held by General Electric on new and improved alkyd resins and paints and varnishes containing them. As shown by the evidence before the court, there was significant prior art on such resins before General Electric conducted its own research testing on same:

Around 1901 a chemist named Watson Smith tried reacting glycerol and phthalic anhydride. His work is recorded in an article entitled "A new glycerol phthalate" which appeared in the *Journal of the Society of Chemical Industries*, of November, 1901. The article in question is mentioned in Schedule I of the amended particulars of objection. It describes Watson Smith's product as follows:

As characterized chiefly by its extraordinary insolubility in almost all solvents. It is practically insoluble in alcohol ether and benzene also petroleum and petroleum spirit. Its best solvent appears to be cold acetone but in this it is sparingly soluble. On pouring some of the solution on a watch glass and letting it evaporate spontaneously, the clear transparent resin deposited in minute drops, solidifying to hard transparent masses of the tasteless resinous body.

Watson Smith had evidently discovered a new synthetic resin which however was wholly insoluble and unusable. Yet it suggested all sorts of possibilities as an entirely new synthetic product and, as time went on, the industry began to consider what might be done with this new synthesis. Around 1912 the Watson Smith resin was investigated by chemists in the employ of General Electric Company in the United States, their names being, among others, Callahan, Arsem, Dawson, Howell and Friedburg. These chemists were trying to make out of this hard glassy substance of Watson Smith, a sample whereof was filed as exhibit 24, something soluble in available solvents and thus industrially useful, something they could spread on a surface as a coating.<sup>89</sup>

The evidence adduced clearly demonstrates that General Electric was in the habit of conducting large-scale routine research on a stable of compounds, and that it was deemed acceptable by the court at the time Fox was writing his book not just for one person skilled in the art, but rather an entire team of skilled chemists employed by this large sophisticated industrial company, to undertake significant experimental research, and that such research should not vitiate the obviousness attack. Notwithstanding the extensive amount of experimental and theoretical research conducted by the General Electric research group, Justice Angers found that the patent was obvious in light of the prior art. The result, and the means to get there, parallels that in the trimethoprim, levofloxacin, cyclosporin and sertraline cases discussed *supra*, where evidence of substantial testing was adduced without automatically vitiating a finding of obviousness.

Finally, all four of the cases cited by Fox in support of his assertion that no testing can be contemplated in the obviousness analysis were released between 1941 and 1945, yet the final edition (4th) of his textbook was published in 1969. Of note is the absence of several decisions released by the Exchequer Court of Canada well before publication of the final edition. In particular, the omission of *Burns & Russell*<sup>90</sup> is notable, as it figures significantly in later decisions supporting a role for testing (cf. Tables 2 and 3). Recall in that case that Justice Gibson found with reference to the existing case law that routine testing is within the skill of persons skilled in the art and thus does not support a patent monopoly. This reasoning was adopted in the leading case of *Apotex v. Wellcome* when the court held “there is no inventiveness in following an obvious and well-charted route using known techniques and processes involving known compositions unless the inventor encounters difficulties that could not have been reasonably expected by a person versed in the art or overcome by the application of ordinary skill”.<sup>91</sup>

Another early case noteworthy for having dealt directly with the issue of testing is the Supreme Court of Canada decision in *Lightning Fastener v. Colonial Fastener*.<sup>92</sup> Justice Rinfret stated that inventions brought about through the exercise of mechanical skill do not involve an exercise of inventive ingenuity, and that it “is not the object of the *Patent Act* to dignify by the name of invention every slight advance in the domain of mechanism”. A similar distinction was made by the Exchequer Court in *Pope Appliance v. Spanish River*.<sup>93</sup> Thus, while the need for caution in distinguishing between inventive and non-inventive experimenting, thought, and research had been sounded by the courts,<sup>94</sup> there can be little question that by 1969 there was a well developed line of cases in Canada distinguishing the type of routine or workshop testing advocated by *Apotex* in *Bayer*, from inventive testing done on the road to a patentable invention.

### (b) Summary

The historical survey undertaken above casts doubt on the legal foundations of the stringent standard for obviousness. In the absence of strong supporting jurisprudence, Professor Fox’s commentary in and of itself stands as poor precedent for the proposition that any scientific testing at all in the lead-up to invention should vitiate a finding of obviousness. Together with the two other lines of jurisprudence relating to this issue reviewed in Part I and summarized in Tables 2 and 3 it is reasonable to conclude there is an absence of an unequivocal and predictable test for obviousness in Canada.

## Part III: Requirement for an Unequivocal, Predictable, and Fair Test

### (a) Implications for the Issues of Certainty and Predictability

As noted above, the case law reviewed so far indicates that there is no clear and consistent line of cases on the issue of testing under the *NOC Regulations*. However, the Supreme Court of Canada has said that one of the primary functions of law is to give the public fair notice of the legal nature and consequences of its conduct with reasonable certainty through the fair application of laws by courts.<sup>95</sup> As stated by Justice Gonthier in *R. v. Nova Scotia Pharmaceutical Society*, this notice function is “broadly linked with the corpus of principles of government known as the ‘Rule of Law’, which lies at the core of our political and constitutional tradition”.<sup>96</sup>

The requirement for fairness, predictability, and certainty in law applies in two important ways to the issue at hand. First, the case law review clearly illustrates that there is a significant lack of certainty and predictability with regard to the standard for testing within the obviousness rubric. This refers to the fact that courts are both releasing inconsistent opinions on the issue (no testing versus some testing) and opinions which are themselves internally inconsistent (judges say they are applying one standard but actually apply another). Secondly, courts are adopting reasoning that flies in the face of normative practices within the pharmaceutical industry and applying this reasoning in a manner that inherently and thus unfairly biases the legal test for obviousness against second persons under the *NOC Regulations*.

In one of its leading patent cases,<sup>97</sup> the Supreme Court of Canada stipulated that the provisions of the Act and interpretation thereof by the judiciary should be fair and predictable. Extending the principles enunciated in *Nova Scotia Pharmaceutical*, Justice Binnie noted that there is a certain minimal standard of predictability that must attach to patent law jurisprudence, beyond which significant and improper economic harm can result to patent litigants. The court further held that it is within the bounds of proper patent policy to maintain this minimal level of certainty and predictability and to keep it from slipping below that threshold:

The scope of patent protection must not only be fair, it must be reasonably predictable. A patent is, after all, a public instrument issued under statutory authority which may result in severe financial consequences for its infringement. The scope of its prohibition should be made clear so that members of the public may know where they can go with impunity. As was said in another public law connection by Gonthier J. in *R. v. Nova Scotia Pharmaceutical*

*Society*, [1992] 2 S.C.R. 606, at p. 639, precision in public enactments is required to “sufficiently delineate an area of risk” ...

The patent owner, competitors, potential infringers and the public generally are thus entitled to clear and definite rules as to the extent of the monopoly conferred. This in turn requires that the subjective or discretionary element of claims interpretation (e.g., the elusive quest for “the spirit of the invention”) be kept to the minimum, consistent with giving “the inventor protection for that which he has actually in good faith invented” (*Western Electric Co. v. Baldwin International Radio of Canada*, [1934] S.C.R. 570, at p. 574). Predictability is achieved by tying the patentee to its claims; fairness is achieved by interpreting those claims in an informed and purposive way.<sup>98</sup>

While the court was concerned with the scope of the claims at suit, the requirement for clear and definite rules can be legitimately extended from claim scope to that of obviousness. Both analyses go to the heart of patent validity; one through the proper scope of the patent monopoly and the other through the existence of the monopoly itself. If a court finds that a given claim or set of claims are broader than the disclosure, then those claims are deemed to be invalid. The same is true for obviousness, which can result in complete invalidation of a patent rather than invalidation on a claim by claim basis.

It could also be argued that maintaining the threshold for allowable testing at the current stringent standard results in significant “chilling” of competition to the benefit of patentees. This follows the resulting ambiguity and uncertainty faced by potential litigants. In *Free World Trust*, the Supreme Court of Canada held that patent policy, not unlike competition law and policy, should encourage and not discourage economic activity. In particular, the court noted that an improperly expanded patent scope results in chilling of competition to the detriment of both competitors and the public:

The patent system is designed to advance research and development and to encourage broader economic activity. Achievement of these objectives is undermined however if competitors fear to tread in the vicinity of the patent because its scope lacks a reasonable measure of precision and certainty. A patent of uncertain scope becomes “a public nuisance” (*R.C.A. Photophone, Ltd. v. Gaumont-British Picture Corp.* (1936), 53 R.P.C. 167 (Eng. C.A.), at p. 195). Potential competitors are deterred from working in areas that are not in fact covered by the patent even though costly and protracted litigation (which in the case of patent disputes can be very costly and protracted indeed) might confirm that what the competitors propose to do is entirely lawful. Potential investment is lost or otherwise directed. Competition is “chilled”. The patent owner is getting more of a monopoly than the public bargained for. There is a high economic cost attached to uncertainty and it is the proper policy of patent law to keep it to a minimum.<sup>99</sup>

In the pharmaceutical industry, the consequences of this type of chilling are significant: First, as noted in *Free World Trust*, patentees accrue more of a monopoly than that bargained for by the public. This skews the balance of patent law against potential competitors, concentrating wealth in the hands of fewer firms, and maintaining monopolistic pricing from the perspective of

consumers. Second, parties attacking a patent will lose more cases under the *NOC Regulations* than would otherwise occur with a fair and predictable test, which in turn will broaden their risk zone. Third, the consequence to the public of not having a test for obviousness that is fair and predictable is that a significant percentage of the population will be at risk of losing access to affordable medications. It is known, for example, that the longer a firm is able to maintain a dominant market position, particularly one relating to patented pharmaceuticals, the longer it will continue to maintain monopolistic pricing schemes.<sup>100</sup> Finally, a high threshold test creates a lack of incentive for innovation in the pharmaceutical sector, which in turn yields fewer and less innovative products for consumers and for potential inventors to build on. Indeed, Varma and Abraham have described the obviousness test as the gate by which patent law minimizes inefficient transfers of wealth under conditions where a patentee obtains a right to exclude others from making or using their invention, yet does not add to the store of public knowledge when a patent is granted on obvious subject matter.<sup>101</sup> The relevance of this to Canadian drug consumers is evident in the Supreme Court of Canada’s recent statement that it “is entirely understandable” that brand-name pharmaceutical firms would avail themselves of provisions in the *NOC Regulations* allowing evergreening by “adding bells and whistles to a pioneering product” after the original patent has expired.<sup>102</sup> The economic rationale for spending \$10 million to make \$500 million in profit instead of spending \$500 million to make \$2 billion is relatively straightforward. The result of this situation is that brand-name drug companies are strongly incited to leverage the regulations to produce products that clearly do not benefit the public.

### (b) Implications for the Issue of Fairness

In addition to issues of certainty and predictability, the decisions of the Supreme Court of Canada in *Nova Scotia Pharmaceutical* and *Free World Trust* stand for the proposition that patent law should also be “fair” to all relevant parties. As noted by the court in the latter decision, fairness is achieved by interpreting patent law in an informed and purposive way. Indeed, this represents a second overarching reason to revisit the test for obviousness to ensure it is “fair, unequivocal and predictable”: a test that *inherently* favours patentees would run afoul of the fairness principal, particularly where the stated purpose and intent of the relevant enabling legislation is to balance the interests of all relevant parties and ensure national public health interests are respected by making affordable medication available. This concern is particularly relevant in light of the fact that expenditures by Canadians on prescription drugs have risen by several hundred per cent in the last two decades,<sup>103</sup> with no slowing in the growth rate expected in the future.

The purpose and intent of legislation can be gleaned by government policy documents, including

those referred to as Regulatory Impact Analysis Statements<sup>104</sup> (“RIAS”). As noted by Justice Bastarache in *Bristol-Meyers Squibb v. Canada*, it is appropriate for the court to look to a RIAS for evidence of legislative intent with respect to the *NOC Regulations*.<sup>105</sup> There have been several important RIAS documents relating to the *NOC Regulations*, most notably in 1993 when they came into force, in 1998 and 1999 following amendment to the *NOC Regulations*, and in December 2004 and June 2006 with regard to data and market exclusivity. On first pass, a reading of the 1993 RIAS suggests the main issue at hand for legislators at the time the regulations came into force was shoring up the rights of patentees following the dismantling by the government at the time of the compulsory licensing provisions.<sup>106</sup> For example, the government stated:

As a general rule, judicial remedies are sufficient to address patent infringement. However, with the enactment of Bill C-91 the government has created an exception to patent infringement allowing generic competitors to undertake any activities necessary to work up a submission to obtain regulatory approval of a product. This removes a patent right that may have otherwise been available to patentees to prevent generic competitors from obtaining such regulatory approval of their products.

These *NOC Regulations* are needed to ensure this new exception to patent infringement is not abused by generic drug applicants seeking to sell their product in Canada during the term of their competitor's patent while nonetheless allowing generic competitors to undertake the regulatory approval work necessary to ensure they are in a position to market their products immediately after the expiry of any relevant patents.<sup>107</sup>

However, as can be gleaned from the second paragraph *supra*, in addition to safeguarding the interests of brand-name pharmaceutical firms, the government also intended to protect the rights of generic firms under the new regulations. The balancing function was been confirmed more explicitly in the December 2004 RIAS:

The proposed amendments are intended to restore the balanced policy underlying the Patented Medicines (Notice of Compliance) *NOC Regulations* (“PM (*NOC*) *NOC Regulations*”) by reaffirming the rules for listing patents on the register and clarifying when listed patents must be addressed.

The Government's drug patent policy seeks to balance effective patent enforcement over new and innovative drugs with the timely market entry of their lower priced generic competitors. The current manner in which that balance is realized was established in 1993, with the enactment of Bill C-91, the *Patent Act Amendment Act, 1992*, S.C. 1993, c. 2.<sup>108</sup>

This balancing of interests was recently acknowledged by the Supreme Court of Canada in its *Biolysse* decision, in which Justice Bastarache stated that amendments to the *NOC Regulations* were intended to “confirm the balance between providing effective enforcement of patent right, while ensuring that second and subsequent entry manufacturers' drugs can enter the market as soon as it is determined that they are not covered by a patent, or, where they are covered by a patent, immediately after the patent expiry”.<sup>109</sup> Similar

language was used by Justice Binnie to the effect that that “[i]t seems clear that the *NOC Regulations* were introduced to help generic drug companies and at the same time curb potential patent abuse by them”.<sup>110</sup> These statements are consistent with those made by Justice Issac of the Federal Court of Appeal writing in dissent in an earlier *NOC* decision.<sup>111</sup>

Based on the above discussion, it is concluded that the purpose and intent of the *NOC Regulations* is to balance competing interests of brand-name and generic pharmaceutical companies in Canada. By balancing these interests the government has taken a well circumscribed step to ensure the availability to the public of access to affordable medication: as stated in the 2004 RIAS, “[t]he Government's drug patent policy seeks to balance effective patent enforcement over new and innovative drugs with the timely market entry of their lower priced generic competitors”.<sup>112</sup>

In light of the balancing function of the *NOC Regulations*, the test for obviousness should be “fair” in that it should be neither *unfairly* biased nor *inherently* skewed to the interests of one party. However, the current test effects just this result as it allows for no scientific testing or research whatsoever without obviating a finding of obviousness, and it does so independent of the common practice in the art to undertake just such testing as a matter of course. There is no recourse for generic firms when the “no testing” approach is applied: a patentee need only demonstrate some testing was performed in the lead-up to the invention and the court *must* find for brand-name firms. The person skilled in the art, who under the provisions of section 28.3 of the Act, is to supply the lens through which the judiciary is to gaze when assessing obviousness, is obliged by law to operate at the highest level of scientific and technical sophistication, yet possess not even a scintilla of creativity or inventiveness when contemplating testing in the obviousness analysis. As discussed elsewhere,<sup>113</sup> this contradicts scientific norms for persons skilled in the art. As such, the test is intrinsically and irrevocably skewed both in theory and in practice to pharmaceutical patentees and thus does not respect a policy of balance. For this reason, the test articulated in *Beloit*, *Bayer*, and progeny runs afoul of the constitutional requirement for fairness by contravening the stated purpose of the *NOC Regulations*.

### (c) Summary

In summary, a requirement for fairness, predictability, and certainty in application of the test for obviousness can be located in the Rule of Law, Supreme Court patent jurisprudence and statements by legislators regarding the intent and purpose of the *NOC Regulations*. This requirement is breached in two ways by the stringent test for obviousness. First, because it yields a situation where there is a substantial lack of certainty and predictability as to the correct standard for testing

within the obviousness rubric. And second, because courts have adopted reasoning in the obviousness analysis that inherently and thus unfairly biases the legal test against generic firms under the *NOC Regulations*.

## Part IV: Suggestion for an Unequivocal, Predictable, and Fair Test

### (a) Purposive Construction of Obviousness

As reviewed above, there is a small but growing number of judges who have moved away from *Beloit* and *Bayer* to allow research or testing in NOC cases without obviating a finding of obviousness. Judicial reasoning in these cases typically entails articulation of “due”, “rational”, “incremental”, “routine”, “mechanical”, or “workshop” testing. In these decisions a finding for or against generic firms was based on the evidence before the court, expert opinion, and an appreciation of contextual practices of persons skilled in the art in the pharmaceutical industry.<sup>114</sup> As such, the tests applied by these courts was objective yet flexible.

A useful starting point for discussion of an unequivocal, predictable, and fair test is by way of analogy to the issue of claim construction, which according to the Supreme Court of Canada must be made in a pragmatic and informed way.<sup>115</sup> In *Whirlpool v. Camco*, for example, the court, following the Federal Court of Appeal in *Eli Lilly v. O'Hara*<sup>116</sup> and the House of Lords in *Catnic v. Hill & Smith*,<sup>117</sup> held that patent claims should be construed “purposively”, whereby emphasis is placed on locating the essence of an invention with the aid of persons skilled in the art (rather than interpreting the words of the inventor literally). Viewing the patent through a skilled interpreter minimizes, in the words of Lord Diplock, reliance on the type of literal and “meticulous verbal analysis in which lawyers are too often tempted by their training to indulge”.<sup>118</sup>

While the courts in *Whirlpool* and *Catnic* were concerned with claim construction rather than validity,<sup>119</sup> an emphasis on the “essential nature” of the invention and how it came to be is a constant feature in both analyses. In the case of claim construction it is distinguishing between essential and non-essential elements of the claim, whereas in the obviousness analysis it is the determination of whether the act of arriving at an invention crosses the line between inventive and non-inventive activity. Moreover, both assessments are to be made contextually,<sup>120</sup> with the help of persons skilled in the art. The issue of context is no less important to the issue of obviousness, as no invention least of all those in the multinational pharmaceutical industry arises *in vacuo*. All advances, be they large or small, evolve based on previous discoveries. To say that obviousness can only be found in the absence of experimentation, thought, or research is to deny the manner in which discoveries are made and reduced to practice, and essentially conflates the test for obviousness into that for anticipation. This is

a particularly important consideration in jurisdictions such as Canada, where regulatory approval of pharmaceuticals is controlled by linkage regulations, which in turn allows for line extension patents that can be continually evergreened.<sup>121</sup>

In addition, the Supreme Court of Canada noted that courts must take a purposive approach not only to infringement but also to validity, in order to avoid construing claims differently for purposes of infringement and validity.<sup>122</sup> Similar reasoning applies to differences between claim construction and obviousness. Finally, as with claim construction, taking a purposive approach to obviousness would satisfy the interpretive objective in patent law of being “reasonable and fair to both the patentee and the public”.<sup>123</sup> As well, it would respect the public notice function of law.<sup>124</sup>

Particularly important to the issue at hand is that a purposive construction is said to achieve “flexibility and fairness” in law by focusing on the essence or so-called “pith and marrow” of an invention.<sup>125</sup> This broad focus can be contrasted to the narrow focus on literal notions of testing versus no testing in the stringent approach to obviousness (or the would *versus* could distinction). A purposive approach would involve an enquiry into the *nature* of the research or testing leading up to the invention, the focal point being a determination of whether or not the testing was *inventive*. The term “purposive” need not be used; any term connoting a functional and pragmatic approach aimed at assessing the essence of inventive activity would suffice. No matter what the terminology used, the purposive approach comports well to the implicit reasoning employed by many of the judges in decisions where testing was allowed, including those where the judiciary claimed to follow the stringent standard but actually applied the more flexible one.

A recent case under the *NOC Regulations* can be used to illustrate how the central elements of a purposive construction might be applied to obviousness. *BMS v. Novopharm*<sup>126</sup> involved gatifloxacin, a quinolonecarboxylic acid antibiotic. Evidence indicated that research into quinalones had been intense and extensive among highly qualified persons skilled in the art for 10 years prior to the claim date.<sup>127</sup> Justice Gibson approved of statements by Novopharm’s lead expert that the science involved in producing the invention (medicinal chemistry) was more predictable than experts for BMS had claimed.<sup>128</sup> Regarding the issue of testing, the court noted the prohibition in *Beloit* against any experiment, thought, or research involving more than a “mere scintilla” of inventiveness. However, given the evidence before him as to the inventive capacity of persons skilled in the art of pharmaceutical science, he rejected the test in *Beloit* in favour of the more flexible approach, casting the definition of persons skilled in the art “well above the concept of an individual having no scintilla of inventiveness or imagination”.<sup>129</sup> Referring to the decisions in *Apotex v. Wellcome*<sup>130</sup> (*AZT*), *Pfizer v. Apotex*<sup>131</sup> (sert-

raline) and *Janssen-Ortho v. Novopharm*<sup>132</sup> (levofloxacin) discussed *supra*, he allowed routine testing that fell below the threshold of undue or inventive testing. This included testing that produces surprising or unexpected results.<sup>133</sup> As in Justice Reed's articulation of allowable testing in the *Apotex v. Hoffmann LaRoche*<sup>134</sup> trimethoprim case, the court noted that what constitutes "routine testing" in the context of obviousness must be dependant upon evidence adduced before the court. Based on such evidence Justice Gibson held that the patent was not obvious, finding specifically that the chief expert for Novopharm admitted on cross-examination that the starting point in his analysis was not the prior art, but rather the invention in question. This led him to conclude that Novopharm's expert was engaged in a classic hindsight analysis.<sup>135</sup>

While the claims were ultimately held to be valid, Justice Gibson's analysis is consistent with the purposive approach outlined above. It was grounded in context at the time of the claim date and evidence adduced before the court. His decision turned on evidence pertaining to the degree of activity in the field at the time of invention, the somewhat predictable nature of the science and techniques involved in producing the invention, the fact that some degree of testing is routinely employed in the pharmaceutical industry, and the fact that persons skilled in the art are in reality not completely devoid of inventive ingenuity. The latter two observations go to the heart of purposive construction as they are directed specifically to whether research conducted by BMS was inventive or not. The fact that evidence showed such testing was inventive does not detract from taking an approach that seeks to understand the pith and marrow of the matter. Rather, it highlights the value of taking a contextual and evidence-based approach to obviousness rather than focusing on binary notions of testing/no testing or would/could. The test is flexible rather than stringent, and thus is fair to both litigants.

A purposive approach would also reconcile important differences in obviousness jurisprudence in Canada and the United Kingdom that persist in spite of the increasingly global nature of drug development and intellectual property rights attaching to pharmaceutical inventions. As noted by Justice Lederman in *Bayer*, a significant discrepancy exists in the inventive capacity of English and Canadian persons skilled in the art such that "making inquiries or testing, seems to be something outside the ken of the notional Canadian skilled technician".<sup>136</sup> Justice Lederman went on to say while it may have been logical to a person skilled in the art to undertake testing, that it was not open to the mythical skilled technician who can not have an inquiring mind. Rather, the law in Canada stands for the proposition that a skilled technician is expected to spontaneously exclaim "I already know the answer and it is obvious". Reasoning of this kind led Justice Blanchard in the recent *Pfizer v. Novopharm* azithromycin "food effects" case to say that it can be scientifically obvious to arrive at an invention

in practice but that this need not be equivalent to legally obvious,<sup>137</sup> even though this scenario runs against the grain of analyzing a patented invention contextually<sup>138</sup> through the eyes of a person skilled in the art,<sup>139</sup> with a mind willing to understand<sup>140</sup> all that is necessary in order to successfully solve the problem before them<sup>141</sup> enabled by all relevant prior art and best-practices in the industry at the time of the claim date.<sup>142</sup>

The Canadian approach can be contrasted with that in the United Kingdom not only with regard to obviousness but also anticipation, the latter of which is traditionally a harder ground of invalidity to make out. For example, in the classic case of *Van Der Lely v. Bramford*,<sup>143</sup> the House of Lords held that ordinary methods of trial and error testing can anticipate an invention, provided they do not involve an inventive step. Included in the scope of allowable testing are ordinary methods of trial and error that involve no inventive step and are generally necessary in applying any discovery to produce a practical result.<sup>144</sup> This contrasts sharply with the Canadian position on anticipation articulated by Fox and applied in *Beloit* and later cases.

The leading United Kingdom case on testing in the context of obviousness is Lord Mustill's Court of Appeal decision in *Genentech*.<sup>145</sup> The case stands for the proposition that an invention is obvious when analyzed contextually if it can be determined through well known testing techniques involving trial and error. The court made a distinction between a notional skilled technician attempting to put an invention into practice and persons skilled in the art operating in a "discovery capacity" in a field where intelligence and problem-solving abilities are both valued and normative. The court found it appropriate in cases involving complex biomedical inventions to assume people who are skilled in the art possess a substantial degree of problem-solving ability. Indeed, the court held that "but for" the creative skills of relevant persons skilled in the art they would not have been included on the discovery team in the first place. It is these skilled technicians who make up the population of persons skilled in the art to which the court must look when assessing obviousness. The reasoning of Lord Mustill on this point parallels that of Justice Gibson in *BMS v. Novopharm*, *Apotex v. Hoffmann-LaRoche* and the AZT trial decision,<sup>146</sup> and is present in varying degrees in all of the cases enumerated in Table 2 and many of those in Table 3. Another point of convergence was the court's holding that the skills of the person skilled in the art must be construed contextually, based on evidence brought before the court.<sup>147</sup>

Finally, Lord Mustill laid the burden for weighing considerations of obviousness squarely on the judiciary notwithstanding the caution to avoid hindsight in the obviousness analysis.<sup>148</sup> In looking to the essence of the issue, courts in the United Kingdom are therefore charged with the burden of determining whether the problem faced by the inventor "could have been over-

come by pertinacity, sound technique, or trial and error, with no more, or whether there would have been required a spark of imagination” beyond that properly attributable to persons skilled in the art. It is left to the judge to form a mental picture of the art and skilled practitioner, and see how the latter measures up against the problem which he or she is assumed to be attempting to solve. Given the pragmatic and functional approach taken by him it is not surprising that numerous Canadian tribunals, including the Patent Appeals Board,<sup>149</sup> the Federal Court of Canada,<sup>150</sup> and the Supreme Court of Canada,<sup>151</sup> have cited various portions of Lord Mustill’s decision with approval, including that on obviousness.<sup>152</sup>

### (b) Comparison with Calls for Law Reform in the United States

There have been significant calls for reform in the law of obviousness in the United States. In particular, patent scholars have observed that the threshold for obviousness has been increasingly construed by the Federal Circuit as too onerous in light of the actual skills and knowledge of persons skilled in the relevant art, particularly when compared with that in other research-heavy sectors such as information technology. The law differs significantly from that in Canada, however, as courts in the United States have tended to focus on differences between the structure and function of biomedical inventions,<sup>153</sup> ignoring strong evidence of functional obviousness in favour of analyzing the prior art in light of the level of uncertainty relating to the structural aspect of therapeutic molecules. Canadian courts, by contrast, tend to take the evidence as they find it in cases under the *NOC Regulations*, focusing on structure or function as alleged by the attacking party in its Notice of Allegation.

The role of persons skilled in the art in the obviousness analysis has recently garnered considerable attention in the United States. In May 2006 the United States Supreme Court solicited the opinion of the Solicitor General on whether it should hear *KSR International Co. v. Teleflex Inc. et al.*,<sup>154</sup> a case involving a combination patent directed to an adjustable gas pedal for use in throttle control and an electronic control to communicate adjustments from the adjustable gas pedal to the engine. KSR, a Canadian corporation, was granted summary judgment against Teleflex in its infringement suit. The lower court decision was overturned on appeal to the Federal Circuit, leading to the petition by KSR. The case is highly pertinent to the present analysis as it involves the first substantial determination of the nature of a court’s proper reliance on persons skilled in the art when deciding the issue of obviousness by the United States Supreme Court since *Graham v. John Deere*.<sup>155</sup> The court granted *certiorari* June 26, 2006 and heard oral argument in late November 2006. A decision is expected in spring 2007.

The primary ground of appeal in *Teleflex* is that the Federal Circuit has retreated significantly from the test laid down by the Supreme Court in its *John Deere* decision:

While the ultimate question of patent validity is one of law, the condition set forth in the *Patent Act* of 1952, 35 U.S.C.S. § 103, which is but one of three conditions, each of which must be satisfied, lends itself to several basic factual inquiries: (1) the scope and content of the prior art are to be determined; (2) differences between the prior art and the claims at issue are to be ascertained, and (3) the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.<sup>156</sup>

Consequently, determinations of patentability were made on the basis of a comparison of the essential characteristics of the alleged invention with those present in the relevant prior art. The court was clear that such determinations were to be made in light of knowledge possessed by relevant persons skilled in the art under the specific auspices of §103 of the 1952 *Patent Act*:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title (novelty), 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.<sup>157</sup>

Thus, as in Canadian patent law, the lens through which the judiciary must gaze when determining whether the invention was a patentable advance over the relevant prior art was that of the person having ordinary skill in the art, typically referred to in American legal commentary as the PHOSITA. However, counsel for KSR and numerous *amicus curiae*, including the United States Solicitor General and Twenty Four Intellectual Law Professors (“Law Professors”), claim that the Federal Circuit has retreated from the *John Deere* factors, replacing them instead with a more stringent and inflexible test requiring that a specific “suggestion, teaching or motivation” to combine the relevant prior art teachings in the manner claimed *must* be demonstrated to support a finding of obviousness.<sup>158</sup> This is analogous to Canadian courts adopting the more stringent test in the context of testing. As noted by one prominent patent scholar,<sup>159</sup> this has resulted in the gradual marginalization of persons skilled in the art in obviousness cases generally, leaving room for considerable judicial review of lower court findings of fact based on a less deferential standard of review.<sup>160</sup>

The requirement to find in evidence such a specific piece of prior art contravenes the Supreme Court’s direction in *John Deere* toward applying a “functional approach” articulated by the court earlier in *Hotchkiss v. Greenwood*.<sup>161</sup> As noted by Justice Clark in *John Deere*, the *Hotchkiss* formulation, “lies not in any label, but in its functional approach to questions of patentability”.<sup>162</sup> In practice, *Hotchkiss* has required a comparison

between the subject matter of the patent, or patent application, and the background skill of the calling. It has been from this comparison that patentability was in each case determined. As such, *Hotchkiss* and the pragmatic approach advocated in Part IV(a) *supra* share a basic focus on the essence of an invention and the manner in which it came to be. Another point of convergence is that the law is to be applied in a contextual manner on a case-by-case basis. As is true of obvious determinations in Canada and the United Kingdom,<sup>163</sup> the United States Supreme Court was mindful of the burden on the judiciary in rendering such determinations. However, as in the United Kingdom (but not Canada) the court was clear that such difficulties were not unlike those encountered in any other type of case before the courts:

This is not to say, however, that there will not be difficulties in applying the nonobviousness test. What is obvious is not a question upon which there is likely to be uniformity of thought in every given factual context. The difficulties, however, are comparable to those encountered daily by the courts in such frames of reference as negligence and *scienter*, and should be amenable to a case-by-case development. We believe that strict observance of the requirements laid down here will result in that uniformity and definiteness which Congress called for in the 1952 Act.<sup>164</sup>

Despite the clarity of the decisions in *Hotchkiss* and *John Deere*, it is claimed<sup>165</sup> that the Federal Circuit has minimized the role of persons skilled in the art in the obviousness analysis through the assumption,<sup>166</sup> paralleled in Canadian jurisprudence, that such persons are incapable of innovation and inventiveness, and by viewing obviousness as a question of law rather than one of fact.<sup>167</sup> As in Canadian cases where the judiciary recite law standing for the proposition that no testing is allowed but then find that the testing undertaken was in fact non-inventive, the Federal Circuit's jurisprudence on obviousness has apparently created a similar type of double standard in the law by reciting the importance of persons skilled in the art to the obviousness analysis, then not depending on the skills or knowledge of such persons when rendering decisions.<sup>168</sup> As claimed by the Solicitor General and the Law Professors in their respective briefs, this has resulted in a substantial lowering of the bar for patentability, with a concomitant diminution in new discoveries and foreclosure of competitors' use of knowledge that would otherwise be in the public domain.<sup>169</sup> This is reminiscent of the discussion by the Supreme Court of Canada in *Free World Trust* of the effect of an improperly defined patent scope to create an undue "commercial risk zone" for competitors discussed *supra*.

The Federal Circuit has historically justified the relatively inflexible teaching-suggestion approach based on the effort to avoid hindsight analysis, whereby persons skilled in the art use the hindsight of prior art disclosed after the priority date when analyzing the alleged invention at the time of the claim date. Hindsight is a difficult problem to be sure, and was part of the reason for Justice Hugessen's claim in *Beloit* that the obviousness test "is

very difficult to satisfy".<sup>170</sup> It will be recalled that the same concern was articulated by Justice Lederman in *Bayer* as grounds for the no testing/worth a try approach and the could/would distinction. As noted by the Solicitor General in its *Teleflex* brief, however, the strict test articulated by the Federal Circuit constricts the test laid down by the Supreme Court in *John Deere*, which calls for a flexible approach to obviousness. The Federal Circuit's test thus "fails to account for the problem-solving abilities of persons of ordinary skill in the art" and "underestimates the capabilities of courts and patent examiners to 'resist the temptation' of hindsight and to consider fairly the question of obviousness".<sup>171</sup> As noted by Justice Clark in *John Deere*, the "ultimate question" of patent validity rests on the judgment, informed by relevant facts on a case-by-case basis, of whether a person of ordinary skill in the art would have found the invention as a whole obvious.<sup>172</sup> This echoes the more flexible and purposive approach taken by Justice Gibson and Lord Mustill in their *BMS v. Novopharm* and *Genentech* decisions, respectively.

The test articulated by the Federal Circuit does further violence to the scope of obviousness as it conflates it into that for anticipation. As noted by the Law Professors, the obviousness requirement asks of the court to determine *not* what is already present in the prior art as of the claim date, but rather whether a person skilled in the art would deem the subject matter obvious in light of whatever prior art exists as of the claim date.<sup>173</sup> In contrast, the Federal Circuit's teaching-suggestion approach requires the prior art to contain a particularized suggestion, teaching, or motivation to ground a finding of obviousness: if no such specific suggestion, teaching, or motivation is put in evidence, then the invention must be deemed nonobvious. This is clearly contrary to the United States Supreme Court's ruling in *John Deere*, leading the Solicitor General to recommend that KSR's petition for writ of *certiorari* be granted. It is again reminiscent of arguments made above in the context of Professor Fox's legal commentary that the stringent standard for obviousness differs little from that for anticipation under current Canadian law with regard to testing.

A final important issue arising out of *Teleflex* is the distinction between inventive and non-inventive (or mechanical) testing. In its *John Deere* decision, the United States Supreme Court made comments regarding the role of persons skilled in the art relating to "routine testing" that are pertinent to the analysis of cases under the *NOC Regulations*. As noted *supra*, the court looked to its previous decision in *Hotchkiss* to interpret the proper scope of obviousness following its codification in the United States *Patent Act* in 1952. In *Hotchkiss*, the court grappled with developing legal means of facilitating the public disclosure of inventions that would not otherwise be disclosed or created but for the inducement of the patent monopoly. The court held:

Unless more ingenuity and skill ... were required ... than were possessed by an ordinary mechanic acquainted with the business, there was an absence of that degree of skill and ingenuity which constitute essential elements of every invention. In other words, the improvement is the work of the skillful mechanic, not that of the inventor.<sup>174</sup>

A patent is therefore granted to an inventor who goes beyond the level of skill of “an ordinary mechanic”. The reasoning in *Hotchkiss*, as in Canadian decisions released somewhat contemporaneously (*Lightning Fastener* and *Burns & Russell*) is clearly pragmatic in nature and aimed at the essential nature of the inventive activity in each case. It will be recalled that Justice Gibson’s decision was applied subsequently in the AZT trial decision<sup>175</sup> and in other cases employing the more flexible standard when terms such as “mechanical”, “routine”, and “incremental” testing have been employed. As noted by the United States Supreme Court in *John Deere*, *Hotchkiss* has had enormous implications for American patent law.<sup>176</sup>

Regarding the issue of who makes the decision as to whether or not an invention is the work of a skillful mechanic or an inventor, the court was clear that it was to be relevant persons skilled in the art. This determination is to be made on a case-by-case basis, giving rise to the “functional approach” to patentability advocated by the Solicitor General in its *amicus curiae* brief. In *John Deere*, it was disputed by several parties that the requirement for obviousness under §103 was specifically inserted by amendment to the United States *Patent Act* in 1952 to overrule previous considerations of what constitutes “the flash of inventive genius”,<sup>177</sup> and thus to specifically lower the bar for obviousness.<sup>178</sup> The court rejected this claim however, holding that the language in *Cuno* referring to inventive genius was nothing other than “rhetorical embellishment” and did not create a differing standard. Rather, the court’s previous decision in *Cuno* stood for the continuing proposition that non-obvious subject matter is subject matter that extends “beyond the skill of the calling”.<sup>179</sup> These are the exact words of Justice Gibson in *Burns & Russell*. This concept was also picked up on by the Solicitor General in its *Teleflex* brief, as well as by the Law Professors in their *Teleflex* brief.<sup>180</sup> The Law Professors extended this notion specifically to litigation involving biomedical technologies. In particular, they claimed that “methodological advances provided an obvious path to new results that should not themselves be patentable”, and that the Federal Circuit has sufficiently minimized the role of persons skilled in the art that it routinely applies the obviousness test such that inventions are deemed to be nonobvious “even where the prior art demonstrates a clear path for producing the invention”.<sup>181</sup>

### (c) Summary

A purposeful approach to obviousness is advocated for cases under the *NOC Regulations*. The proposed approach focuses not on binary notions of testing/no

testing or would/could, but rather on the essence of inventive activity from the perspective of skilled persons in the art casting their mind back to the claim date. That is, was the experimenting or research that led up to the invention inventive or not? An approach which focuses on the essence or pith and marrow of such activity lends itself well to a legal test for obviousness that satisfies the constitutional requirement for fairness and predictability. Moreover, such a test has sufficient flexibility to be employed in a wide range of factual settings and would not be inherently biased to brand-name or generic pharmaceutical firms. Finally, a purposive construction would be in line with English appellate jurisprudence on obviousness, and calls for law reform in the United States.

## Part V: Application to Non-NOC Cases

Unlike parallel legislation in the United States, litigation under the *NOC Regulations* is by way of judicial review and does not constitute an action for infringement.<sup>182</sup> Judicial review under the *NOC Regulations* is considered to be an expedited proceeding and thus summary in nature. It does not entail a full determination of validity or exploration of evidentiary matters that would otherwise be before the court in an infringement proceeding.<sup>183</sup> Therefore, formal conclusions on patent validity cannot be determined in litigation under the *NOC Regulations*, notwithstanding that judicial reasoning and pronouncements on the issue of validity may parallel those in actions under sections 55 (infringement) or 60 (impeachment) of the Act. The object of litigation under the *NOC Regulations* is solely to prohibit the issuance of a NOC under the *Food and Drug Regulations*,<sup>184</sup> if a party desires a formal decision on the issue of invalidity, they must avail themselves of remedies under the Act.<sup>185</sup> Under this reasoning, applied recently in a post-NOC infringement action,<sup>186</sup> the law of obviousness would not be applicable to cases outside the *NOC Regulations*.

While operation of the *NOC Regulations* entails the odd result of a determination of validity which is only enforced within the ambit of the regulations themselves, it is clear from the common law and the addition of section 28.3 to the Act in 1996 that determinations of validity generally are to be made through the lens of persons skilled in the art in light of all of the relevant prior art available as of the claim date. In addition, both hurdles over which generic firms must jump (Fox’s injunction against testing *per se* and the “no scintilla” cases) in order to obtain a finding of invalidity, and their application to pharmaceutical cases generally, are outside the rubric of the *NOC Regulations*. Indeed, the judiciary have made no attempt to discriminate between the two streams of case law in rendering decisions under the *NOC Regulations*. Finally, jurisprudence and legal scholarship from the United States and the United Kingdom are outside the scope of the Regulations, yet apply to the issue at hand through the identity and inventive capacity

of persons skilled in the art. Thus, there is no reason why application of arguments made here regarding the role of scientific testing in the lead-up period to an invention in the obviousness analysis can not be extended to litigation beyond the *NOC Regulations*.

A note of caution in this regard is the recent infringement opinion of Justice Hughes in *Janssen-Ortho v. Novopharm*.<sup>187</sup> In this case it was held that even though a prior decision under the *NOC Regulations* found Novopharm's allegation that the impugned claims were invalid on grounds of obviousness was justified, the same claims were held to be valid and infringed in the context of subsequent infringement litigation.<sup>188</sup> Justice Hughes arrived at his decision based on his finding that an action under the *NOC Regulations* does not constitute *res judicata* in subsequent infringement litigation.<sup>189</sup> It remains to be seen whether this decision will withstand appellate scrutiny.

## V. Summary and Conclusions

The purpose of this article was to analyze Canadian case law on obviousness pertaining to scientific research and testing leading up to invention under the *NOC Regulations*, and to highlight confusion in the courts and the manner in which the judiciary have attempted to grapple with the issue of testing in the obviousness analysis. Some decisions were found to stand for the proposition that no experimenting or research whatsoever is allowed, while other cases stand for the opposite proposition that significant testing does not vitiate the obviousness attack, while still others purport to use the former standard while actually applying the latter. Thus, there is significant confusion in Canadian case law on obviousness under the *NOC Regulations*.

An analysis of the historical cases cited by Professor Fox in his injunction against experimentation, thought, or research in the lead-up to invention does not support the "no testing" approach to obviousness. Indeed, analysis of this body of case law, along with decisions released contemporaneously but not cited by Fox, reveal that in fact extensive testing is routinely undertaken by persons skilled in the art of pharmaceutical research, and that courts had allowed such testing without vitiating a finding of obviousness. This discrepancy was demonstrated clearly by evidence adduced in an early *Sherwin-Williams*<sup>190</sup> chemical case, as well as in later cases involving pharmaceuticals both outside of and under the umbrella of the *NOC Regulations*.

A lack of clear and definitive guidance by the courts has resulted in considerable arbitrariness, uncertainty, and a lack of predictability in the case law. It was argued that this runs afoul of the direction of the Supreme

Court of Canada that patent law should lend a degree of certainty and predictability to potential litigants and provide them with fair notice of when they can reasonably expect to infringe the intellectual property rights of others. Moreover, courts have adopted reasoning in the obviousness analysis that inherently, and thus unfairly, biases the legal test in favour of patentees. The result is that generic pharmaceutical firms often lose cases improperly on the issue of obviousness, in turn maintaining dominant market positions for brand-name firms and monopolistic pricing on products that have often come off patent on the original new chemical entity. As such, it was argued the current test creates an improperly expanded "risk zone" for both the public and generic firms.

In addition, setting the threshold for scientific testing to a *de minimus* level has the effect of placing an unfair evidentiary burden on generic pharmaceutical companies to prove invalidity within the context of a regulatory system that the Supreme Court of Canada has often referred to as "Draconian".<sup>191</sup> This burden is onerous under conditions where the legal test departs from the policy objective underpinning the *NOC Regulations* to balance the interests of brand-name and generic pharmaceutical companies. Indeed, both government policy documents and Supreme Court of Canada jurisprudence clearly indicate concern for balancing the interests of both parties under the *NOC Regulations*. The same concerns have been expressed in the United States, which, ironically, given its strong innovation agenda and pharmaceutical presence has undertaken significant reforms to its linkage regime in order to facilitate precisely such a balance. It is submitted that the lack of a clear, consistent, and appropriate test for obviousness represents a departure from maintaining an appropriate balance between the various private and public actors involved in the commercialization, regulation, and consumption of pharmaceutical products in Canada.

Finally, a suggestion was made toward a fair, unequivocal, and predictable test which has its locus in Canadian law, federal policy underlying the *NOC Regulations*, and Supreme Court of Canada jurisprudence in its leading patent decisions. The proposed "purposive construction" of obviousness focuses contextually on whether or not experimentation or research conducted in the lead-up to invention was inventive, rather than focusing on binary notions of testing/no testing or could/would. It provides a test that is fair and flexible for all parties to litigation, is wholly consistent with appellate jurisprudence, and which calls for law reform in other jurisdictions with similar patent legislation and policy.

## VI. Appendix 1

**Table 1. Summary of cases supporting the “no testing” approach to obviousness**

Case, Judge	NOC Cases Precedent(s) Cited, Notes	Non-NOC Cases Precedent(s) Cited, Notes
<b>A. Trace to Fox</b>		
<i>Abbott v. Canada</i> <sup>†</sup> 2006 FC 69 Campbell J.	No Testing: <i>Procter &amp; Gamble v. Canada</i> (2004), 32 C.P.R. (4th) 224 at para. 36 (F.C.T.D.); <i>Procter &amp; Gamble Inc. v. Canada</i> (2004), 37 C.P.R. (4th) 289 at paras. 43–47 (C.A.); <i>AB Hassle v. Genpharm Inc.</i> , (2003) F.C.J. No. 1910 (QL). Claims valid — MOH prohibited from issuing NOC (clarithromycin).	
<i>Pfizer v. Canada</i> 2005 FC 1205 Heneghan J.	No Testing: <i>Bayer v. Apotex</i> , [1995] O.J. No. 141 (Ont. Gen. Div.) (QL). Claims not obvious. Patent invalid on other grounds. (quinapril)	
<i>Pfizer v. Novopharm</i> 2005 FC 1299 Blanchard J.	No Testing: <i>Apotex/Novopharm v. Wellcome</i> , [1998] F.C.J. No. 382. Claims valid — MOH prohibited from issuing NOC (azithromycin)	
<i>Sanofi-Synthalebo v. Apotex</i> 2005 FC 390 Shore J.	No Testing: <i>Bayer v. Apotex</i> , [1995] O.J. No. 141 (Ont. Gen. Div.) (QL); <i>Cabot Corp. v. 318062 Ont. Ltd</i> (1988), 20 C.P.R. (3d) 132; <i>Farbwerke Hoescht Aktiengesellschaft v. Halocarbon (Ontario) Ltd.</i> (1979), 42 C.P.R. (2d) 145 (S.C.C.); Harold Fox, <i>Canadian Law and Practice Relating to Letters Patent for Inventions</i> , 4th ed. (Toronto: Carswell, 1969). Claims valid — MOH prohibited from issuing NOC (clopidogrel)	
<i>Procter &amp; Gamble v. Canada</i> 2004 FC 204 Snider J.	No Testing: <i>Smithkline Beecham v. Apotex</i> , 2001 FCT 770; <i>Bayer v. Apotex</i> , [1995] O.J. No. 141 (Ont. Gen. Div.); <i>Farbwerke Hoescht Aktiengesellschaft v. Halocarbon (Ontario) Ltd.</i> (1979), 42 C.P.R. (2d) 145 (S.C.C). Claims valid — MOH prohibited from issuing NOC. (etidronate)	
<i>AB Hassle v. Genpharm</i> 2003 FC 1443 Layden-Stevenson J.	No Testing: <i>Pfizer v. Apotex</i> , 2002 FCT 1138; <i>Bayer v. Apotex</i> , [1995] O.J. No. 141 (Ont. Gen. Div.) (QL); <i>Cabot Corp. v. 318062 Ont. Ltd.</i> (1988), 20 C.P.R. (3d) 132; Harold Fox, <i>Canadian Law and Practice Relating to Letters Patent for Inventions</i> , 4th ed. (Toronto: Carswell, 1969). Claims valid — MOH prohibited from issuing NOC. (omeprazole)	
<i>671905 Alberta v. Q'Max Solutions</i> 2003 FCA 241 Stone J.A.		No Testing: <i>Bayer v. Apotex</i> , [1995] O.J. No. 141 (Ont. Gen. Div.) (QL). Note: FCA said first that no patent ensues where mechanical testing is involved, citing <i>Lightning Fastener v. Colonial Fastener</i> , [1933] S.C.R. 371 and FCA decision in <i>Apotex v. Wellcome</i> , [2000] 10 C.P.R. (4th) 65. However, trial judge was guided by the decision in <i>Bayer</i> , that expert evidence was adduced at trial that the inventions were not obvious, and that appeal courts should not interfere in the absence of a palpable and over-riding error, citing FCA decisions in <i>Apotex v. Wellcome</i> , (2000) 10 CPR (4th) 65 and <i>Creations v. Canper Industrial Products</i> , (1990) 34 CPR (3d) 178. Claims valid and infringed. Appeal dismissed. (drilling machine)
<i>Baker PetroLite v. Canwell</i> 2001 FCT 889 Gibson J.		No Testing: <i>Bayer v. Apotex</i> , [1995] O.J. No. 141, 60 C.P.R. (3d) 58 (Ont. Gen. Div.); <i>Cabot Corp. v. 318062 Ont. Ltd</i> [1988], 20 C.P.R. (3d) 132; Harold Fox, <i>Canadian Law and Practice Relating to Letters Patent for Inventions</i> , 4th ed. (Toronto: Carswell, 1969). Claims valid and infringed. Appeal dismissed 2002 FC 3 (FCA). (hydrocarbon sweetening process)

<i>Smithkline Beecham v. Apotex</i> 2001 FCT 770 Gibson J.	No Testing: <i>Bayer v. Apotex</i> , [1995] O.J. No. 141, 60 C.P.R. (3d) 58 (Ont. Gen. Div.); <i>Takach</i> 1993; <i>Cabot Corp. v. 318062 Ont. Ltd.</i> (1988), 20 C.P.R. (3d) 132; Harold Fox, <i>Canadian Law and Practice Relating to Letters Patent for Inventions</i> , 4th ed. (Toronto: Carswell, 1969). Claims valid. Application dismissed on other grounds — anticipation. (paroxetine)	
<i>Apotex v. Wellcome</i> [1998] FCJ No. 382 (QL) Wetston J.		No Testing: <i>Bayer v. Apotex</i> , [1995] O.J. No. 141 (Ont. Gen. Div.) (QL); <i>Takach</i> 1993; <i>Farbwerke Hoescht Aktiengesellschaft v. Halocarbon (Ontario) Ltd.</i> (1979), 42 C.P.R. (2d) 145 (S.C.C.); Harold Fox, <i>Canadian Law and Practice Relating to Letters Patent for Inventions</i> , 4th ed. (Toronto: Carswell, 1969). Claims (in part) valid and infringed. Action for declaration of invalidity dismissed. Upheld on appeal [2001] 1 F.C. 495 (F.C.A.), aff'd (2002) 4 S.C.R. 153. (AZT)
<i>Bayer v. Apotex</i> [1995] O.J. No. 141 (QL) Lederman J.		No Testing: <i>Cabot Corp. v. 318062 Ont. Ltd.</i> (1988), 20 C.P.R. (3d) 132; Harold Fox, <i>Canadian Law and Practice Relating to Letters Patent for Inventions</i> , 4th ed. (Toronto: Carswell, 1969); <i>Diversified Products Corp. v. Tye-Sil Corp.</i> (1991), 35 C.P.R. (3d) 350 (F.C.A.); <i>Beloit Canada Ltd. v. Valmet OY</i> (1986), 8 C.P.R. (3d) 289 (F.C.A.); <i>Farbwerke Hoescht Aktiengesellschaft v. Halocarbon (Ontario) Ltd.</i> (1979), 42 C.P.R. (2d) 145 (S.C.C.). Breach of compulsory license. Upheld on appeal: affirmed [2002] O.J. No. 193 (O.C.A.), appeal dismissed [1998] S.C.C.A. No. 563 (S.C.C.).
<i>Farbwerke v. Halocarbon</i> (1979) 42 C.P.R. (2d) 145 (S.C.C.) Pigeon J.		No Testing: Same 2 cases, along with Majority opinion by Pigeon, also include “testing and development” processes, citing: <i>Pope Appliance Corp. v. Spanish River Pulp and Paper Mills</i> , [1929] 1 D.L.R. 209; <i>CGE Co. v. Fada Radio</i> , [1930] 1 D.L.R. 449. Note: Significant minority (3 of 7) disagreed, saying invention was more or less verification
<b>B. Trace to No Scintilla</b>		
<i>Pfizer v. Canada</i> 2005 FC 1205 Heneghan J.	No Scintilla: <i>Farbwerke Hoescht Aktiengesellschaft v. Halocarbon (Ontario) Ltd.</i> (1979), 42 C.P.R. (2d) 145 (S.C.C.).	
<i>Pfizer v. Canada</i> 2005 FC 1421 Mosley J.	No Scintilla: <i>Farbwerke Hoescht Aktiengesellschaft v. Halocarbon (Ontario) Ltd.</i> (1979), 42 C.P.R. (2d) 145 (S.C.C.)	
<i>Aventis v. Apotex</i> 2005 FC 1504 Tremblay-Lamer J.	No Scintilla: <i>Diversified Products Corp. v. Tye-Sil Corp.</i> (1991), 35 C.P.R. (3d) 350 (F.C.A.).	
<i>Janssen-Ortho v. Novopharm</i> 2004 FC 1631 Mosley J.	No Scintilla: <i>Farbwerke Hoescht Aktiengesellschaft v. Halocarbon (Ontario) Ltd.</i> (1979), 42 C.P.R. (2d) 145 (S.C.C.).	
<i>Procter &amp; Gamble v. Canada</i> 2004 FC 204 Snider J.	No Scintilla: <i>Diversified Products Corp. v. Tye-Sil Corp.</i> (1991), 35 C.P.R. (3d) 350 (F.C.A.); <i>Farbwerke Hoescht Aktiengesellschaft v. Halocarbon (Ontario) Ltd.</i> (1979), 42 C.P.R. (2d) 145 (S.C.C.).	
<i>AB Hassle v. Genpharm</i> 2003 FC 1443 Layden-Stevenson J.	No Scintilla: <i>Farbwerke Hoescht Aktiengesellschaft v. Halocarbon (Ontario) Ltd.</i> (1979), 42 C.P.R. (2d) 145 (S.C.C.)	
<i>Pfizer v. Apotex</i> (2002) 22 C.P.R. (4th) 466 (F.C.C.) Dawson J.	No Scintilla: <i>Farbwerke Hoescht Aktiengesellschaft v. Halocarbon (Ontario) Ltd.</i> (1979), 42 C.P.R. (2d) 145 (S.C.C.)	
<i>Diversified Products v. Tye-Sil</i> (1991) 35 C.P.R. (3d) 350 (F.C.A.) Decary J.		No Scintilla: <i>Samuel Parkes v. Cocker Bros.</i> , [1929] 46 R.P.C. 241; <i>Canada v. Uhlemann Optical</i> , [1952] 1 S.C.R. 143

<i>Farbwerke v. Halocarbon</i> † (1979), 42 C.P.R. (2d) 145 (S.C.C.) Pigeon J.		No Scintilla: <i>Pope Appliance Corp. v. Spanish River Pulp and Paper Mills</i> , [1929] 1 D.L.R. 209; <i>CGE Co. v. Fada Radio</i> , [1930] 1 D.L.R. 449.
<i>Scragg v. Leeson</i> † [1964] Ex. C.R. 649 Thorson J.		No Scintilla: <i>Samuel Parkes v. Cocker Bros.</i> , [1929] 46 R.P.C. 241; <i>Non-Drip Measure v. Strangers</i> , [1943] 60 R.P.C. 135; <i>Cleveland Graphite v. Glacier Metal</i> [1950] 67 R.P.C. 149; <i>Martin and Brio Swan v. Millwood</i> , [1956] R.P.C. 125

†Deals directly with the issue of testing

**Table 2. Summary of cases supporting some degree of testing in the obviousness analysis**

Case, Judge	NOC Cases Precedent(s) Cited, Notes	Non-NOC Cases Precedent(s) Cited, Notes
<i>Janssen-Ortho v. Novopharm</i> † 2006 FC 1234 Hughes J.		Yes Testing. Factors (primary and secondary) laid out in a new test. Grafts <i>Whirlpool Corp. v. Camco Inc.</i> , [2000] 2 S.C.R. 1067 (diligent in keeping up) onto <i>Beloit Canada Ltd. v. Valmet OY</i> (1986), 8 C.P.R. (3d) 289 (F.C.A.). Explicitly rejects such terms as “worth a try” and “routine testing”. The length of time and expenses are irrelevant. Inventive effort is at the core. Stipulates that tests are different under NOC Regs and infringement — “justification” has a different standard. Acknowledges, that court must weigh all factors and make a decision. Based on evidence, impugned claim is valid and infringed. (levofloxacin)
<i>BMS v. Novopharm</i> † 2005 FC 1458 Gibson J.	Yes Testing: <i>Pfizer v. Apotex</i> , 2002 FCT 1138; <i>Janssen-Ortho v. Novopharm</i> , 2004 FC 1631; <i>Apotex/Novopharm v. Wellcome</i> , [1998] F.C.J. No. 382. Note: Based on evidence, finds for Applicant. Claims valid — MOH prohibited from issuing NOC. (gatifloxacin)	
<i>Aventis Pharma v. Apotex</i> 2005 FC 1504 Tremblay-Lamer J.	Yes Testing: <i>Janssen-Ortho v. Novopharm</i> , 2004 FC 1631; <i>Apotex/Novopharm v. Wellcome</i> , [1998] F.C.J. No. 382. Claims invalid — Application dismissed. (ramipril)	
<i>Pfizer Canada Inc. v. Apotex Inc.</i> 2005 FC 1421 Mosley J.	Yes Testing: Statement (at 131) favouring routine experimentation as long as it is not undue testing. Claims invalid — Application dismissed. (azithromycin)	
<i>Janssen-Ortho v. Novopharm</i> 2004 FC 1631 Mosley J.	Yes Testing: <i>Pfizer v. Apotex</i> , 2002 FCT 1138; <i>Apotex/Novopharm v. Wellcome</i> , [1998] F.C.J. No. 382. Claims invalid — Application dismissed. (levofloxacin)	
<i>Glaxosmithkline v. Canada</i> 2003 FC 899 Noël J.  <i>Glaxosmithkline v. Canada</i> 2004 FC 116 Noël J.	Yes Testing: <i>Apotex/Novopharm v. Wellcome</i> , [1998] F.C.J. No. 382. Claims invalid — Application dismissed. (carvedilol)	
<i>Pfizer v. Apotex</i> (2002) 22 C.P.R. (4th) 466 (F.C.C.) Dawson J.	Yes Testing: <i>Apotex/Novopharm v. Wellcome</i> , [1998] F.C.J. No. 382. Note: court also said that a PSA is a paragon of deduction and dexterity (Beloit) and also reasonably diligent in keeping up with advances in the field: <i>Whirlpool Corp. v. Camco</i> [2000] 2 S.C.R. 1067 at para. 74. Claims invalid — Application dismissed. (sertaline)	
<i>Novartis v. Apotex</i> 2001 FCT 1129 Blais J.	Yes Testing: <i>Apotex/Novopharm v. Wellcome</i> , [1998] F.C.J. No. 382, but mainly Genentech Inc.’s Patent, [1989] R.P.C. 147 (C.A.) and an article by John Bochnovic in 1994. Claims invalid — Application dismissed. (cyclosporin)	

<i>Apotex v. Hoffmann-La Roche</i> (1987) 15 C.P.R. (3d) 217 Reed J.		Yes Testing: Testing was not inventive. It was routine: <i>Beloit Canada Ltd. v. Valmet OY</i> (1986), 8 C.P.R. (3d) 289 (F.C.A.); <i>Windsurfing International Inc. v. Trilantic Corp.</i> , (1985) 8 C.P.R. (3d) 241 (F.C.A.). Application for declaration patent was invalid allowed. (sulphonamide trimethoprim)
<i>Burns &amp; Russell Canada v. Day</i> (1965) 48 C.P.R. 207 (Ex. Ct.) Gibson J.		Yes Testing: Testing is allowable provided it is not “beyond the expected skill of the calling” or “beyond the skill of the routineer”. Sees as extension of Cripps question. Infringement action dismissed and counterclaim for invalidity allowed. (masonry-coating)
<i>Canadian Industries v. Sherwin-Williams</i> (1964) Ex. C.R. 65 Angers J.		Yes Testing: Mechanical testing by skilled workshop worker is not inventive. (resinous condensation products)
<i>Lightning Fastener v. Colonial Fastener</i> [1933] S.C.R. 371 Rinfret J.		Yes Testing: Exercise of mechanical skill does not equate with exercise of inventive faculty and does not deserve a patent monopoly: <i>Durable Electric Appliance v. Renfrew Electric Products</i> , [1928] S.C.R. 8; <i>Atlantic Works v. Brady</i> , 107 U.S. 192 (2002). Appeal of action for infringement dismissed. (slide fasteners)
<i>Pope Appliance v. Spanish River Pulp and Paper</i> [1927] Ex. C.R. 29 Maclean P.		Yes Testing: The exercise of mechanical skill, including experimenting, does not amount to a patentable invention where such experiments are not inventive.

†Deals directly with the issue of testing

**Table 3. Summary of cases purporting to apply the stringent standard but actually applying the flexible test for obviousness**

Case, Judge	NOC Cases Precedent(s) Cited, Notes	Non-NOC Cases Precedent(s) Cited, Notes
<b>I. Testing Allowed</b>		
<i>Aventis v. Apotex</i> 2005 FC 1504 Tremblay-Lamer J.	Yes Testing: <i>Janssen-Ortho v. Novopharm</i> , 2004 FC 1631; <i>Apotex/Novopharm v. Wellcome</i> , [1998] F.C.J. No. 382. No Testing: <i>Sanofi-Synthalebo v. Apotex</i> , 2005 FC 390; <i>Diversified Products Corp. v. Tye-Sil Corp.</i> (1991), 35 C.P.R. (3d) 350 (F.C.A.). Claims invalid — Application dismissed. (ramipril)	
<i>Pfizer Canada Inc. v. Apotex Inc.</i> 2005 FC 1421 Mosley J	Yes Testing: Statement (at 131) favouring routine experimentation as long as not undue testing. No Testing: <i>Apotex/Novopharm v. Wellcome</i> , [1998] F.C.J. No. 382; <i>Bayer</i> 1995; <i>Farbwerke Hoescht Aktiengesellschaft v. Halocarbon (Ontario) Ltd.</i> (1979), 42 C.P.R. (2d) 145 (S.C.C.); Harold Fox, <i>Canadian Law and Practice Relating to Letters Patent for Inventions</i> , 4th ed. (Toronto: Carswell, 1969). Claims invalid — Application dismissed. (azithromycin)	
<i>Janssen-Ortho v. Novopharm</i> 2004 FC 1631 Mosley J.	Yes Testing: <i>Pfizer v. Apotex</i> , 2002 FCT 1138; <i>Apotex/Novopharm v. Wellcome</i> , [1998] F.C.J. No. 382. No Testing: <i>Bayer v. Apotex</i> , [1995] O.J. No. 141 (Ont. Gen. Div.) (QL); <i>Farbwerke Hoescht Aktiengesellschaft v. Halocarbon (Ontario) Ltd.</i> (1979), 42 C.P.R. (2d) 145 (S.C.C.). Claims invalid — Application dismissed. (levofloxacin)	

<p><i>Glaxosmithkline v. Canada</i> 2003 FC 899 Noël J. <i>GlaxoSmithKline v. Canada</i> 2004 FC 116 (FCC) Noël J.</p>	<p>Yes Testing: <i>Apotex/Novopharm v. Wellcome</i>, [1998] F.C.J. No. 382. No Testing: <i>Bayer v. Apotex</i>, [1995] O.J. No. 141 (Ont. Gen. Div.) (QL); <i>Cabot Corp. v. 318062 Ont. Ltd</i> (1988), 20 C.P.R. (3d) 132; <i>Takach</i> 1993; Harold Fox, <i>Canadian Law and Practice Relating to Letters Patent for Inventions</i>, 4th ed. (Toronto: Carswell, 1969). Claims invalid — Application dismissed. (carvedilol)</p>	
<p><i>Pfizer v. Apotex</i> (2002) 22 C.P.R. (4th) 466 Dawson J.</p>	<p>Yes Testing: <i>Apotex/Novopharm v. Wellcome</i>, [1998] F.C.J. No. 382. No Testing: <i>Bayer v. Apotex</i>, [1995] O.J. No. 141 (Ont. Gen. Div.) (QL); <i>Cabot Corp. v. 318062 Ont. Ltd</i> (1988), 20 C.P.R. (3d) 132; Harold Fox, <i>Canadian Law and Practice Relating to Letters Patent for Inventions</i>, 4th ed. (Toronto: Carswell, 1969); <i>Diversified Products Corp. v. Tye-Sil Corp.</i> (1991), 35 C.P.R. (3d) 350 (F.C.A.); <i>Beloit Canada Ltd. v. Valmet OY</i> (1986), 8 C.P.R. (3d) 289 (F.C.A.); <i>Farbwerke Hoescht Aktiengesellschaft v. Halocarbon (Ontario) Ltd.</i> (1979), 42 C.P.R. (2d) 145 (S.C.C.). Claims invalid — Application dismissed. (sertraline)</p>	
<p><i>Novartis v. Apotex</i> 2001 FCT 1129 Blais J.</p>	<p>Yes Testing: <i>Apotex/Novopharm v. Wellcome</i>, [1998] F.C.J. No. 382; <i>Genentech Inc.'s Patent</i>, [1989] R.P.C. 147 (C.A.); Bochnovic 1994 article. No Testing: <i>Bayer v. Apotex</i>, [1995] O.J. No. 141 (Ont. Gen. Div.) (QL); <i>Cabot Corp. v. 318062 Ont. Ltd</i> (1988), 20 C.P.R. (3d) 132; <i>Beloit Canada Ltd. v. Valmet OY</i> (1986), 8 C.P.R. (3d) 289 (F.C.A.); Harold Fox, <i>Canadian Law and Practice Relating to Letters Patent for Inventions</i>, 4th ed. (Toronto: Carswell, 1969). Claims invalid — Application dismissed. (cyclosporin)</p>	
<b>I. No Testing Allowed</b>		
<p><i>Smithkline Beecham v. Apotex</i> 2001 FCT 770 Gibson J.</p>	<p>No Testing: <i>Bayer v. Apotex</i>, [1995] O.J. No. 141 (Ont. Gen. Div.) (QL); <i>Takach</i> 1993; <i>Cabot Corp. v. 318062 Ont. Ltd</i> (1988), 20 C.P.R. (3d) 132; Harold Fox, <i>Canadian Law and Practice Relating to Letters Patent for Inventions</i>, 4th ed. (Toronto: Carswell, 1969). Yes Testing: Can turn to a logical first step, including testing, and still not have inventive testing. Note: This analysis was for anticipation. Obviousness failed on same grounds. Claims valid — Application dismissed on other grounds (anticipation).</p>	
<p><i>Apotex v. Wellcome</i> [1998] F.C.J. No. 382 Wetston J.</p>		<p>No Testing: <i>Bayer v. Apotex</i>, [1995] O.J. No. 141 (Ont. Gen. Div.) (QL); <i>Takach</i> 1993; <i>Farbwerke Hoescht Aktiengesellschaft v. Halocarbon (Ontario) Ltd.</i> (1979), 42 C.P.R. (2d) 145 (S.C.C.); Harold Fox, <i>Canadian Law and Practice Relating to Letters Patent for Inventions</i>, 4th ed. (Toronto: Carswell, 1969). Yes Testing: <i>Burns &amp; Russell v. Day</i>, [1967] 48 C.P.R. 207 (Ex. Ct.); <i>Genentech Inc.'s Patent</i>, [1989] R.P.C. 147 (C.A.); <i>Leithiser et al. v. Pengo Hydra-Pull of Canada Ltd.</i> (1974), 17 C.P.R. (2d) 110 (F.C.A.). Claims (in part) valid and infringed. Action for declaration of invalidity dismissed. Upheld on appeal [2001] 1 F.C. 495 (F.C.A.); [2002] 4 S.C.R. 153. (AZT)</p>

## Notes:

<sup>1</sup> Gunar K. Gaikis, “Pharmaceutical patents in Canada. An update on compulsory licensing” (1992) 42 Patent World 19; Ed Hore, “A comparison of US and Canadian laws as they affect generic pharmaceutical drug entry” (1992) 55 Food & Drug LJ. 373; Donald G. McFetridge, “Intellectual property rights and the location of innovative activity: The Canadian experience with compulsory licensing of patented pharmaceuticals” (Working Paper for the NBER Summer Institute, 1997 (unpublished)).

<sup>2</sup> S.O.R./93-133.

<sup>3</sup> *Drug Price Competition and Patent Restoration Act 1984*, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 USC § 355 (2000)), commonly known as Hatch-Waxman. For an analysis of linkage regulations in the context of patent law generally, see Rebecca Eisenberg, “The shifting functional balance of patents and drug regulation.” (2001) 20 Health Affairs 119.

- <sup>4</sup> United States Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002), online: Federal Trade Commission <<http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>>; Andrew A. Caffrey & Jonathan M. Rotter, "Consumer protection, patents and procedure: Generic drug market entry and the need to reform Hatch-Waxman" (2004) 9 *Virg. J.L. & Tech.* 1.
- <sup>5</sup> *Patent Act*, R.S.C. 1985, c. P-4, s. 28.3. See *infra* note 8 for text.
- <sup>6</sup> *Beloit Canada Ltd. v. Valmet OY* (1986), 8 C.P.R. (3d) 289 at 294 (F.C.A.) [*Beloit*]; *Crosley Radio Corp. v. Canadian General Electric Co.*, [1936] S.C.R. 551 at 555-556 [*Crosley*]; *Beecham Canada Ltd. et al. v. Procter & Gamble Co.* (1982), 61 C.P.R. (2d) 1 at 27 (F.C.A.) [*Beecham*]; *Samuel Parkes & Co. Ltd. v. Crocker Bros. Ltd.* (1929), 46 R.P.C. 248 at 248. [Samuel Parkes]; *Martinray Industries v. Les Fabricants National Dagendor* (1991), 41 C.P.R. (3d) 1 at 30 (F.C.T.D.); *Canadian Gypsum Co. Ltd. v. Gypsum, Lime & Alabastine Canada Ltd.*, [1931] Ex. C.R. 180 at 187.
- <sup>7</sup> *Supra* note 6. See also, *Bayer Aktiengesellschaft v. Apotex Inc.*, [1995] O.J. No. 141, 60 C.P.R. (3d) 58 (Ont. Gen. Div.) (QL) [*Bayer* cited to QL], *aff'd* (2002) 16 C.P.R. (4th) 417, (2002) O.J. No. 193 (O.C.A.) (QL), leave to appeal to S.C.C. refused [1998] S.C.C.A. No. 563 (QL).
- <sup>8</sup> 2005 FC 1458 at paras. 70–74 [*BMS v. Novopharm*].
- <sup>9</sup> *Supra* note 5. Section 28.3 of the Act provides that
- 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.
- <sup>10</sup> Applications before 1989 continue to be subject to the common law requirement for obviousness.
- <sup>11</sup> *Canamould Extrusions Ltd. v. Driangle Inc.*, 2003 FCT 224 at para. 61.
- <sup>12</sup> Roger T. Hughes & John H. Woodley, *Hughes and Woodley on Patents*, looseleaf (Markham, ON: LexisNexis Butterworths, 2005) at §12.
- <sup>13</sup> *Beloit*, *supra* note 6 at 294-295.
- <sup>14</sup> According to Quicklaw, in the 20 years since it was released, *Beloit* has been mentioned in 87, followed in 17, and explained in 8 cases (June 28, 2006). *Beloit* was recently upheld by the Federal Court of Appeal in *Procter & Gamble Pharmaceuticals Canada Inc. v. Canada (Minister of Health)*, [2004] F.C.J. No. 1973 at para. 45 (QL) where in response to argument from counsel for Genpharm that the Supreme Court's decisions in *Whirlpool Corp. v. Camco Inc.*, [2000] 2 S.C.R. 1067 [*Whirlpool*] and the *Apotex Inc. v. Wellcome Foundation Ltd.*, [1998] F.C.J. No. 382, 79 C.P.R. (3d) 193 (QL) [*Apotex v. Wellcome*] AZT case lowered the standard for obviousness, Justice Rothstein stated he saw "nothing in *Whirlpool* that would make the test for obviousness less difficult to satisfy than that expressed in *Beloit*."
- <sup>15</sup> *SmithKline Beecham Pharma Inc. v. Apotex*, 2001 FCT 770 [*SmithKline Beecham*].
- <sup>16</sup> See data in Table 1.
- <sup>17</sup> Harold Fox, *Canadian Law and Practice Relating to Letters Patent for Inventions*, 4th ed. (Toronto: Carswell, 1969) at 70-71.
- <sup>18</sup> A search of Quicklaw (May 14, 2006) using key terms from the passage on obviousness turns up 570 hits mentioning Fox and 86 decisions quoting the above passage verbatim.
- <sup>19</sup> *Diversified Products Corp. v. Tye-Sil Corp.* (1991), 35 C.P.R. (3d) 350 (F.C.A.) [*Diversified*]; *Farbwerke Hoechst Aktiengesellschaft v. Halocarbon (Ontario) Ltd.* (1979), 42 C.P.R. (2d) 145 (S.C.C.) [*Farbwerke*]; *Ernest Scragg & Sons Ltd. v. Leesona Corp.*, [1964] Ex. C.R. 649 (QL) [*Ernest Scragg*] and references therein.
- <sup>20</sup> *Beloit*, *supra* note 6 at 294.
- <sup>21</sup> *Supra* note 7.
- <sup>22</sup> *Bayer*, *supra* note 7 at para. 56–59.
- <sup>23</sup> (1988), 20 C.P.R. (3d) 132 at 146 [*Cabot Corp.*].
- <sup>24</sup> *Bayer*, *supra* note 7 at para. 73.
- <sup>25</sup> *Bayer*, *supra* note 7 at paras. 61, 66. See also *Cabot Corp.*, *supra* note 23; *Fox*, *supra* note 17; *Diversified*, *supra* note 19; *Beloit*, *supra* note 6; *Farbwerke*, *supra* note 19.
- <sup>26</sup> *Diversified*, *supra* note 19; *Farbwerke*, *supra* note 19; *Ernest Scragg*, *supra* note 19 and references therein.
- <sup>27</sup> See e.g., *Samuel Parkes*, *supra* note 6 at 248; affirmed by Lord Russell of Killowen in *Non-Drip Measure Corp. Ltd. v. Strangers Ltd. et al.* (1943), 60 R.P.C. 135 at 143, Lord Normand in *Cleveland Graphite Bronze Corp. et al. v. Glacier Metal Corp. Ltd.* (1950), 67 R.P.C. 149 at 156, and by Lord Morton of Henryton in *Martin and Biro Swan Ltd. v. H. Millwood Ltd.* (1956), R.P.C. 125 at 139.
- <sup>28</sup> *Pope Appliance Corp. v. Spanish River Pulp & Paper Mills*, [1929] 1 D.L.R. 209 (P.C.) [*Pope Appliance P.C.*]; *CGE Co.Ltd. v. Fada Radio*, [1930] 1 D.L.R. 449 (P.C.); *Lightning Fastener v. Colonial Fastener*, [1933] S.C.R. 371 [*Lightning Fastener*]; *Ernest Scragg*, *supra* note 19; *Burns & Russell v. Day & Campbell*, [1967] 48 C.P.R. 207 (Ex. Ct.); *Farbwerke*, *supra* note 19.
- <sup>29</sup> *Bayer*, *supra* note 7 at para. 59: "Thus, Apotex's position is that the invention of '582 was the product of mere workshop analysis, i.e. you try one thing and if not successful you try a few other well known tests to deal with the problem to arrive at the composition of an effective dosage form". [Emphasis added]
- <sup>30</sup> *Bayer*, *supra* note 7, at paras. 66-67.
- <sup>31</sup> *Beecham*, *supra* note 6 at 27.
- <sup>32</sup> *Ibid.*
- <sup>33</sup> Justice Lederman's decision (on the point of obviousness) was upheld on appeal to the Ontario Court of Appeal, appeal to the Supreme Court of Canada denied, see details at *Bayer*, *supra* note 7. A recent review of Quicklaw (May 14 2006) indicates that this decision has been followed in 1, explained in 2, and mentioned in 24 cases.
- <sup>34</sup> *Supra* note 19.
- <sup>35</sup> The Cripps Question is: "The real question is: was it for all practical purposes obvious to any skilled chemist in the state of chemical knowledge existing at the date of the patent ... that he could manufacture valuable therapeutic agents by making the high alkyl resorcinols". *Sharp and Dohme Inc. v. Boots Pure Drug Co. Ltd.*, (1928) 45 R.P.C. 153 at 173. Note that the question uses "could" not "would".
- <sup>36</sup> Michael Polanyi, *The Tacit Dimension* (New York: Anchor Books, 1967); David A. Wolfe, Charles Davis & Matthew Lucas, "Global Networks and Local Linkages: An Introduction" in David A. Wolfe & Matthew Lucas, eds., *Global Networks and Local Linkages: The Paradox of Cluster Development in an Open Economy* (Montreal & Kingston: McGill-Queen's University Press, 2005) 1.
- <sup>37</sup> *Pfizer Canada Inc. v. Apotex Inc.*, 2003 FC 1428 at para. 30 [*Pfizer v. Apotex* 2003].
- <sup>38</sup> Boatman J.A. and Johnson J.B. "A four-stage approach to new-drug development." *Pharm. Techn.* 5(1), Jan. 1981; Berge S.M. et al. "Pharmaceutical Salts." *J. Pharm. Sci.* 66(1) 1–19, 1977; Fung H.L. "Chemical kinetics and drug stability." In *Modern Pharmaceutics*. Ed. Banker G.S. and Rhodes C.T. 1979; Gould P.L. "Salt selection for basic drugs." *Int. J. Pharm.* 33: 201–217, 1986; Greene D.S. "Preformulation". In *Modern Pharmaceutics*. Ed. Banker G.S. and Rhodes C.T. 1979; Wadke D.A., and Jacobson H. "Preformulation Testing". In *Pharmaceutical Dosage Forms: Tablets*. Ed. Lieberman H.A., and Lachman L. 1980.
- <sup>39</sup> *Wolfe et al.*, *supra* note 36 at 8-9.
- <sup>40</sup> According to Wolfe "synthetic knowledge" is knowledge directed to finding technical solutions to specific problems and is particularly important for product development. Synthetic knowledge is informed by both tacit "knowing" and applied knowledge. "Analytical knowledge" refers to the intellectual skills underpinning analyzing and synthesizing information, e.g., constructing rational and/or cognitive models. For Wolfe, analytical knowledge depends primarily on focal rather than tacit knowledge.
- <sup>41</sup> Ron A. Bouchard, "Living Separate and Apart Is Never Easy: Inventive Capacity of the PHOSITA as the Tie that Binds Obviousness and Inventiveness" U. Ottawa L. & Tech. J. (forthcoming 2007); see also, Ron. A. Bouchard, *What is the Right Approach to Obviousness in Patent Litigation under Canada's Pharmaceutical Linkage NOC Regulations: To Test or Not To Test?* (LL.M. Thesis, University of Toronto Faculty of Law, 2006) (unpublished).
- <sup>42</sup> (1987), 15 C.P.R. (3d) 217 [*Hoffmann-La Roche*].

- <sup>43</sup> *Ibid.* at 224-25.
- <sup>44</sup> *Ibid.* at 232.
- <sup>45</sup> *Ductmate Industries Inc. v. Exanno Products Ltd.* (1984), 2 C.P.R. (3d) 289 at 307.
- <sup>46</sup> *Burns & Russell*, *supra* note 28. See also, *Lightning Fastener*, *supra* note 28; *Pope Appliance Corp. v. Spanish River Pulp and Paper Mills*, [1927] Ex. C.R. 28 [*Pope Appliance*]; and *infra* for a discussion of the phrase “beyond the expected skill of the calling” in United States Supreme Court jurisprudence relating to obviousness and persons skilled in the art.
- <sup>47</sup> *Apotex v. Wellcome*, *supra* note 14 at para. 243.
- <sup>48</sup> The “pink hue” problem refers to the situation whereby tablets of paroxetine turn pink on exposure to oxygen.
- <sup>49</sup> *Supra* note 15 at para. 40.
- <sup>50</sup> 2004 FC 1631 [*Janssen-Ortho* 2004].
- <sup>51</sup> *Ibid.* at paras. 54, 65, 69, 71, 82.
- <sup>52</sup> *Apotex v. Wellcome*, *supra* note 14 at para. 243.
- <sup>53</sup> *Ibid.*
- <sup>54</sup> *Burns & Russell*, *supra* note 28 at para. 62.
- <sup>55</sup> *Apotex v. Wellcome*, *supra* note 14 at para. 264.
- <sup>56</sup> *Pfizer Canada Inc. v. Apotex Inc.*, 2002 FCT 1138 at para. 113 [*Pfizer v. Apotex* 2002].
- <sup>57</sup> *Ibid.* at para. 117.
- <sup>58</sup> 2003 FC 1443.
- <sup>59</sup> *Ibid.* at para. 51.
- <sup>60</sup> *Ibid.* at paras. 50, 71-72.
- <sup>61</sup> *AB Hassle v. Apotex Inc.*, 2003 FCT 771.
- <sup>62</sup> 2001 FCT 1129 [*Novartis*].
- <sup>63</sup> *Ibid.* at paras. 117-118.
- <sup>64</sup> *Ibid.* at paras. 150, 154, 159.
- <sup>65</sup> *Ibid.* at paras. 137-138.
- <sup>66</sup> *Ibid.* at paras. 139-143.
- <sup>67</sup> *GlaxoSmithKline Inc. v. Canada (Minister of Health)*, 2003 FC 899 [*GlaxoSmithKline*].
- <sup>68</sup> *Pfizer Canada Inc. v. Apotex Inc.*, 2005 FC 1421 [*Pfizer v. Apotex* 2005].
- <sup>69</sup> *Ibid.* at para. 103.
- <sup>70</sup> *Ibid.* at para. 131.
- <sup>71</sup> *GlaxoSmithKline*, *supra* note 67 at para. 44.
- <sup>72</sup> *GlaxoSmithKline*, *supra* note 67 at para. 46.
- <sup>73</sup> *Bouchard*, *supra* note 41.
- <sup>74</sup> I recently tried to purchase a used copy of Fox’s 1969 textbook through several well-known used books sites (March 2006). There was not one single copy available anywhere in the world.
- <sup>75</sup> *Fox*, *supra* note 17 at 70-71.
- <sup>76</sup> As noted by Justice Hugessen in *Beloit*, *supra* note 6 at 293, 298: “Obviousness is an attack on a patent based on its lack of inventiveness. The attacker says, in effect, ‘Any fool could have done that.’ Anticipation or lack of novelty, on the other hand, in effect assumes that there has been an invention but asserts that it has been disclosed to the public prior to the application for the patent. The charge is: ‘Your invention, though clever, was already known.’ . . . It will be recalled that anticipation, or lack of novelty, asserts that the invention has been made known to the public prior to the relevant time. The inquiry is directed to the very invention in suit and not, as in the case of obviousness, to the state of the art and to common general knowledge.”
- <sup>77</sup> *Fox*, *supra* note 17 describes the test for anticipation at 100-101: “Has it been disclosed before? If there is an earlier specification for the very same thing, the second invention is not new; but if the two things are different, the nature and extent of the difference have to be considered. The question then becomes one of degree. But unless it can be said that the differences are practically immaterial; that there is no ingenuity in the second invention, no experiment necessary to show whether it can be usefully carried out or not, the second cannot be said to have been anticipated by the first”. [Emphasis added]
- <sup>78</sup> *Janssen-Ortho Inc. v. Novopharm Ltd.*, 2006 FC 1234 at para. 112 [*Janssen-Ortho*].
- <sup>79</sup> *SmithKline Beecham*, *supra* note 15.
- <sup>80</sup> [1941] Ex. C.R. 69 (QL) [*Short Milling*].
- <sup>81</sup> *Ibid.* at para. 21.
- <sup>82</sup> *Merco Nordstrom Valve Company & Peacock Brothers Ltd. v. Comer*, [1942] Ex. C.R. 138; *Thermionics Ltd. v. Philco Products Ltd.*, [1941] Ex. C.R. 209.
- <sup>83</sup> [1977] F.C.J. No. 603 at paras. 74, 75 (QL).
- <sup>84</sup> *Supra* note 17 and accompanying text.
- <sup>85</sup> *Supra* note 35 at 173.
- <sup>86</sup> *Canadian Industries Ltd. v. Sherwin-Williams Co. of Canada*, [1946] Ex. C.R. 65 (QL) [*Sherwin-Williams*].
- <sup>87</sup> *Supra* note 6.
- <sup>88</sup> *Sherwin-Williams*, *supra* note 86 at para. 51.
- <sup>89</sup> *Sherwin-Williams*, *supra* note 86 at paras. 45-46.
- <sup>90</sup> *Burns & Russell*, *supra* note 28. See also discussion of same regarding United States Supreme Court obviousness jurisprudence at pp. 40-41, *infra*.
- <sup>91</sup> *Apotex v. Wellcome*, *supra* note 14 at para. 243.
- <sup>92</sup> *Lightning Fastener*, *supra* note 28.
- <sup>93</sup> *Pope Appliance*, *supra* note 46.
- <sup>94</sup> *Ernest Scragg*, *supra* note 19 at para. 190; *Samuel Parkes*, *supra* note 6 at 248.
- <sup>95</sup> *Reference re ss. 193 and 195.1(1)(c) of the Criminal Code (Man.)*, [1990] 1 S.C.R. 1123 at 1152.
- <sup>96</sup> *R. v. Nova Scotia Pharmaceutical Society*, [1992] 2 S.C.R. 606 at para. 43 [*Nova Scotia Pharmaceutical*].
- <sup>97</sup> *Free World Trust v. Electro Sante Inc.*, 2000 SCC 66 [*Free World Trust*].
- <sup>98</sup> *Ibid.* at paras. 41, 43.
- <sup>99</sup> *Ibid.* at para. 42.
- <sup>100</sup> Rebecca S. Eisenberg, “Patents, Product Exclusivity, and Information Dissemination: How Law Directs Biopharmaceutical Research and Development” (2003) 72 *Fordham L. Rev.* 477; Hee Hong, Marvin D. Shepherd, David Scoones, & Thomas T.H. Wan Hong, “Product-line extensions and pricing strategies of brand-name drugs facing patent expiration”. 11(9) *Journal of Managed Care & Pharmacy* 746 (2005).
- <sup>101</sup> Anita Varma & David Abraham, “DNA is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market” (1996) 9 *Harv. J.L. & Tech.* 53 at 55.
- <sup>102</sup> *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49 at para. 39 [*AstraZeneca*].
- <sup>103</sup> A recent article by Dr. Andre Picard (“Drug costs jump to \$25 billion a year” *The Globe and Mail* (11 May 2006)), indicated that Canadians spent \$25B on drugs in 2005, an 11 per cent jump in spending from the previous year. Of this, \$20B was spent on prescription drugs compared to \$3B in 1986. Thus, expenditures on prescription drugs increased ~700% over the last 20 years. This amount exceeded that spent on physician services and is second only to spending on hospitals, prompting one commentator to refer to the pattern of drug expenditures as a “health-care crisis in slow motion”. Data were from IMS Health Canada and the CIHI.
- <sup>104</sup> *Francis v. Baker*, [1999] 3 S.C.R. 250 at para. 35 (QL). The court held that statutory interpretation principles require that all evidence of legislative intent be considered provided it is “relevant and reliable”.
- <sup>105</sup> 2005 SCC 26, [2005] 1 S.C.R. 533 at paras. 156, 157 [*Biolysse*].
- <sup>106</sup> *Merck & Co. v. Canada (Attorney General)*, [1999] F.C.J. No. 1825, 176 F.T.R. 21 at para. 51 (QL). See also Justice Binnie’s comments in *Biolysse*, *ibid.* at para. 46.
- <sup>107</sup> Regulatory Impact Analysis Statement, C. Gaz. 1993. II. 1388 (S.O.R./93-133).
- <sup>108</sup> Regulatory Impact Analysis Statement, C. Gaz. 2004. II. (S.O.R./93-133 Dec. 11, 2004). See also the June 2006 RIAS: Regulatory Impact Analysis Statement. Regulations Amending the Patented Medicines (Notice of Compliance) Regulations, C. Gaz. 2006. Vol. 140, No. 24.
- <sup>109</sup> *Biolysse*, *supra* note 105 at para. 171 regarding the 1999 RIAS (C. Gaz. 1999. II. 2357 (S.O.R./99-379)). Balancing of competing objectives was also recently discussed by Justice Binnie in *AstraZeneca*, *supra* note 102 at para. 39.
- <sup>110</sup> *Biolysse*, *supra* note 105 at para. 47.

- <sup>111</sup> *Eli Lilly Canada Inc. v. Canada (Minister of Health)*, 2003 FCA 24 at paras. 73-74.
- <sup>112</sup> *Supra* note 108.
- <sup>113</sup> Bouchard, *supra* note 41.
- <sup>114</sup> For a review of normative practices in biomedical litigation as it relates to patentability, see Rebecca S. Eisenberg, "Obvious to Whom? Evaluating Inventions from the Perspective of the PHOSITA" (2004) 19 Berkeley Tech. L. J. 885; Arti Kaur Rai, "Regulating Scientific Research: Intellectual Property Rights and the Norms of Science" (1999) 94 Nw. U.L. Rev. 77.
- <sup>115</sup> *Whirlpool*, *supra* note 14 at paras. 42-50; *Free World Trust*, *supra* note 97 at paras. 44-51.
- <sup>116</sup> (1989), 26 CPR (3d) 1 (F.C.A.).
- <sup>117</sup> [1982] R.P.C. 183 [Catnic].
- <sup>118</sup> *Ibid.* at 242-43. See also, *Janssen Pharmaceutica Inc. v. Apotex Inc.*, 2001 FCA 247; *671905 Alberta Inc. v. QMax Solutions Inc.*, 2003 FCA 241; *Monsanto Canada Inc. v. Schmeiser*, 2002 FCA 309; *Janssen-Ortho*, *supra* note 78, citing *General Tire & Rubber Company v. Firestone Tyre & Rubber Company Limited*, [1972] R.P.C. 195 at pages 211-12.
- <sup>119</sup> *Whirlpool*, *supra* note 14 at paras. 49(a) and (b).
- <sup>120</sup> *Ibid.* at para. 49(d).
- <sup>121</sup> Evergreening refers to the undue extension of the statutory monopoly attached to a given patent by means of a series of patents with obvious or uninventive modifications. The patentee prolongs its monopoly beyond what the public has agreed to pay: *Whirlpool*, *supra* note 14 at para. 37; *BioLyse*, *supra* note 105 at para. 66; *AstraZeneca*, *supra* note 102 at para. 39.
- <sup>122</sup> *Whirlpool* *supra* Note 12, at 49.
- <sup>123</sup> *Whirlpool*, *ibid.* at para. 49(g); *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 SCR 504 at 520-521.
- <sup>124</sup> *Whirlpool*, *ibid.* at para. 49(h); see discussion in Part III *supra*.
- <sup>125</sup> *Ibid.* at para. 48; *Catnic*, *supra* note 117 at 243.
- <sup>126</sup> *Supra* note 8 at paras. 70-74.
- <sup>127</sup> *Ibid.* at para. 72.
- <sup>128</sup> *Ibid.* at para. 50.
- <sup>129</sup> *Ibid.* at para. 70.
- <sup>130</sup> *Supra* note 14.
- <sup>131</sup> *Supra* note 56.
- <sup>132</sup> *Supra* note 50.
- <sup>133</sup> Justice Gibson also included testing that produced new uses or properties that were superior to those already disclosed, but only singled out surprising results in his analysis at paragraph 73.
- <sup>134</sup> *Supra* note 42.
- <sup>135</sup> *BMS v. Novopharm*, *supra* note 8 at para. 86.
- <sup>136</sup> *Bayer*, *supra* note 7, at para. 66.
- <sup>137</sup> 2005 FC 1299 at para. 119.
- <sup>138</sup> *Whirlpool*, *supra* note 14 at paras. 42-50; *Free World Trust*, *supra* note 97, at 15, 19, 44-51.
- <sup>139</sup> *Sherwin-Williams*, *supra* note 86; *Hoffmann-La Roche*, *supra* note 42; *Apotex v. Wellcome*, *supra* note 14; *SmithKline Beecham*, *supra* note 15.
- <sup>140</sup> *Baldwin International Radio Co. of Canada v. Western Electric Co.*, [1934] S.C.R. 94; *Ernest Scragg*, *supra* note 19 at para. 25, *Burton Parsons Chemicals Inc. et al. v. Hewlett-Packard (Canada) Ltd. et al.*, [1976] 1 S.C.R. 555.
- <sup>141</sup> *SmithKline Beecham*, *supra* note 15 at para. 20.
- <sup>142</sup> *Beecham*, *supra* note 6; *Free World Trust*, *supra* note 97; *Genentech Inc.'s Patent*, [1989] R.P.C. 147 (C.A.) [*Genentech*].
- <sup>143</sup> [1963] R.P.C. 61 at 71.
- <sup>144</sup> *No-Fume Ltd. v. Pitchford*, [1935] 52 R.P.C. 231.
- <sup>145</sup> *Genentech*, *supra* note 141 at 276, 279.
- <sup>146</sup> *Supra* notes 8, 44 and 49.
- <sup>147</sup> *Genentech*, *supra* note 141 at 276, 279.
- <sup>148</sup> *Ibid.* at 110, 116.
- <sup>149</sup> *Re Certain Teed Corp. Patent Application No. 2,055,020*, [2004], 39 C.P.R. (4th) 437 at 444 [*Certain Teed*].
- <sup>150</sup> *Apotex v. Wellcome*, *supra* note 14 at paras 243-245; *SmithKline Beecham*, *supra* note 15 at para. 47.
- <sup>151</sup> *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153 at para. 83 (QL).
- <sup>152</sup> See *Certain Teed*, *supra* note 144 and *Wellcome*, *supra* note 125 at 243, 245; *Wellcome*, *supra* note 126 at para 83.
- <sup>153</sup> Dan L. Burk & Mark A. Lemley, "Biotechnology's Uncertainty Principle" (2004) 54 Case W. Res. L.Rev. 691.
- <sup>154</sup> 127 S. Ct. 617 (2006) [*Teleflex*] (Brief of the *amicus curiae*, United States Solicitor General [Solicitor General's Brief]). [*amicus curiae*]
- <sup>155</sup> 383 U.S. 1 (1966) [*John Deere*].
- <sup>156</sup> *Ibid.*
- <sup>157</sup> *Patent Act* 35 USC 103.
- <sup>158</sup> *Teleflex*, *supra* note 153 (Brief of the *amicus curiae*, Twenty-Four Law Professors *amicus curiae* at 2 [Law Professor's Brief]).
- <sup>159</sup> Eisenberg, *supra* note 114 at 888-892.
- <sup>160</sup> See e.g., *Aktiebolaget Karlstads Mekaniska Werkstand v. US International Trade Commission*, 705 F.2d 1565 at 1575 (Fed. Cir. 1983) [*Aktiebolaget*].
- <sup>161</sup> *Hotchkiss v. Greenwood*, 11 How. 248 (U.S. 1851) [*Hotchkiss*].
- <sup>162</sup> *John Deere*, *supra* note 154 at 12.
- <sup>163</sup> *BMS v. Novopharm*, *supra* note 8; *Genentech*, *supra* note 141 and discussion thereof, *supra* pp. 27-30.
- <sup>164</sup> *John Deere*, *supra* note 154 at 18.
- <sup>165</sup> Eisenberg, *supra* note 114 at 889.
- <sup>166</sup> See also *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448 at 454 (Fed. Cir. 1985).
- <sup>167</sup> *Aktiebolaget*, *supra* note 159.
- <sup>168</sup> Eisenberg, *supra* note 114 at 890.
- <sup>169</sup> Solicitor General's Brief, *supra* note 153 at 9-10, 16-18; Law Profs Brief, *supra* note 157 at 10, 13.
- <sup>170</sup> *Supra* note 6 at 294.
- <sup>171</sup> *Supra* note 153 at 15-16. See also Eisenberg, *supra* note 114 at 888, 897-898.
- <sup>172</sup> *John Deere*, *supra* note 154 at 17. See also discussion of same in Solicitor General's Brief, *supra* note 153 at 11.
- <sup>173</sup> Law Profs Brief, *supra* note 157 at 6-7. See also Eisenberg, *supra* note 114 at 888.
- <sup>174</sup> *Hotchkiss*, *supra* note 160 at 267.
- <sup>175</sup> *Apotex v. Wellcome*, *supra* note 14.
- <sup>176</sup> The court stated that "*Hotchkiss*, by positing the condition that a patentable invention evidence more ingenuity and skill than that possessed by an ordinary mechanic acquainted with the business, merely distinguished between new and useful innovations that were capable of sustaining a patent and those that were not. The *Hotchkiss* test laid the cornerstone of the judicial evolution suggested by Jefferson and left to the courts by Congress. The language in the case, and in those which followed, gave birth to 'invention' as a word of legal art signifying patentable inventions". *John Deere*, *supra* note 154 at 11.
- <sup>177</sup> *Cuno Corporation v. Automatic Devices Corporation*, 314 U.S. 84 at 91 (1941) [*Cuno*].
- <sup>178</sup> *John Deere*, *supra* note 154 at 16, n. 7.
- <sup>179</sup> *Ibid.*
- <sup>180</sup> Solicitor General's Brief, *supra* note 153 at 3.
- <sup>181</sup> Law Profs Brief, *supra* note 157 at 12, referring to Burk & Lemley, *supra* note 148.
- <sup>182</sup> *Apotex Inc. v. Canada (Minister of Health and Welfare)* (1997), 76 C.P.R. (3d) 1 at 5-6 (F.C.A.).
- <sup>183</sup> *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)* (1994), 55 C.P.R. (3d) 302 at 320 (F.C.A.) [*Merck Frosst* 1994].
- <sup>184</sup> *Ibid.* at 319; *Merck Frosst Canada Inc. v. Canada*, [1998] 2 S.C.R. 193 at para. 30, 80 C.P.R. (3d) 368.
- <sup>185</sup> *Pharmacia Inc. v. Canada (Minister of National Health and Welfare)* (1994), 58 C.P.R. (3d) 209 at 217 (F.C.A.); *Merck Frosst* 1994, *supra* note 178 at 320.

<sup>186</sup> *Janssen-Ortho*, supra note 78.

<sup>187</sup> *Ibid.*

<sup>188</sup> *Janssen-Ortho* 2004, supra note 52, aff'd 2005 FCA 6, leave to appeal to the Supreme Court of Canada dismissed; *Janssen-Ortho Inc. v. Novopharm Ltd.*, [2005] 1 S.C.R. 776.

<sup>189</sup> *Novartis AG v. Apotex Inc.*, 2002 FCA 440, 22 C.P.R. (4th) 450 at para. 9 (QL).

<sup>190</sup> *Supra* note 86.

<sup>191</sup> *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)*, [1998] 2 S.C.R. 193, at para. 33; *Bristol Myers Squibb Co. v. Canada (Attorney General)*, [2005] 1 S.C.R. 533, 2005 SCC 26, at paras. 24 and 146; *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, [2006] 2 S.C.R. 560, 2006 SCC 49, at para. 17.