

Demythologizing PHOSITA

Applying the Non-Obviousness Requirement Under Canadian Patent Law to Keep Knowledge in the Public Domain and Foster Innovation

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The Supreme Court of Canada recently revised the doctrine of non-obviousness in a pharmaceutical “selection patent” case, *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.* Although the Court was cognizant of changes to the same doctrine in the United States and the United Kingdom, a critical flaw in how the doctrine is being applied in Canada escaped its attention. Using content analysis methodology, this article shows that Canadian courts frequently fail to characterize the “person having ordinary skill in the art” (PHOSITA) for the purpose of the obviousness inquiry. The article argues that this surprisingly common analytical mistake betrays a deep misunderstanding of innovation—one which assumes that actors consult patents to learn about scientific developments, devalues the importance of the public domain, and ignores the industry-specific nature of innovation. The article also describes the historical evolution of the non-obviousness test, identifies factors that undermine PHOSITA’s characterization, and develops a multi-layered prescription to remedy the problem.

Dernièrement, la Cour suprême du Canada a révisé la doctrine de non-évidence lors d’une affaire de « brevet de sélection » pharmaceutique à savoir, *Apotex Inc. c. Sanofi-Synthelabo Canada Inc.* Bien que la Cour était consciente des changements à la même doctrine aux États-Unis et au Royaume-Uni, une faille critique dans la manière dont la doctrine est appliquée au Canada a échappé à son attention. Au moyen de la méthodologie de l’analyse du contenu, cet article démontre que les tribunaux canadiens échouent souvent à qualifier la « personne douée de la compétence normale dans le métier » (PHOSITA) aux fins de l’enquête sur l’évidence. L’article avance que cette erreur analytique, étonnement répandue, révèle une incompréhension profonde de l’innovation, laquelle assume que les protagonistes consultent les brevets en vue de s’informer sur les progrès scientifiques, dévalorise l’im-

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portance du domaine public et enfin, ignore la nature de l'innovation propre à l'industrie. Par ailleurs, l'article décrit l'évolution historique du test de non évidence, identifie les facteurs qui ébranlent la qualification de la PHOSITA, et met au point une solution à plusieurs niveaux en vue de résoudre le problème.

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THE DOCTRINE OF NON-OBVIOUSNESS is intended to ensure that an invention be a non-trivial extension of what is already known¹—in other words, that a

1. This framing of the doctrine's purpose is well established in the United States. See generally Robert Patrick Merges & John Fitzgerald Duffy, eds., *Patent Law and Policy: Cases and Materials*, 3d ed. (Newark: LexisNexis, 2002) at 644ff. In marked contrast, Canadian courts seldom examine the purpose of the non-obviousness requirement. For an exception to this general trend, see *Apotex Inc. v. Syntex Pharmaceuticals Ltd.* (1999), 1 C.P.R. (4th) 22 at para. 62 (F.C.T.D.).

patent's claims do not encompass knowledge that is effectively already part of the "public domain."² That is the doctrine's essential purpose. Wary that requiring the subject matter simply be "new" and "useful" would reward mere work-shop improvements with a time-limited legal monopoly, the judiciary added non-obviousness or "inventive step" (as it is referred to in Europe³ and elsewhere⁴) to the criteria of a "true invention," despite the "obvious" circularity involved.⁵ Defining with greater precision what the non-obviousness requirement should entail has remained elusive. Instead, over time, courts have devised imaginative analytical protocols so as to manage the inquiry.⁶ Assessing whether the putative invention would have been obvious to the "skilled technician" or the "person having ordinary skill in the art" (the "PHOSITA") has become the defining feature of the protocol for determining obviousness in several of the world's patent systems.⁷

Many allege that the obviousness inquiry had run amuck in the United States—that, contrary to the US Supreme Court's direction in the 1966 case of *Graham v. John Deere Co.*,⁸ the Court of Appeals for the Federal Circuit had

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2. Usage of this particular phrase, "the public domain," in relation to intellectual property rights (including copyrights, patents, and trademarks) is actually relatively new. See James Boyle, "The Second Enclosure Movement and the Construction of the Public Domain" (2003) 66 *Law & Contemp. Probs.* 33 at 59. Nevertheless, the idea of using the non-obviousness requirement to distinguish what is already known from what is not is quite old. See Part I(A), below.
 3. See *Convention on the Grant of European Patents*, 5 October 1973, 1065 U.N.T.S. 199, art. 52(1). The article reads: "European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step."
 4. India and Australia's patent statutes, for example, both use the term "inventive step." See, respectively, *The Patents (Amendment) Act*, 2005 No. 15 of 2005; *Patents Act 1990* (Cth.), s. 7.
 5. John F. Witherspoon, ed., *Nonobviousness: The Ultimate Condition of Patentability* (Washington: Bureau of National Affairs, 1980).
 6. For good reason: non-obviousness is the most commonly litigated issue in patent disputes today. See John R. Allison & Mark A. Lemley, "Empirical Evidence on the Validity of Litigated Patents" (1998) 26 *A.I.P.L.A.Q.J.* 185 at 209.
 7. This term is more commonly used in the United States than in Canada. Nevertheless, it will be used throughout this article, both to highlight how developments in the United States are relevant to the analysis and to reveal a problem in the Canadian jurisprudence attributable to the conflation of the skilled reader (and his or her role in claim construction) with the ordinary technician (and his or her function in the obviousness inquiry). See Part V, below.
 8. 383 U.S. 1 (1966) [*Graham*].

gradually “marginalized” PHOSITA from the obviousness test.⁹ In 2007, however, the Supreme Court resuscitated PHOSITA in *KSR International Co. v. Teleflex Inc. et al.*,¹⁰ reasserting his or her ability to rely upon common sense and draw inferences from information while overcoming a technological hurdle.¹¹ On behalf of a unanimous Court, Justice Kennedy underscored the importance of knowledge in the public domain to innovation:

We build and create by bringing to the tangible and palpable reality around us new works based on instinct, simple logic, ordinary inferences, extraordinary ideas, and sometimes even genius. These advances, once part of our shared knowledge, define a new threshold from which innovation starts once more. And as progress beginning from higher levels of achievement is expected in the normal course, the results of ordinary innovation are not the subject of exclusive rights under the patent laws.¹²

By signalling a more sophisticated understanding of the relationships between the public domain, proprietary knowledge, and innovation, some contend that the US Supreme Court finally saw the forest for the trees in *KSR*.¹³ Others worry that the ruling’s application will leave much to be desired because particular aspects of the non-obviousness standard left unaddressed by the Court—“the trees,” to twist the metaphor—matter greatly.¹⁴

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9. According to the following commentators, the “teaching, suggestion, motivation” (TSM) test developed by the Federal Circuit is one of the principal reasons why PHOSITA has been marginalized. See John H. Barton, “Non-Obviousness” (2003) 43 IDEA 475; Rebecca S. Eisenberg, “Obvious to Whom? Evaluating Inventions from the Perspective of PHOSITA” (2004) 19 Berkeley Tech. L.J. 885. But see Christopher A. Cotropia, “Nonobviousness and the Federal Circuit: An Empirical Analysis of Recent Case Law” (2007) 82 Notre Dame L. Rev. 911.
 10. 550 U.S. 398 (2007) [*KSR*].
 11. In this case, the Federal Circuit invoked the TSM test to determine that the adjustable electronic sensor gasoline pedal at issue was non-obvious, even though both adjustable accelerator pedals and electronic sensors on (non-adjustable) accelerator pedals were known in the prior art.
 12. *KSR*, *supra* note 10 at 1750-51.
 13. See *e.g.* Ron A. Bouchard, “*KSR v. Teleflex* Part 1: Impact of U.S. Supreme Court Patent Law on Canadian Intellectual Property and Regulatory Rights Landscape” (2007) 15 Health L.J. 221.
 14. See *e.g.* Gregory N. Mandel, “Another Missed Opportunity: The Supreme Court’s Failure to Define Nonobviousness or Combat Hindsight Bias in *KSR v. Teleflex*” (2008) 12 Lewis & Clark L. Rev. 323; Janice M. Mueller, “Chemicals, Combinations, and ‘Common Sense’: How the Supreme Court’s *KSR* Decision is Changing Federal Circuit Obviousness Determinations in Pharmaceutical and Biotechnology Cases” (2008) 35 N. Ky. L. Rev. 281.

Even if *KSR*'s application proves troublesome, the situation may be worse in Canada. Although decided after *KSR*, the Supreme Court of Canada arguably saw neither the forest nor the trees while reformulating the standard of non-obviousness in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*¹⁵ Instead, paying no heed to Justice Kennedy's words in *KSR*, the Court, along with lower Canadian courts, continues to devalue the public domain vis-à-vis patents, to the detriment of our innovation system as a whole. This deep misunderstanding of innovation is rooted in a simple, yet surprisingly common analytical mistake: in applying the non-obviousness doctrine, courts frequently fail to adequately characterize, through specific findings of fact, the knowledge and capacities of the PHOSITA¹⁶—the very tool used to distinguish between inventions that are obvious, and, therefore, already part of the public domain, versus those that are not.

Perhaps the gravity of the issue would have been cast in sharper relief if leave to appeal had been granted in a separate proceeding, *Novopharm Limited v. Janssen-Ortho Inc.*,¹⁷ given that legal counsel for Novopharm also represented *KSR*, the brake pedal system manufacturer that successfully defended itself against allegations of patent infringement in the United States.¹⁸ Within a month of the *KSR* ruling, counsel for Novopharm filed leave to appeal to the Supreme Court of Canada, alleging, *inter alia*, that the Federal Court of Appeal wrongly determined the issue of obviousness.¹⁹

15. [2008] 3 S.C.R. 265 [*Apotex* (2008)]. This case, pertaining to the multi-billion dollar drug "Plavix," was commenced pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R. 93-133 [*PMNOC Regulations*]. As such, the Supreme Court of Canada's ruling does not constitute a final determination of issues of patent validity or infringement (although the latter was not at issue in this case). Rather, the Court simply determined that the three allegations of invalidity (based on anticipation, obviousness, and double patenting) made by Apotex were not justified (at para. 116).

16. This mistake is also quite ironic, given Rothstein J.'s call to move beyond "acontextual" applications of patent standards. See *Apotex* (2008), *ibid.* at para. 62.

17. (2007), 59 C.P.R. (4th) 116 (F.C.A.) [*Novopharm* (2007)].

18. This statement is not intended to imply that the same counsel who represented *KSR* before the US Supreme Court also appeared before the Supreme Court of Canada in connection with Novopharm's application for leave.

19. See *Novopharm* (2007), *supra* note 17, Notice of Application for Leave to Appeal of the Applicant (S.C.C. File No. 32200) at para. 7 [*Novopharm* (2007), Application for Leave to Appeal].

In its application for leave, Novopharm conceded that its case presented issues parallel to those raised by *Sanofi-Sybelabo Canada Inc. v. Apotex Inc.*,²⁰ which the Supreme Court of Canada had at that point already agreed to hear but had not decided.²¹ Both cases involved the same subject matter: a drug composed of a chemical compound known as an “enantiomer.”²² And both raised the same fundamental question: could a drug that is itself a member of a previously-disclosed (and patented) class of compounds be claimed in a subsequent patent? Like the appellant in *Apotex* (2008), counsel in *Novopharm* (2007) submitted that such “selection patents,”²³ as they are commonly called, are invalid because they are obvious and that the Court should hear its case, if only in conjunction with Apotex’s appeal.²⁴

However, that is not what transpired. Novopharm’s application for leave to appeal was dismissed and, in the process of substantially altering the test of obviousness under Canadian law, the issue of how PHOSITA is characterized completely escaped the Court’s attention in *Apotex* (2008).²⁵

The argument advanced here is that this outcome is fundamentally problematic. It is problematic because the manner in which the Federal Court of Appeal characterized PHOSITA in *Novopharm* (2007), as well as in *Apotex* (2006)—or, to be more precise, the manner in which it failed to characterize PHOSITA—appears to be a pervasive feature of the jurisprudence. And, if left uncorrected, this feature will compromise the patent system’s principal function of stimulating and facilitating innovation.²⁶

20. (2006), 282 D.L.R. (4th) 179 (F.C.A.) [*Apotex* (2006)], affg (2005), 39 C.P.R. (4th) 202 (F.C.T.D.) [*Apotex* (2005)].

21. *Apotex* (2006), *ibid.*, leave to appeal to S.C.C. granted, *Apotex* (2008), *supra* note 15.

22. The drug in both the *Novopharm* and the *Apotex* cases was developed from a racemic compound, which is typically composed of two otherwise identical molecules called “enantiomers” that have three-dimensional structures that are mirror images of each other.

23. Rothstein J. defined “selection patents” as follows: “In the context of chemical compounds, in general terms, a selection patent is one whose subject matter (compounds) is a fraction of a larger known class of compounds which was the subject matter of a prior patent.” *Apotex* (2008), *supra* note 15 at para. 1.

24. See *Novopharm* (2007), Application for Leave to Appeal, *supra* note 19 at para. 9.

25. This may have been partially attributable to the fact that the two parties did not dispute PHOSITA’s identity. See *Apotex* (2008), *supra* note 15 at para. 74.

26. This article assumes that this is the case. However, the purpose of the Canadian patent system merits further inquiry, especially from a comparative constitutional perspective, given

There are essentially two reasons for this. First, the patent system's function of promoting innovation will, in the future, increasingly depend upon a court's ability to calibrate patent law standards, including non-obviousness, in light of the realities of particular industries.²⁷ PHOSITA is the primary doctrinal tool at a court's disposal to perform such calibration.²⁸ Failing to deploy the PHOSITA construct fully, then, not only handicaps judicial analysis, but also threatens the integrity of the patent system. Second, undermining PHOSITA's role in the non-obviousness inquiry devalues the public domain of knowledge²⁹—a sphere which, depending on the industry involved, and contrary to what members of the Supreme Court of Canada appear to believe, is just as, if not more, important to innovation than proprietary knowledge, such as patented inventions.

In summary, the overarching purpose of this article is to expose the present gap between patent law doctrine—specifically, the non-obviousness doctrine—and innovation, in theory and in practice. It will explain why this gap is a problem, how *Apotex* and related decisions perpetuate it, and what should be done to correct it. The two methodologies employed to investigate this problem and substantiate the foregoing claims are described in detail in Part II of the article. Parts III and IV present empirical findings generated through content analysis (methodology one) and a critique of the jurisprudence based on doctrinal analysis (methodology two), respectively. Finally, Part V offers a multi-layered prescription for the problem. The following provides historical background about the evolution of the non-obviousness doctrine—a necessary primer for the content analysis coding scheme described in Part II.³⁰

that the UK *Constitution Act* simply grants the federal government jurisdiction over “Patents of Invention and Discovery.” See *Constitution Act, 1867* (U.K.), 30 & 31 Vict., c. 3, s. 91(22) reprinted in R.S.C. 1985, App. II, No. 5. Other jurisdictions, most notably the United States, attach a clear purpose to certain intellectual property laws. The US Constitution indicates that: “Congress shall have the power ... To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.” See U.S. Const., art. I, § 8, cl. 8. For an informative discussion of this particular clause's purpose, see Malla Pollack, “What Is Congress Supposed to Promote? Defining ‘Progress’ in Article I, Section 8, Clause 8 of the United States Constitution, or Introducing the Progress Clause” (2001) 80 Neb. L. Rev. 754.

27. See generally Dan L. Burk & Mark A. Lemley, *The Patent Crisis and How the Courts Can Solve It* (Chicago: University of Chicago Press, 2009).

28. *Ibid.* at 114-17.

29. See Parts IV and V, below.

30. The author acknowledges that the methodology section should typically follow the

I. NON-OBVIOUSNESS: A PRIMER

This Part is divided into three sections. The first two detail the origins of the non-obviousness doctrine and review the analytical protocols adopted in the United States, the United Kingdom, and Canada (at least prior to *Apotex*). The third explains in depth how the Federal Court of Appeal characterized PHOSITA in *Novopharm* (2007) and *Apotex* (2006). Because the issues uncovered here were not raised before the Supreme Court of Canada, a discussion of the changes made to the doctrine of non-obviousness in deciding *Apotex's* appeal is postponed until Part V of the article.

A. THE EMERGENCE OF THE NON-OBVIOUSNESS TEST AND PHOSITA (GENERALLY) DEFINED

Novelty and utility have always been integral to the notion of invention under Canadian patent statutes. The definition of “invention” under the present *Patent Act* reads: “Any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture, or composition of matter.”³¹

Both criteria have, however, proven relatively easy thresholds to overcome in order to obtain a patent in Canada, as elsewhere.³² Conversely, disproving the novelty or utility of an invention as a defence to patent infringement is typically difficult. One must produce a single piece of prior art that teaches every essential element of the patented invention to demonstrate that an invention is not new.³³ Courts seldom find that the prior art so anticipates.³⁴ Successfully demonstrating that an invention is not useful is likewise rare. Minimal utility will normally suffice.³⁵

introduction. However, further background about the law of non-obviousness is critical to understanding why particular variables were chosen for the content analysis.

31. R.S.C. 1985, c. P-4, s. 2.

32. Merges & Duffy, *supra* note 1 at 643.

33. *Beloit Canada Ltd. v. Velmet Oy* (1986), 8 C.P.R. (3d) 289 at 297 (F.C.A.) [*Beloit*].

34. See the empirical findings in Part III, below.

35. According to the Canadian Intellectual Property Office (CIPO), an invention will be deemed useful if it relates to a useful art, is “operable, controllable, and reproducible,” has some economic result, and is more than a “mere scientific principle or abstract theorem.” Canadian Intellectual Property Office, *Manual of Patent Office Practice*, 1998 ed. (Ottawa-Gatineau: Patent Office, 2009) c. 12 (“Utility and Subject Matter”) at 12.08, 12.05.01,

Courts have thus long espoused the view that an invention should entail “something more” than novelty and utility to be patentable. The Exchequer Court, for instance, stated in 1931:

To support a valid patent there must be something more than a new and useful manufacture, it must have involved somehow the application of the inventive mind: the invention must have required for its evolution some amount of ingenuity to constitute subject matter, or in other words invention.³⁶

Yet, in so holding, courts are immediately confronted with a paradox: possessing “something more” may be crucial, but defining what that is seems to border on the impossible. In *Canada v. Uhlemann Optical Co.*,³⁷ Justice Thorson of the Privy Council stated:

No one has really succeeded in defining ... the difference between an advance that is obvious as a workshop improvement and one that involves inventive ingenuity. One of the difficulties is that there is no objective standard of invention. What one person might regard as inventive another would consider as obvious.³⁸

One of the most colourful jurists of his time, Justice Learned Hand of the Circuit Court for the District of New York, stated that determining what constitutes a true invention is “as fugitive, impalpable, wayward, and vague a phantom as exists in the whole paraphernalia of legal concepts.”³⁹

Various formulations of a test to determine the obviousness of an invention were nonetheless put forth, beginning in the United States. A ruling from 1850, *Hotchkiss v. Greenwood*,⁴⁰ is the earliest formulation of a requirement resembling non-obviousness. In *Hotchkiss*, the US Supreme Court held that a door-knob invention was not patentable “unless more ingenuity and skill in applying the old method of fastening the shank and the knob were required in the application of it to the clay or porcelain knob than were possessed by an *ordinary mechanic acquainted with the business*.”⁴¹ Although it is unclear whether the ma-

online: <[http://strategis.gc.ca/eic/site/cipointernet-internetopic.nsf/vwapj/chapitre12-chapter12-eng.pdf/\\$file/chapitre12-chapter12-eng.pdf](http://strategis.gc.ca/eic/site/cipointernet-internetopic.nsf/vwapj/chapitre12-chapter12-eng.pdf/$file/chapitre12-chapter12-eng.pdf)>.

36. *Canadian Gypsum Co. Ltd. v. Gypsum, Lime & Alabastine, Canada Ltd.*, [1931] Ex. C.R. 180.

37. [1950] Ex. C.R. 142 [*Uhlemann Optical*].

38. *Ibid.* at para. 30.

39. *Harries v. Air King Products*, 183 F.2d 158 (2d Cir. 1950) at 162.

40. 52 U.S. 248 (1850) [*Hotchkiss*].

41. *Ibid.* at 267 [emphasis added].

majority was attempting to capture something beyond novelty when the opinion is read in its entirety, modern day PHOSITA, or at least the US version thereof, is often traced back to this particular passage in *Hotchkiss*.⁴²

In the United Kingdom, counsel by the name of Sir Stafford Cripps supplied what would become the hallmark formulation of the test. In *Sharpe & Dohme Inc. v. Boots Pure Drug Coy. Ltd.*,⁴³ the English Court of Appeal quoted the following “Cripps question” with approval:

Was it obvious to *any skilled chemist, in the state of chemical knowledge existing at the date of the Patent*, that he could manufacture valuable therapeutic agents by making the higher alkyl resorcinols by the use of the condensation and reduction processes described? If the answer is “No” the Patent is valid as regards subject-matter; if “Yes” the Patent is not valid.⁴⁴

While Canadian courts do not seem to have been influenced by *Hotchkiss* and the evolving non-obviousness doctrine south of the border, they did eventually integrate the Cripps question into Canadian patent law. In *Burns & Russell of Canada Ltd. v. Day & Campbell Limited*,⁴⁵ the Exchequer Court accepted the Cripps question in principle, even though it did not find it applicable to the case at bar. In 1979, however, Justice Pigeon of the Supreme Court of Canada finally applied the Cripps question in *Hoechst v. Halocarbon (Ontario) Ltd. et al.*⁴⁶

Despite the fact that the Cripps question casts PHOSITA in relatively benign terms—someone skilled but ordinary—courts have long shown a tendency to describe PHOSITA more pejoratively. This might, in part, be attributable to how the question of non-obviousness was framed before PHOSITA entered on the scene. In *The Edison Bell Phonograph Corporation, Limited v. Smith and Young*,⁴⁷ for instance, the House of Lords stated:

It really comes to this, that, although the invention is new—that is, that nobody has thought of it before—and although it is useful, yet, when you consider it, you come to the conclusion that it is so easy, so palpable, that everybody who thought for a mo-

42. See *e.g.* L. James Harris, “Section 103 Revisited” (1966) 9 Pat. Trademark & Copy. J. Res. & Ed. 617 at 619.

43. (1928), 45 R.P.C. 153.

44. *Ibid.* at 162-63 [emphasis added].

45. [1966] Ex. C.R. 673 at 681-82.

46. [1979] 2 S.C.R. 929 at 945 [*Halocarbon*].

47. (1894), 11 R.P.C. 389.

ment would come to the same conclusion; or, in more homely language, hardly judicial, but rather business like, it comes to this, it is so easy that any fool could do it.⁴⁸

While that may no longer be an accurate description, PHOSITA is regularly qualified as “unimaginative,” “uncreative,” or “non-innovative.”⁴⁹ Justice Hugessen’s portrays PHOSITA in *Beloit* as follows:

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.⁵⁰

Although the non-obviousness requirement is now codified by statute in the United States, the United Kingdom, and Canada (see Table 1), the influence of the common law remains crucial.⁵¹ While *KSR* promises to re-shape the application of the requirement in the United States, Justice Hugessen’s eccentric words in *Beloit* have embodied the test for non-obviousness (and the attributes of PHOSITA) in Canada for over twenty years.⁵²

B. TEST AS ANALYTICAL PROTOCOL: JURISDICTIONAL IDIOSYNCRASIES

In addition to variations in how PHOSITA’s capacities are generally defined, courts in different jurisdictions have developed different analytical protocols to manage the non-obviousness inquiry. In *Graham*, the US Supreme Court

48. *Ibid.* at 398.

49. See e.g. *Procter & Gamble Co. v. Beecham Canada Ltd.* (1982), 61 C.P.R. (2d) 1 at 27 (F.C.A.) [*Beecham*].

50. *Supra* note 33 at 294.

51. Of course, the statute trumps in the event of any inconsistency. For example, under *Beloit*, the relevant date upon which to assess obviousness was the “claimed date of invention,” to be ascertained as a matter of fact. *Ibid.* at 294. However, amendments made to the *Patent Act*, as Canada moved to a “first-to-file” (as opposed to “first-to-invent”) system, have required the assessment to be made at the date of patent application filing. See *Patent Act*, *supra* note 31, ss. 28.3, 27.1.

52. In *Apotex* (2008), *supra* note 15, the Supreme Court of Canada created a new framework for analyzing the issue of obviousness.

TABLE 1: STATUTORY FORMULATIONS OF THE NON-OBVIOUSNESS REQUIREMENT IN THE UNITED STATES, UNITED KINGDOM, AND CANADA

35 U.S.C. §103	103. A patent may not be obtained though the invention is not identically disclosed or described as in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.
<i>Patents Act 1977</i> (U.K.), 1977, c. 37, s. 3	3. An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art by virtue only of section 2(2) above (and disregarding section 2(3) above). 2(2) The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, by use or in any other way.
<i>Patent Act, R.S.C. 1985,</i> c. P-4, s. 28.3	28.3 The subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to (a) information disclosed more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant in such a manner that the information became available to the public in Canada or elsewhere; and (b) information disclosed before the claim date by a person not mentioned in paragraph (a) in such a manner that the information became available to the public in Canada or elsewhere.

parsed section 103 into four discrete steps:

Under § 103, [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. [4] Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or non-obviousness, these inquiries may have relevancy.⁵³

53. *Supra* note 8 at 17.

Putting aside the reference to “secondary considerations” for the moment, the test governing the obviousness inquiry in the United Kingdom bears a broad resemblance to the protocol envisaged in *Graham*. As originally formulated by the English Court of Appeal, the test espoused in *Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd.*⁵⁴ entails the following four steps:

The first step is to identify the inventive concept embodied by the patent in suit. Thereafter, the court has to assume the mantle of the normally skilled but unimaginative addressee in the art at the priority date and to impute to him what was, at that date, common general knowledge in the art in question. The third step is to identify what, if any differences exist between the matter cited as being “known or used” and the alleged invention. Finally, the court has to ask itself whether viewed without any knowledge of the alleged invention, those differences constitute steps which would have been obvious to the skilled man or whether they require any degree of invention.⁵⁵

Lord Justice Jacob recently reformulated the *Windsurfing* test in *Pozzoli SPA v. BDMO SA* as follows:

- 1) (a) Identify the notional “skilled person in the art”;
- (b) Identify the relevant common general knowledge of that person;
- 2) Identify the inventive concept of the claim in question or if that cannot be readily done, construe it;
- 3) Identify what, if any, differences exist between the matter cited as forming part of the “state of the art” and the inventive concept of the claim or the claim as construed;
- 4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?⁵⁶

The Lord Justice’s reasons for reformulating the test reveal the relative primacy of PHOSITA over the prior art in the United Kingdom as compared to the United States. A re-ordering of the first two steps was necessary because, as he describes, it is “only through the eyes of the skilled man that one [can] properly understand what such a man would understand the patentee to have meant and thereby set about identifying the [inventive] concept.”⁵⁷ Under the *Graham*

54. [1985] R.P.C. 59 [*Windsurfing*].

55. *Ibid.* at 73.

56. [2007] EWCA Civ 588 at para. 14 [*Pozzoli*].

57. *Ibid.* at para. 15.

protocol, in contrast, PHOSITA is not even explicitly named. This perhaps partly explains the onset (and increasingly rigid application) of a requirement that some explicit or implicit “teaching, suggestion, or motivation” to combine various bits of information must exist in the prior art for an invention to be found obvious. Dissociated from the person—even a fictitious one—who might be shown (based on evidence) to be capable of synthesizing various sources of information, the prior art (and what it does or does not reveal by explicit or implicit teaching, motivation, or suggestion) became all-important in the United States, at least prior to *KSR*.⁵⁸

Note, however, that the process of determining whether an alleged invention is obvious in both jurisdictions involves some degree of claim construction: differences between the prior art and the patent’s claims are to be identified under steps two and three of the American and English tests, respectively.⁵⁹ In Canada, the scope of the invention in question vis-à-vis the prior art and/or PHOSITA is instead loosely described as one factor amongst several in a non-exhaustive list of factors that may or may not help decide the issue of obviousness.⁶⁰

C. MORE SPECIFIC FACT-FINDING: SECONDARY CONSIDERATIONS AND PHOSITA CHARACTERIZATION

Within the parameters of the applicable non-obviousness test and corresponding protocol,⁶¹ courts in all three jurisdictions are supposed to arrive at several

58. Provided the TSM test is not applied in an excessively rigid manner (for example, so as to preclude the PHOSITA from looking at prior art designed to solve the same problem, or from relying upon his or her common sense) then it remains good law. See *KSR*, *supra* note 10 at 1743.

59. In contrast, claim construction has historically been framed as a distinct, antecedent exercise in Canada. See *Free World Trust v. Electro Santé Inc.*, [2000] 2 S.C.R. 1024 at para. 19 [*Free World Trust*]; *Whirlpool Corp. v. Camco Inc.*, [2000] 2 S.C.R. 1067 at para. 43 [*Whirlpool*]. *Apotex* changed this, however, with the Supreme Court of Canada adopting the test put forth by Jacob L.J. in *Pozzoli*, *supra* note 56. As a result, a degree of claim construction has now been incorporated into the Canadian obviousness analysis.

60. *Novopharm* (2007), *supra* note 17 at para. 27.

61. Whereas courts in the United States and the United Kingdom clearly view the test as a procedure to be determined in a step-wise fashion, Canadian courts appear to view obviousness as a singular question, with Hugessen J.’s words in *Beloit* representing the leading expression. See *Beloit*, *supra* note 33 at 294. Consideration of the consequence of this conceptual difference is beyond the scope of this article and is likely rendered moot, given the Supreme Court of Canada’s decision in *Apotex* (2008), *supra* note 15.

findings of fact during the course of the obviousness analysis. Some findings of fact, the so-called “secondary considerations,” are not strictly required, but have been recognized as potentially relevant to the obviousness inquiry in the United States, the United Kingdom, and Canada. The “commercial success” of the invention usually garners the most attention. If an invention can be shown to be commercially successful, courts sometimes appear more comfortable with finding an invention truly inventive.⁶² However, courts can also be persuaded that any such success is just as attributable to sophisticated marketing and other business strategies.⁶³ Other secondary factors include long felt need,⁶⁴ acceptance by the relevant community and/or awards,⁶⁵ and the failure of others.⁶⁶ While, in some cases, secondary factors have been elevated to the status of “objective criteria,”⁶⁷ they usually do not play a determinative role in the decision.⁶⁸

Conversely, findings of fact about PHOSITA’s knowledge, skill, et cetera, should, under the *Beloit* test, effectively answer the question of whether an invention is obvious or not in most cases. Yet, while the Court of Appeal’s characterizations of PHOSITA in *Novopharm* and *Apotex* were critical, neither outcome was rooted in factual findings purely about who the PHOSITA was, what he or she knew, or what he or she could perform. On the contrary, PHOSITA was, in each case, characterized *relative* to the inventor named on the patent in dispute.

As the starting point for the overarching problem framed and studied in this article, this observation merits careful explanation. In *Novopharm*, Justice Sharlow described Dr. Hayakawa as “not only a person skilled in the art, but a person who is an acknowledged inventor.”⁶⁹ Convinced of his inventive ability,

62. See *Uhlemann Optical, supra* note 37 at 33; *Diversified Products Corp. v. Tye-Sil Corp.* (1991), 35 C.P.R. (3d) 350 at 368 (F.C.A.) [*Diversified Products*].

63. See e.g. *Illinois Tool Works Inc. v. Cobra Fixations Cie/Cobra Anchors Co.* (2002), 20 C.P.R. (4th) 402 at para. 126 (F.C.T.D.) [*Illinois Tool*].

64. See e.g. *Eli Lilly Canada Inc. v. Apotex Inc.* (2007), 58 C.P.R. (4th) 353 at para. 356 (F.C.) [*Eli Lilly*].

65. *Novopharm* (2007), *supra* note 17 at para. 25.

66. *CertainTeed Corp. v. Canada (Attorney General)* (2006), 50 C.P.R. (4th) 177 at para. 43 (F.C.) [*CertainTeed*].

67. *Almecon Industries Ltd. v. Nutron Manufacturing Ltd.* (1996), 65 C.P.R. (3d) 417 (F.C.T.D.); *Bourgault Industries Ltd. v. Flexi-Coil Ltd.* (1998), 80 C.P.R. (3d) 1 at para. 63 (F.C.T.D.).

68. Rather, they are most often cited to buttress a conclusion of non-obviousness.

69. *Novopharm* (2007), *supra* note 17 at para. 35.

the court found that the “evidence discloses no sound basis for concluding that a person of ordinary skill in the art with knowledge of the 1985 Gerster poster”—the key piece of “prior art” that Dr. Hayakawa himself once attended a presentation of, before filing an application for the patent under dispute—“would have made the same connections as Dr. Hayakawa.”⁷⁰ Thus, the invention was found to be non-obvious.⁷¹ In essence, then, Justice Sharlow effectively conducted the inquiry in reverse by concluding that PHOSITA—whomever he or she may have been—would have lacked the ability to make the same inferences as Dr. Hayakawa. The Court of Appeal did not say who PHOSITA was, but rather who PHOSITA was not—that is, the court engaged in what we might call “negative characterization.”

In contrast, the Federal Court of Appeal (and the Federal Court below) in *Apotex* clearly struggled with the task of determining the obviousness of an invention from the perspective of an ordinary-skilled person, given that the evidence at its disposal primarily spoke to the knowledge, skills, and challenges endured by the inventor himself, Mr. Badorc. Despite Justice Noël’s words to the contrary,⁷² the recital of the lower court’s findings of fact as to what PHOSITA would have known, while in the same breath, highlighting Mr. Badorc’s evidence as to the technical difficulties of identifying the drug in question,⁷³ inevitably conflates the distinction between the two. Mr. Badorc essentially supplied the perspective of both PHOSITA and patentee: he was “possessed of the characteristics” of a person skilled in the art, but, at the same time, displayed “intuitive abilities.”⁷⁴ In *Apotex*, then, PHOSITA would appear more real compared to *Novopharm*, but still secondary to the evidence of the inventor or expert.

70. *Ibid.* at para. 36.

71. It is interesting to speculate about what the basis for the distinction between Dr. Hayakawa and PHOSITA was. Relying on the subject invention as proof of Dr. Hayakawa’s inventiveness would be tautological, given that the obviousness of that very invention was at issue. Alternatively, assuming that he, as the author of other patented inventions, was more likely to possess or exhibit the requisite inventiveness would appear to support a double standard. Could the burden upon non-established inventors (defined as those who do not hold other patents) in terms of showing that their inventions would not have occurred to PHOSITA be higher relative to established inventors such as Dr. Hayakawa? This question is beyond the scope of this article.

72. See *Apotex* (2006), *supra* note 20 at para. 35.

73. *Ibid.* at paras. 36, 42.

74. *Ibid.* at paras. 35-36.

To the extent that courts do consult PHOSITA's perspective, whether through negative characterization or otherwise, commentators also charge that they do so only for the limited purposes of assessing what prior art references would reveal to a suitably trained reader.⁷⁵ *Novopharm* is illustrative: Justice Sharlow keyed upon what the Gerster poster would have conveyed (albeit to Dr. Hayakawa, as opposed to PHOSITA) without also determining what PHOSITA would have come to know through his or her cumulative experience.⁷⁶

However, while prior art is *an* important source of information about what PHOSITA would have known at the relevant time, it is not the sole source. Depending on the technological field or type of industry, PHOSITA may owe much of his or her capacities to his or her "tacit knowledge"⁷⁷—that is, knowledge or know-how possessed by individuals, acquired over time and through experience, and not already disclosed in printed publications, patent applications, or other forms of prior art theoretically discoverable to PHOSITA. Focusing predominantly, if not exclusively, on what prior art would have been known to PHOSITA, and how PHOSITA would have interpreted it or put it to use, potentially omits a sizeable portion of PHOSITA's corpus of knowledge and skills.

The next Part sets out the methodologies used to investigate whether the shortcomings observed in *Novopharm* and *Apotex* represent aberrations within Canadian patent jurisprudence or are, instead, commonplace.

II. RESEARCH METHODOLOGIES

Beginning in the mid-twentieth century, a few scholars began to analyze the law in a quantitative fashion using a social science methodology known as "content analysis." To perform content analysis, "a scholar collects a set of documents, such as judicial opinions on a particular subject, and systematically reads them, recording consistent features of each and drawing inferences about their use and meaning."⁷⁸

75. See *e.g.* Eisenberg, *supra* note 9.

76. As explained below, however, both inquiries are required under the *Patent Act*. See *Patent Act*, *supra* note 31, s. 28.3.

77. Michael Polanyi was the first to identify and discuss the importance of tacit knowledge. See Michael Polanyi, *The Tacit Dimension* (New York: Anchor Books, 1967).

78. Mark A. Hall & Ronald F. Wright, "Systematic Content Analysis of Judicial Opinions" (2008) 96 Cal. L. Rev. 63 at 64.

Although content analysis has significant value as a way of “generating objective, falsifiable, and reproducible knowledge about what courts do and how and why they do it,”⁷⁹ this methodology also has clear limitations. Content analysis trades quality for quantity. Coding cases for the presence or absence of pre-selected facts or factors cannot, for example, capture the strength of a particular judge’s rhetoric nor a variety of other nuances in legal reasoning that inform the legal community’s sense of what precedential value to assign to a judicial decision.

There is also a deeper problem with this methodology: using content analysis to predict judicial outcomes is at serious risk of being tautological, as the facts or factors courts choose to rely upon may only reflect, rather than generate, the legal result in question. Certain facts may also form part of the overall record for the proceeding (through *viva voce* testimony, affidavit evidence, et cetera), but be omitted from the final decision.

However, when what is being sought after is a sense of the facts or factors courts choose to give explicit focus to—rather than an assessment of how those variables might predict specific legal outcomes—content analysis can serve as a valuable complement to more interpretive modes of legal analysis.⁸⁰ Although examining the entire record for every proceeding would be ideal,⁸¹ a content analysis of judicial decisions alone can help us to discover previously unnoticed patterns in the jurisprudence, setting the stage for deeper inquiries.

That is the intended pairing here. Content analysis is used to describe, in empirical terms, how Canadian courts apply the non-obviousness requirement—and, more specifically, to examine the extent to which they characterize PHOSITA during the inquiry while “controlling for” (that is, recording) a host of other variables that may or may not prove relevant.⁸² Against this body of data, a deeper critique of the jurisprudence is then developed, incorporating insights from intellectual property-related literatures in the fields of sociology, management, and economics. Details about the specific population of cases under

79. *Ibid.* at 64.

80. *Ibid.* at 66.

81. For practical reasons, such a comprehensive review of the cases included in this content analysis was not performed.

82. Given the centrality of PHOSITA to the question of obviousness, it was assumed that the court should include any and all findings of fact made related to PHOSITA in the body of a decision.

scrutiny and the coding system that was developed to carry out the analysis are described next.

A. THE POPULATION

Findings of fact (or the absence thereof) made in connection with the obviousness inquiry are the primary focus here. Thus, only decisions at the trial level were included in the content analysis. For practical reasons, the pool was further limited to decisions issued by the Federal Court, where the majority of patent disputes are litigated in Canada.⁸³ Since *Beloit* was assumed to be the leading statement of the non-obviousness test, the pool was also limited to those decisions where the Federal Court of Appeal's decision is referenced. A search of the QuickLaw database, limited to Federal Court decisions with the terms "patent" and "obvious"⁸⁴ appearing in the headnote, as well as the term "Beloit" anywhere in the text, returned eighty decisions.⁸⁵

B. DATA COLLECTION

A coding system for recording twenty variables was developed to perform the content analysis on the case population (see Table 2). Proponents of content analysis caution that it is better to code for as many different variables as possible, even though certain variables may not appear relevant to the specific inquiry. Perhaps the way in which the non-obviousness test is applied will vary depending on the technological field of the alleged invention, the nature of the proceeding, how the question of obviousness is framed, whether novelty is also at issue, or the number of prior art references tendered as evidence before the court. As a result, for each decision in the pool, a number of general features were recorded, including: the technological field of the invention; the type of proceeding (either a summary proceeding under the *PMNOC Regulations* or an ordinary action for patent infringement);⁸⁶ whether obviousness is framed as a

83. Decisions by other Canadian courts have had an impact upon the direction of Canadian patent law. While those decisions were not included in the content analysis, they were incorporated into the doctrinal analysis. See Part IV, below.

84. The search was conducted so as to capture any decisions where the word "obvious" appeared, whether as a whole word or as the root of other words.

85. This search was conducted in August 2007.

86. Proceedings under the *PMNOC Regulations*, *supra* note 15, are intended to be summary in nature, and the patent-holder is entitled to bring a separate action for patent infringement.

question of fact, mixed fact and law, or pure law; whether anticipation was pled and found; and the total number of prior art references recorded.

A second cluster of variables focuses on how the obviousness analysis was executed. With the exception of whether or not PHOSITA is deployed for the purpose of patent claim construction,⁸⁷ these “analytic variables” flow from the foregoing primer regarding the non-obviousness doctrine and the Federal Court of Appeal’s decisions in *Novopharm* and *Apotex*. They are intended to capture whether PHOSITA is used to interpret the prior art, the extent to which PHOSITA is characterized, and the role of secondary considerations. However, the actual coding system corresponding to each of these variables requires further explanation.

Two variables concern whether PHOSITA is used to interpret the prior art or, alternatively, whether the court relies solely upon expert evidence for that task. Each variable is coded in a binary fashion. The court must do more than simply quote from *Beloit* or some other authority stating that the prior art should be interpreted through PHOSITA’s eyes in order to be coded as a “1.” For example, the court must explicitly choose between two competing interpretations of a particular prior art reference, based on what the court deems PHOSITA to know or not know. Without such a meaningful use of PHOSITA in interpreting the prior art, the decision is coded as a “0” for this variable. On the other hand, if the court fails to utilize PHOSITA for this purpose, and also selects an expert’s interpretation of the prior art without explicitly acknowledging that PHOSITA is the proper lens through which such interpretation is to be performed, the decision is then coded as a “1” under this second prior art-related variable.

The next set of variables attempts to track whether courts make specific findings of fact about PHOSITA. Whether a court specifies that PHOSITA would have a Ph.D. degree in biochemistry versus several years of post-secondary education should not, in principle, pre-determine the question of obviousness. Rather, what is important is that the court turns its mind to meaningfully assess

This is precisely what occurred in *Novopharm*. Prior to the decision by the Federal Court of Appeal, Mosley J., in the context of an application pursuant to the *PMNOC Regulations*, found the patent invalid due to obviousness. See *Janssen-Ortho Inc. v. Novopharm Ltd.* (2004), 35 C.P.R. (4th) 353 (F.C.) [*Janssen-Ortho*]. With the benefit of what he described as more “extensive evidence,” Hughes J. later arrived at the opposite conclusion. See *Janssen-Ortho Inc. v. Novopharm Ltd.* (2006), 57 C.P.R. (4th) 6 (F.C.) [*Novopharm* (2006)], aff’d *Novopharm* (2007), *supra* note 17.

87. The reason for coding for this variable will become apparent in the analysis below.

what PHOSITA would know and be able to accomplish; the presence or absence of certain specific findings of fact may be indicators of the same. Thus, to register as a “1” under level of education, it was sufficient, but not necessary, for the court to specify a particular degree. The court could simply make some generic statement about PHOSITA being “highly educated”; otherwise the decision would be coded as a “0” for this variable. Similarly, noting that PHOSITA had several years of post-graduate training would earn a “1” under level of experience.

Coding for whether the court acknowledged the existence of PHOSITA’s tacit knowledge was particularly challenging. Any explicit acknowledgment of PHOSITA’s “tacit knowledge,” “know-how,” or “experiential knowledge”—terms that are sometimes used interchangeably in other disciplines—would garner a “1.” However, the decision was made to code discussion about whether PHOSITA would have to engage in experimentation or testing in order to know something as a “0,” unless the court talked about PHOSITA’s pre-existing store of knowledge and skill acquired through such experimentation or testing. This distinction is perhaps too fine—but, as explained below, the issue, as the courts saw it, usually reduced to whether PHOSITA could even engage in experimentation, quite apart from what level of tacit knowledge PHOSITA possessed, past or present.

The fourth characterization variable was intended as a catch-all. If a court qualified PHOSITA in any other way—for instance, by acknowledging that PHOSITA was a composite of individuals and skill sets, that PHOSITA was able to synthesize multiple prior art references, or that PHOSITA exhibited a particular tendency to publish his/her work—then this variable was scored as a “1.”

To help ensure reliability, the coding criterion for negative characterization was intentionally narrow. Cases were read with a view to finding statements similar to those espoused by Justice Sharlow in *Novopharm* (2007)—in other words, where the court *explicitly* assigns PHOSITA with a status inferior to the alleged inventor.

The next grouping of variables comprises factors considered relevant, but secondary to an invention’s obviousness. Coding was straightforward, save for the fact that if a court found commercial success (or some other secondary factor), but questioned its significance to obviousness based on the facts, then the decision received a “0.”

The final two variables are not specifically concerned with analysis execution. The penultimate variable aims to provide insight into the role of innovation.

TABLE 2: CONTENT ANALYSIS – VARIABLES AND CODING SYSTEM

Variable	Coding System
Technological Field	The number 1, 2, 3, 4, 5, 6, 7, or 8 was assigned depending on whether the putative invention belonged to the agricultural, electrical, pharmaceutical, biomedical, computer-related, general, chemical, or oil/mining-related fields, respectively.
Whether <i>PMNOC</i> Case	0 – No; 1 – Yes
Question Frame	0 – If the issue of non-obviousness was not framed at all; 1 – If the issue of non-obviousness was framed as a question of fact; 2 – If the issue of non-obviousness was framed as a mixed question of law and fact; 3 – If the issue of non-obviousness was framed as a question of law
Anticipation at Issue	0 – No; 1 – Yes
No. of Prior Art References	When possible, the actual number of prior art references cited by the court was noted. (In some decisions the court did not state the precise number.)
Claims Construed Using PHOSITA	0 – No; 1 – Yes
Prior Art Interpreted through PHOSITA	0 – No; 1 – Yes
Prior Art Interpreted through Experts Only	0 – No; 1 – Yes
PHOSITA's Level of Education*	0 – No; 1 – Yes
PHOSITA's Level of Experience*	0 – No; 1 – Yes
Reference to PHOSITA's Tacit Knowledge*	0 – No; 1 – Yes
Any Other Reference to PHOSITA's Identity, Knowledge, or Skill*	0 – No; 1 – Yes
Negative Characterization	0 – No; 1 – Yes
Positive Finding of Commercial Success**	0 – No; 1 – Yes
Positive Finding of Long Felt Need**	0 – No; 1 – Yes
Positive Finding of Failure by Others**	0 – No; 1 – Yes
Positive Finding of Community Acceptance or Awards**	0 – No; 1 – Yes
Any Reference to the Public Domain or the "Commons"	0 – No; 1 – Yes
Patent Found Invalid for Obviousness	0 – No; 1 – Yes

* These four variables were added together to generate a "Total Characterization Score" (between 0 and 4) for each decision. Note that the 'negative characterization' variable was excluded from this score.

** These four variables were added together to generate a "Total Secondary Factor Score" (between 0 and 4) for each decision.

theory in the jurisprudence by attempting to capture whether courts are cognizant of the interface between the proprietary and the non-proprietary realms—an interface which, as explained in Part V below, is critically important for scientific innovation. Decisions where the court made mention of the “public domain” or “the commons,” potentially signalling a basic awareness that knowledge that is not patented has some role to play in the innovation process, were coded as a “1.” The final variable recorded the outcome of the obviousness inquiry in each case.

III. EMPIRICAL FINDINGS

A. GENERAL

Fifty-two Federal Court decisions from the total population of eighty were coded.⁸⁸ Although there were more cases (twenty-three) involving pharmaceutical inventions than inventions from other technological fields, the population was relatively diverse.⁸⁹ Other general features of these decisions are summarized in Table 3. Anticipation was often alleged in tandem with obviousness, but with less success.⁹⁰ Two other general findings are noteworthy insofar as they appear inconsistent with the caselaw. First, only eight of the decisions explicitly framed obviousness as a factual inquiry.⁹¹ Courts instead typically quoted the *Beloit* test

88. This group was assumed to be representative of the total pool. The cases were coded in two passes. First, every third case (in chronological order) was coded; then, every second case was coded.

89. The remaining 29 cases included agricultural (3), electrical (2), biotechnological (1), mechanical (18), chemical (4), and mining (1) inventions.

90. This contrasts slightly with the findings of Allison & Lemley, *supra* note 6. They found that patented inventions were found invalid due to anticipation in 37 out of 91 decisions (40.7 per cent), whereas allegations of obviousness were more common but less successful (58 out of 160 decisions, or 36.3 per cent). The decisions where anticipation was found are: *Beloit Canada Ltd. et al. v. Valmet Oy* (1984), 78 C.P.R. (2d) 1 (F.C.T.D.); *J.M. Voith GmbH v. Beloit Corp.* (1989), 27 C.P.R. (3d) 289 (F.C.T.D.) [*J.M. Voith*]; *SmithKline Beecham Pharma Inc. v. Apotex Inc.* (2001), 14 C.P.R. (4th) 76 (F.C.T.D.) [*SmithKline Beecham*]; *Novartis AG v. Apotex Inc.* (2001), 15 C.P.R. (4th) 417 (F.C.T.D.) [*Novartis*]; *Abbott Laboratories v. Canada (Minister of Health)* (2005), 42 C.P.R. (4th) 121 (F.C.); *Abbott Laboratories v. Canada (Minister of Health)* (2007), 54 C.P.R. (4th) 356 (F.C.) [*Abbott*]; and *AstraZeneca AB v. Apotex Inc.* (2007), 60 C.P.R. (4th) 199 (F.C.) [*AstraZeneca*].

91. The eight decisions were: *Computalog Ltd. v. Comtech Logging Ltd.* (1990), 32 C.P.R. (3d) 289 (F.C.T.D.); *Martinray Industries Ltd. v. Fabricants National Dagendor Manufacturing*

(which does not, strictly speaking, name the factual nature of the inquiry) and proceeded to evaluate the expert evidence. Second, in less than half of the decisions was PHOSITA meaningfully used in the exercise of claim construction, despite the Supreme Court of Canada's clear direction to do so in *Free World Trust* and *Whirlpool*.⁹²

It is difficult to determine whether these findings reflect actual errors in judicial reasoning or are instead a by-product of content analysis methodology (or the specific coding system employed here). Weighing the opinions of experts is intrinsic to the trier of fact. Perhaps it does not matter that the Federal Court is not in the habit of naming obviousness as a question of fact, despite the importance placed upon doing so in other contexts⁹³ and because, unlike in the United States, there are no contrasting authorities.⁹⁴

That PHOSITA was seemingly seldom used in claim construction may also be misleading. Courts frequently, if not always, identified the ordinary skilled person as the individual to whom the patent claims were addressed. The

Ltd. (1991), 41 C.P.R. (3d) 1 (F.C.T.D.); *CFM Inc. v. Wolf Steel Ltd.* (1993), 50 C.P.R. (3d) 215 (F.C.T.D.) [*Wolf Steel*]; *Apotex Inc. v. Wellcome Foundation Ltd.* (1998), 79 C.P.R. (3d) 193 (F.C.T.D.) [*Wellcome Foundation*]; *AB Hassle v. Apotex Inc.* (2003), 27 C.P.R. (4th) 465 (F.C.T.D.) [*AB Hassle*]; *CertainTeed*, *supra* note 66; *Novopharm* (2006), *supra* note 86; and *AstraZeneca*, *ibid.*

92. The twenty-one decisions were: *Reading and Bates Construction Co. v. Baker Energy Resources Corp.* (1986), 13 C.P.R. (3d) 410 (F.C.T.D.); *Diversified Products Corp. v. Tye-Sil Corp. Ltd.* (1987), 16 C.P.R. (3d) 207; *J.M. Voith*, *supra* note 90; *Wolf Steel*, *ibid.*; *Anderson v. Machineries Yvon Beaudoin Inc.* (1994), 58 C.P.R. (3d) 449 (F.C.T.D.); *Almecon Industries Ltd. v. Nutron Manufacturing Ltd.* (1996), 65 C.P.R. (3d) 417 (F.C.T.D.); *Apotex Inc. v. Syntex Pharmaceuticals International Ltd.* (1999), 1 C.P.R. (4th) 22 (F.C.T.D.); *Novartis*, *supra* note 90; *Illinois Tool*, *supra* note 63; *Westaim Corp. v. Royal Canadian Mint* (2002), 23 C.P.R. (4th) 9 (F.C.T.D.); *GlaxoSmithKline Inc. v. Genpharm Inc.* (2003), 30 C.P.R. (4th) 360 (F.C.); *Halford v. Seed Hawk Inc.* (2004), 31 C.P.R. (4th) 434 (F.C.); *Janssen-Ortho*, *supra* note 86; *Abbott*, *supra* note 90; *Pfizer Canada Inc. v. Novopharm Ltd.* (2005), 42 C.P.R. (4th) 502 (F.C.); *Pfizer Canada Inc. v. Apotex Inc.* (2005), 43 C.P.R. (4th) 81 (F.C.); *Aventis Pharma Inc. v. Apotex Inc.* (2005), 44 C.P.R. (4th) 108 (F.C.); *Abbott Laboratories v. Canada (Minister of Health)* (2006), 46 C.P.R. (4th) 324 (F.C.); *Dimplex North America Ltd. v. CFM Corp.* (2006), 54 C.P.R. (4th) 435 (F.C.); *Novopharm* (2006), *ibid.*; and *AstraZeneca*, *ibid.*
93. In the administrative law context, for instance, the nature of the question has long been an important consideration (albeit not a determinative one) in arriving at the applicable standard of review. This remains the case, notwithstanding the recent reformulation of what the different possible standards are. See *Dunsmuir v. New Brunswick*, [2008] 1 S.C.R. 190 at para. 53.
94. Prior to *KSR*, *supra* note 10, the Federal Circuit had, on occasion, framed obviousness as a question of law.

TABLE 3: GENERAL FEATURES

Variable	Coding System
Question Frame	Only 8/52 cases (-15%) explicitly framed obviousness as a factual inquiry.
Anticipation at Issue	In 73.08% of the cases (38/52) anticipation was also raised.
Anticipation Found	Anticipation was found in 7/38 (-18%) cases in which it was plead.
Claims Construed Using PHOSITA	In 21/52 cases (-40%) PHOSITA was used for claim construction.
Prior Art Interpreted through PHOSITA	PHOSITA was meaningfully used to interpret the prior art in 32/52 (-62%) cases.
Prior Art Interpreted through Experts Only	The prior art was interpreted through experts only in 11/52 (-21%) decisions.
Any Reference to the “Public Domain” or the “Commons”	In 7/52 (-13%) cases the term ‘public domain’ appeared.
Patent Found Invalid for Obviousness	The patents in question were found invalid due to obviousness in 13/52 (25%) decisions.

skilled person was simply not invoked when choosing one party’s offered interpretation of the claims over the other. Rather, the court frequently said that it found one expert’s view more credible than the other, at times for reasons wholly unrelated to the technological field and claims.⁹⁵ Under the coding system employed here, that does not register as using PHOSITA in claims construction.

References to the “public domain” were made in seven decisions.⁹⁶ This, too, reveals a limitation of coding cases. The term was intended to identify passages where the court grapples with the interplay between the proprietary and non-proprietary in terms of its importance for scientific innovation. However, in none of the seven cases where the term “public domain” appeared was that interplay discussed. Courts were instead dealing with the issue of whether a particular

95. Courts often opted for one expert over the other because they found the other expert to be biased or less credible.

96. The term “commons” did not appear in any decision. For the seven decisions in which the phrase “public domain” occurred, see *J.M. Voith*, *supra* note 90; *Risi Stone Ltd. v. Groupe Permacon Inc.* (1995), 65 C.P.R. (3d) 2 (F.C.T.D.); *Whirlpool Corp. v. Camco Inc.* (1997), 76 C.P.R. (3d) 150 (F.C.T.D.); *GlaxoSmithKline Inc. v. Canada (Minister of Health)* (2003), 28 C.P.R. (4th) 307 (F.C.); *Janssen-Ortho*, *supra* note 86; *Pfizer Canada Inc. v. Canada (Minister of Health)* (2005), 43 C.P.R. (4th) 241 (F.C.); and *Eli Lilly*, *supra* note 64.

TABLE 4: PHOSITA CHARACTERIZATION

Variable	Coding System
PHOSITA's Level of Education	Only 11/52 (-21%) cases specified anything about PHOSITA's level of education.
PHOSITA's Level of Experience	Only 12/52 (-23%) cases gave some indication about PHOSITA's level of experience in the technological field in question.
Reference to PHOSITA's Tacit Knowledge	In <u>zero</u> decisions was any specific finding made about PHOSITA being able to rely on any particular form of 'tacit knowledge.'
Any Other Reference to PHOSITA's Identity, Knowledge or Skill	In 19/52 (-37%) cases, the court made some other remark that characterized PHOSITA.
Negative Characterization	In 5/52 (-10%) decisions, the court explicitly engaged in <i>Novopharm</i> -like negative characterization.

publication or invention formed part of the public domain and thus counted against the patent in question as prior art.

B. PHOSITA CHARACTERIZATION

Findings for each of the individual characterization variables are presented in Table 4, above. Strikingly, when the first four of these five variables are added and averaged across all decisions, the mean Total Characterization Score is 0.81. In numerical terms, the Federal Court averaged less than one specific finding of fact about who PHOSITA is, what he or she is capable of, et cetera. On the other hand, coding also reveals that negative characterization in the form witnessed in *Novopharm* is rare.⁹⁷

It is also worth noting that in the process of coding the cases for variables related to PHOSITA's characterization, no instances were found where the court referred to some form of empirical or sociological evidence (*e.g.*, surveys) tendered by counsel to show whether a particular invention would or would not have been obvious to PHOSITA.

97. Negative characterization was found in the following five decisions: *Mahurkar v. Vas-Cath of Canada Ltd.* (1988), 18 C.P.R. (3d) 417 at 435-36 (F.C.T.D.) [*Mahurkar*]; *Control Data Canada Ltd. v. Senstar Corp.* (1989), 23 C.P.R. (3d) 449 (F.C.T.D.) [*Control Data*]; *Stiga Aktiebolag v. S.L.M. Canada Inc.* (1990), 34 C.P.R. (3d) 216 (F.C.T.D.) [*Stiga Aktiebolag*]; *Wolf Steel, supra* note 91; *671905 Alberta Inc. v. Q'Max Solutions Inc.* (2001), 14 C.P.R. (4th) 129 (F.C.T.D.).

TABLE 5: SECONDARY FACTORS

Variable	Coding System
Positive Finding of Commercial Success	Courts made a positive finding of commercial success in 19/52 (-37%) decisions.
Positive Finding of Long Felt Need	Courts made a positive finding of long felt need/want in 5/52 (-10%) decisions.
Positive Finding of Failure by Others	Courts made a positive finding of failure of others in 11/52 (-21%) decisions.
Positive Finding of Community Acceptance or Awards	Courts made a positive finding of acceptance by others / meritorious awards in 13/52 (25%) decisions.

C. SECONDARY CONSIDERATIONS

Secondary factor data are provided in Table 5. Similar to the analogous characterization figure, the mean Total Secondary Factor Score was less than one (0.65). As with several other variables, the jurisprudence highlighted the limits of the process of coding secondary factors. For example, while only eleven decisions noted the failure of others in order to buttress a conclusion of non-obviousness, another oft-quoted passage from *Beloit* surrounding hindsight bias arguably amounts to the same finding.⁹⁸

D. STATISTICAL TESTS

Statistical tests were performed with the aid of computer software, despite the questionable value of such tests.⁹⁹ Briefly, there was some statistical support for the notion that the extent to which PHOSITA is characterized impacts other elements of the court's analysis. There was, for example, a statistically significant positive correlation between the Total Characterization Score in each case and the use of PHOSITA for claim construction.¹⁰⁰ The greater the degree of

98. See Parts IV(C)(1)–(2), below.

99. These statistical tests were of questionable value because of the small population size. Once armed with the coding data, however, it was impossible to resist performing these tests (using SPSS software).

100. Statistical significance is a function of probability (or p). When the probability that a correlation exists between two variables exceeds the 95 per cent confidence interval (*i.e.* $p < 0.05$), the correlation is considered statistically significant. In this case, the correlation between the Total Characterization Score and the use of PHOSITA during claim construction surpassed that threshold ($p = 0.035$).

characterization, in other words, the more likely we would see PHOSITA being used in claim construction. There was likewise a statistically significant positive correlation between the Total Characterization Score and the use of PHOSITA to interpret the prior art.¹⁰¹ The greater the Total Characterization Score, the more likely it was that PHOSITA was used to interpret prior art.

To reiterate, assessing whether PHOSITA characterization was a reliable predictor of obviousness outcomes was not the object of this content analysis. As expected, no statistical support for the notion that characterization impacts obviousness outcomes was found.¹⁰²

IV. BEYOND NUMBERS: A DEEPER CRITIQUE

Content analysis is useful here insofar as it clearly documents the lack of findings of fact made by the Federal Court in performing the non-obviousness inquiry. This Part embarks on a deeper critique of the jurisprudence—probing what the foregoing data-driven exercise only scratches at the surface of, or perhaps misses entirely. The argument that is developed in detail in this Part is essentially as follows: PHOSITA’s capacities have been interpreted by the courts in ways that may depart from the notion of a skilled, albeit ordinary, technician. More worrisome, though, are the rulings that tend to nullify the need for specific findings of fact about at least two of PHOSITA’s capacities. In lieu of contextually characterizing PHOSITA, courts engage in negative characterization (whether in its explicit *Novopharm*-esque form or in the sort of subtler “characterization con-fusions” witnessed in *Apotex*), invoke a concern over hindsight bias, or do both. Both phenomena should be of significant concern.

A. PHOSITA PHRENOLOGY

The essence of PHOSITA is ordinariness within his or her particular domain of science or art. The point at which the capacity to invent begins is, theoretically, where PHOSITA’s ordinary capacities end. A closer examination of the jurispru-

101. This correlation was very significant, statistically speaking ($p < 0.005$ (0.003)).

102. The correlation between the Total Characterization Score and whether the patented invention was found to be obvious was not significant, and this remained true when the type of invention and nature of the proceeding were controlled for (technological field, *PMNOC* versus non-*PMNOC*, et cetera). Further, regression analysis did not reveal that any of the characterization variables were significant predictors of obviousness outcomes.

dence reveals that the (hemi)sphere of inventiveness may encroach upon several capacities that would otherwise appear quite ordinary in the plain language sense of the term, if not also in Justice Hugessen's accepted depiction of PHOSITA in *Beloit*. But focusing on what is inside and outside the realm of the scientifically ordinary, as a purely conceptual matter, would seem nearly as intractable as answering what is obvious in the abstract. On the other hand, interpreting a particular capacity so as to render findings of fact unnecessary for the case at bar should attract increased scrutiny. Consider four capacities in turn.

1. CAPACITY ONE: LITERATURE REVIEW

The Supreme Court of Canada has noted, on repeated occasion, that PHOSITA evolves and grows in parallel with the state of the art.¹⁰³ This would appear to imply that PHOSITA is more than capable of keeping apprised of published developments in his or her field. On the other hand, the Federal Court has often been persuaded that, in the absence of objective proof that PHOSITA would have been aware of a particular piece of prior art, there is no reason to assume the same. In *Mahurkar*,¹⁰⁴ for instance, Justice Strayer (as he then was) stated:

[A]n objective test should be applied to determine whether [PHOSITA] could be reasonably assumed to have knowledge of such prior art. ... No evidence was produced by the defendants to show that [PHOSITA] should be assumed to have been aware of all of this prior art. Frankly, I find it difficult to believe...¹⁰⁵

This proposition was cited with approval by Justice Hansen in *Westaim Corp. v. Royal Canadian Mint*,¹⁰⁶ amongst several other decisions. We can debate as to whether the opposite presumption would be more in keeping with the Supreme Court's rulings. However, the more important point is that PHOSITA's capacity for literature review is to be determined in each case according to what the ordinary scientist conducting research in the real world would be able to find. In bridging this divide between PHOSITA and the real world, PHOSITA's capacity for literature review stands in absolute contrast to the United States where, even post-*KSR*, PHOSITA is presumed to be "perfectly informed" of all the prior art.¹⁰⁷

103. See e.g. *Whirlpool*, *supra* note 59 at para. 74.

104. *Supra* note 97, *aff'd* 32 C.P.R. (3d) 409 (F.C.A.).

105. *Ibid.* at 435-36.

106. *Supra* note 92 at para. 114.

107. See Daralyn Durie & Mark Lemley, "A Realist Approach to the Obviousness of Inventions"

2. CAPACITY TWO: SYNTHESIZING INFORMATION AND DRAWING INFERENCES

Assuming that a reasonably diligent review would produce multiple pieces of prior art, the next logical question concerns what PHOSITA would be able to decipher from that body of information. Because obviousness, unlike anticipation, can be shown through a “mosaic” of prior art,¹⁰⁸ some capacity to synthesize information from multiple sources and potentially apply it in executing the tasks of an ordinary practitioner seems to be implied. Justice Hugessen’s depiction of PHOSITA as a “paragon of deduction” is also consistent with this.¹⁰⁹

However, in several instances, the court seems sceptical of PHOSITA’s ability to make inferences. For example, in *Pfizer Canada Inc. v. Novopharm Ltd.*,¹¹⁰ Justice Blanchard concluded that, while certain general principles of chemistry were well-known to PHOSITA, such principles would not have been sufficient to deduce that the compound at issue, in a particular dosage form, would be less likely to cause adverse reactions to food.¹¹¹ Yet such a determination is difficult to impugn, provided it is rooted in the evidence as to what those general principles were and whether an ordinary scientist could have drawn the necessary inferences to arrive at the invention in question. If, on the other hand, Justice Blanchard had articulated a blanket rule as to what PHOSITA’s inferential reasoning ability should be, then the ruling would have been problematic, tipping the balance in favour of fiction over fact.

3. CAPACITY THREE: COMMON SENSE

The first two of PHOSITA’s capacities were tethered closely to the prior art. But as the distance between his or her capacities and the prior art increases, or the link disappears entirely, courts appear less comfortable (or more willing to rely upon attribute abstractions than factual findings). For example, in the entire pool of decisions, only one case explicitly acknowledged PHOSITA’s

(Stanford Public Law and Legal Theory Working Paper Series, Research Paper No. 1133169, 2008) at 27, online: <<http://ssrn.com/abstract=1133169>>, citing Michael Ebert, “Superperson and the Prior Art” (1985) 67 J. Pat. & Trademark Off. Soc’y 657.

108. See e.g. *AB Hassle*, *supra* note 91.

109. *Beloit*, *supra* note 33 at 294.

110. *Supra* note 92.

111. *Ibid.* at paras. 118-19.

common sense.¹¹² One can wonder about what “common sense” even means. Again, though, the more important point is to not inculcate the analysis with rigid rules and, instead, expect the court to make findings of fact of about what common sense, if any, a given PHOSITA would have.

Recent experience in the United States illustrates this beautifully. In *KSR*, the Federal Circuit had determined that the putative invention—an adjustable electronic sensor accelerator pedal—was non-obvious, notwithstanding that both adjustable accelerator pedals and electronic sensors on (non-adjustable) accelerator pedals were known in the prior art. The Federal Circuit said this was so because there was no “teaching, suggestion, or motivation” to combine those two technologies in the prior art. Conversely, the US Supreme Court held that no such teaching, suggestion, or motivation was needed: “Common sense teaches ... that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle.”¹¹³

In Canada, no parallel “teaching, suggestion, or motivation” test exists.¹¹⁴ Nevertheless, integrating common sense into the Canadian PHOSITA lexicon would be helpful, if only to stress that the court’s fundamental task is to determine whether someone of ordinary skill and knowledge would have been led to the particular invention in dispute, regardless of whether it was on the strength of his or her knowledge of the prior art, common sense, or both.

4. CAPACITY FOUR: TACIT KNOWLEDGE AND EXPERIMENTATION

Common sense is supposedly a product of one’s lived experience. Knowledge that may not be at all common, but is still the result of one’s lived experience, is often referred to as one’s tacit knowledge or know-how. This capacity, too, is, by definition, detached from the prior art: tacit knowledge is knowledge that is not codified or written down.¹¹⁵ While the court has, on occasion, recognized

112. *AstraZeneca*, *supra* note 90 at para. 30.

113. *KSR*, *supra* note 10 at 1743-44.

114. *Novopharm* (2006), *supra* note 86 at para. 113. It is not at all clear that the way Hughes J. described the motivation factor is equivalent to motivation under the American TSM test. Whereas Hughes J. focuses upon the motivation of the inventor, the TSM test contemplates whether PHOSITA would have been motivated to combine information in the prior art.

115. Polanyi, *supra* note 77.

that “[n]ot all knowledge is found in print form,”¹¹⁶ there were zero decisions in which PHOSITA’s tacit knowledge or experiential know-how was highlighted as having a meaningful role in the case.

We should be cautious in equating this empirical finding with an absolute rejection of the very idea of PHOSITA possessing tacit knowledge. Perhaps a better window into the court’s general position regarding tacit knowledge is the body of decisions where PHOSITA’s ability to engage in experimentation is at issue—that is precisely when PHOSITA’s cumulative tacit knowledge would be most relevant. There are two lines of decisions within this body of caselaw.¹¹⁷ In one, “routine testing” and “simple” or “mere verification” are well within the scope of permissible activity. Justice Wetston stated in *Wellcome Foundation*¹¹⁸ 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.¹¹⁹

In an exceptionally well-reasoned ruling, Justice Noël determined that the inventive spark lay not in the conduct of certain experimental activities carried out by the patent-holder, but was rather contained in pre-existing published materials. As such, he declined to hold that the fact of experimentation itself precludes a finding of obviousness:

The evidence shows that all that what was needed were confirmation results; the association between the use of carvedilol and the prolongation of survival in the treatment of patients with CHF happened in 1979 for Beta-Blockers as a class and in the late eighties for carvedilol. I find that the final Phase III results are merely there to eliminate the uncertainty reigning amongst the community of cardiologists and others. That element of creativity which is essential to an invention surely cannot be found in test results. Those results only confirm whether the invention can be used or not. The spark was in the association of the use of carvedilol for the purpose of

116. *Novopharm* (2006), *supra* note 86 at para. 113, *aff’d* *Novopharm* (2007), *supra* note 17.

117. The Federal Court has acknowledged this tension, although it has not sought to resolve it on at least two occasions. See *Pfizer Canada Inc. v. Apotex Inc.* (2002), 22 C.P.R. (4th) 466 at paras. 102-10 (F.C.T.D.); *Abbott Laboratories v. Canada (Minister of Health)*, *supra* note 92 at paras. 99-101.

118. *Supra* note 91, *aff’d* (2000), [2001] 1 F.C. 495 (F.C.A.), *aff’d* [2002] 4 S.C.R. 153.

119. *Wellcome Foundation*, *ibid.* at 243.

prolonging survival for CHF. This is the invention and it was in the public domain prior to [the invention date].¹²⁰

However, these and other similar rulings do not belong to the dominant line of authority. The dominant view is, instead, that PHOSITA cannot engage in any experimentation whatsoever regardless of whether it involves known techniques and substances. Justice Gibson captures this view in *SmithKline Beecham*,¹²¹ wholeheartedly adopting the reasoning of a 1995 decision by the Ontario Court of Justice (General Division):¹²²

[A]lthough one would normally imagine that this mythical person's laboratory is filled with mythical test tubes and Petri dishes and that his or her daily life is spent in experimentation, for the purposes of this legal exercise, no research of any kind can be contemplated. So, although it may have been logical to an actual skilled person at the time, based on the state of the art, to conduct certain testing, that is not open to the mythical skilled technician. The mythical researcher cannot have an inquiring or thinking mind which ultimately would lead him or her to the answer but rather he or she is expected to instantly and spontaneously exclaim, without more, "I already know the answer and it is obvious." Nor is it appropriate to say that there were significant telltales which pointed the way for the mythical expert or that there were sufficient clues which made the invention "worth a try."¹²³

Justice Gibson went on to remark that this is why Justice Hugessen stated that the *Beloit* test was so difficult to satisfy.¹²⁴ As with PHOSITA's capacity to synthesize information from multiple sources, however, this would seem to be at odds with the portion of the test describing PHOSITA as nothing short of a perfect model of "deduction and dexterity." Indeed, this particular internal tension has left other members of the Federal Court perplexed,¹²⁵ or attempting

120. *GlaxoSmithKline Inc. v. Canada (Minister of Health)* (2004), 129 A.C.W.S. (3d) 181 at para. 66 (F.C.) [*GlaxoSmithKline*].

121. *Supra* note 90 at para. 48.

122. *Bayer Aktiengesellschaft v. Apotex Inc.* (1995), 60 C.P.R. (3d) 58 (Ont. Ct. J. (Gen. Div.)) [*Bayer*], aff'd (1998), 82 C.P.R. (3d) 526 (Ont. C.A.) (cross-appeal by Bayer allowed on an issue not relevant to the issue of obviousness), leave to appeal to S.C.C. refused, 26979 (1 April 1999).

123. *Bayer, ibid.* at 80-81.

124. *SmithKline Beecham, supra* note 90 at para. 48.

125. For example, immediately after quoting from *Bayer, supra* note 122, Dawson J. re-emphasized the depiction of PHOSITA as a "paragon of deduction and dexterity." *Beloit, supra* note 33. See *Pfizer Canada Inc. v. Apotex Inc., supra* note 117 at para. 110.

delicately to straddle the two lines of authority.¹²⁶

Insofar as the Ontario General Division ruling in *Bayer* remains the dominant line of authority, PHOSITA's absolute inability to engage in experimentation amounts to a "tacit" rejection of PHOSITA's tacit knowledge. And yet, social science research overwhelmingly supports the view that tacit knowledge is generally critical to success in scientific research and firm competitiveness.¹²⁷ True, the degree to which tacit knowledge has not been codified in some form (either in a publication or a patent's disclosure) may vary substantially according to the technological field. Vaccine research and development, for example, has traditionally been said to be complex relative to pharmaceuticals, not because the requisite information about viruses (*i.e.*, how to manipulate them and produce vaccines) is unknown or unavailable, but because this process of vaccine manufacture is very challenging, technically.¹²⁸ It requires a considerable degree of knowledge and skill acquired through experience over time, which cannot be easily applied after reading a collection of science articles and patents.

From the court's perspective, the challenge is how to operationalize PHOSITA's tacit knowledge in order to assess whether the invention in dispute is beyond PHOSITA's knowledge and other capacities. At a minimum, an awareness of tacit knowledge should underscore the importance of making specific findings of fact in each case about what PHOSITA knows through both the prior art as well as lived experience—findings that, according to the content analysis carried out here, the Federal Court seldom, if ever, makes, and which

126. See *e.g.* *Apotex* (2005), *supra* note 20 at para. 78. Shore J. stated: "The person skilled in the art must know that the solution or the benefits would be present *without testing* (excluding, of course, simple verification of already known information)" [emphasis in original].

127. See Jamie D. Collins & Michael A. Hitt, "Leveraging Tacit Knowledge in Alliances: The Importance of Using Relational Capabilities to Build and Leverage Relational Capital" (2006) 23 J. Eng. Tech. Mgmt. 147; Ajay Agrawal, "Engaging the Inventor: Exploring Licensing Strategies for University Inventions and the Role of Latent Knowledge" (2006) 27 Strat. Mgmt. J. 63.

128. Historically, dating back to Louis Pasteur's development of a vaccine for anthrax, the real barrier to those wishing to manufacture vaccines on their own has been the high degree of technical difficulty. At that time, the laws of France precluded Pasteur from patenting the vaccine (or the methods he developed to make it). Pasteur thus refused to share the technical "know-how" needed to make the vaccine with others. See Maurice Cassier, "Appropriation and Commercial-ization of the Pasteur Anthrax Vaccine" (2005) 36 Stud. Hist. & Phil. Biol. & Biomed. Sci. 722.

the *Bayer* line of authority about PHOSITA's ability to engage in experimentation appears to directly inhibit.

B. DR. HAYAKAWA AND MR. BADORC REVISITED

Conceptualizing a capacity as fixed (*e.g.*, the inability to engage in experimentation) pre-empts findings of fact and therefore undermines PHOSITA's role in the obviousness analysis. Defining PHOSITA relative to others, whether explicitly or implicitly—a second trend uncovered in the jurisprudence—produces the same harm.

Recall that Justice Sharlow's decision in *Novopharm* was rooted in the clear distinction she drew between the capacities of PHOSITA and Dr. Hayakawa.¹²⁹ Based on the content analysis, such *explicit* negative characterization does not appear to be a common phenomenon.¹³⁰ Yet the coding process also uncovered a stronger tendency.¹³¹ Instead of fully characterizing PHOSITA in his own right, or explicitly distinguishing him from the alleged inventor, courts tended to conflate the two, searching for a “proxy” for PHOSITA amongst the expert witnesses put forth by the two parties to the dispute.¹³² While this may lead the court to make more findings of fact about PHOSITA by clothing him or her with attributes similar to the inventor, the crucial point is that the implication of such conflated characterization *is precisely the same* as negative characterization. By simultaneously accepting (1) the inventor as proxy for the skilled tech-

129. (2007), *supra* note 17 at para. 36.

130. As noted above, in only five decisions was explicit negative characterization observed. In *Mahurkar*, Strayer J. concluded that “[i]f the invention was not obvious to Doctor Uldall [who was himself an inventor as well as colleague of the patent-holder], it would not have been obvious to a mere skilled but unimaginative technician.” *Supra* note 97 at 433. Cullen J. cited this passage with approval in *Control Data*, adopting the argument of counsel that resolving the issue of obviousness is contingent upon finding a “Newman Darby” in each case and determining whether the invention would be obvious to such a character. *Supra* note 97. See also *Windsurfing International Inc. v. BIC Sports Inc.* (1985), 8 C.P.R. (3d) 241 at 259 (F.C.A.). In this case, Urie J. described Darby, the alleged prior inventor in the case, as “unquestionably a person skilled in the art.”

131. The coding system developed for the content analysis did not anticipate this tendency to conflate PHOSITA and expert witnesses, and thus the exact number of cases in which this occurred was not recorded. However, in nearly all decisions where explicit negative characterization did not occur, it was apparent that the court was attempting to assess which experts could best speak to what the PHOSITA would have known.

132. See *e.g. Whirlpool Corp. v. Camco Inc.* (1997), 76 C.P.R. (3d) 150 (F.C.T.D.).

nician and (2) the inventor's trials and tribulations as proof of non-obviousness, PHOSITA necessarily becomes inferior.¹³³ This is what the Court of Appeal's ruling in *Apotex* necessarily implied: negative characterization, just not in so many words. Consider the relevant passage from Justice Noël's decision on behalf of the Court of Appeal in *Apotex* in its entirety:

Apotex further argues that Shore J. erred in confusing the inventor of the compound (Mr. Badorc) with the ordinary person skilled in the art. According to Apotex, this error was compounded when Shore J. concluded that, since Mr. Badorc did not easily arrive at the invention, it could not have been anticipated.

With respect, I do not believe that to be the case. Shore J. set the parameters of the ordinary person skilled in the art, based on the description proposed by the parties at paragraphs 18 and 19 of his reasons, and concluded at paragraph 69 that Mr. Badorc "possessed the characteristics" of a person skilled in the art. In my view, this shows that Shore J. did not equate Mr. Badorc to the notional construct of the skilled person. Rather, he held that, although the inventor, Mr. Badorc also had the characteristics of the person skilled in the art.

According to Shore J., even though Mr. Badorc possessed these characteristics, he was still unable to separate the isomer "in every event and without the possibility of error." Not only does this show that the prior art was lacking in clarity and direction for the separation of the isomers in question, it also serves to demonstrate that, despite Mr. Badorc's intuitive abilities, he was unable to replicate the experiment without difficulty and without error.¹³⁴

Regardless of whether the court is willing to admit that this conflates the expert with PHOSITA,¹³⁵ the fact of Mr. Badorc's struggles to arrive at the invention in question was essentially determinative of the question of obviousness.¹³⁶ PHOSITA's abilities must, by definition then, be inferior to those of Mr. Badorc. And although counsel for Apotex did not succeed in persuading the Court of Appeal of the gravity of this error, relativist characterizations of PHOSITA, whether negative or conflated, explicit or implicit, should be of significant concern for at least two reasons.

133. Because, in so doing, the court is relying upon the evidence of the patent-holder's experts as to how challenging the process of arriving at the putative invention was, the court is necessarily using the experts to set a benchmark that no ordinary skilled technician could hope to achieve.

134. *Apotex* (2006), *supra* note 20 at paras. 34-36 [citations omitted].

135. *Ibid.* According to Noël J.A., possessing the characteristics of PHOSITA somehow falls short of equating the expert or inventor with PHOSITA.

136. *Ibid.* at para. 40.

1. TENSION WITH THE STATUTE?

Intuitively, distinguishing PHOSITA from inventors would seem in keeping with the policy of the *Patent Act*. “Inventors by definition are inventive,”¹³⁷ Justice Hugessen remarked—thus, PHOSITA, by necessary implication, is not. However, a closer reading of the legislation indicates that negative characterization actually inverts the relationship between the knowledge or skill level of PHOSITA and patentability. The *Patent Act* states that an invention is patentable if, in addition to satisfying other criteria, the invention “would not have been obvious on the claim date to a person skilled in the art or science to which it pertains.”¹³⁸ In other words, PHOSITA serves as a “floor” for patentability. Yet, by engaging in *Novopharm*- or *Apotex*-like negative characterization, courts are actually imposing a “ceiling” on PHOSITA’s capacity and inferring that the invention is not obvious as a result. Negative characterization is thus technically at odds with the wording of the *Patent Act*, not to mention circular: “defining non-obviousness ... by reference to the skill level of PHOSITA, and then defining PHOSITA’s skill level by reference to capacity to make patentable (that is, non-obvious) inventions.”¹³⁹

2. PHOSITA DECONTEXTUALIZED: PART A

Moreover, this circularity creates a practical impediment to making obviousness determinations. Rebecca Eisenberg explains:

If practitioners in a particular field tend to be innovative (or, for that matter, to get patents), one must, apparently, consult the perspective of practitioners who have *less* than ordinary skill (or at least less than average skill) in order to maintain [the] presumption that PHOSITA “is not one who undertakes to innovate.”¹⁴⁰

Patenting is indeed an increasingly common practice around the globe,¹⁴¹ even though it continues to vary across technological fields and settings.¹⁴²

137. *Beloit*, *supra* note 33 at 294.

138. *Supra* note 31, s. 28.3.

139. Eisenberg, *supra* note 9 at 892.

140. *Ibid.* [emphasis in original].

141. World Intellectual Property Organization, Press Release, “Unprecedented Number of International Patent Filings in 2007” (21 February 2008), online: <http://www.wipo.int/pressroom/en/articles/2008/article_0006.html>.

142. *Ibid.* See also Aldo Geuna & Lionel J.J. Nesta, “University Patenting and its Effects on

Eisenberg claims that this

sets the stage for a downward spiral in which the standard of patentability falls as courts exclude patentees from consideration in assessing the skill level of PHOSITA, making it easier to obtain patents, and leading inexorably to a further lowering of judicial expectations for PHOSITA as yet more practitioners become patentees.¹⁴³

As we have just seen, in Canada the analysis typically plays out a little differently. Courts do not *a priori* exclude patentees from consideration in assessing the skill level of PHOSITA. Rather, they often rely directly upon patentees' evidence to deduce what PHOSITA would *not* know. But, provided that negative characterization remains a strong tendency in Canada, judicial interpretations of PHOSITA will continue to diminish as Eisenberg predicts. Ultimately, then, negative characterization will have the effect of decontextualizing PHOSITA from the modern research environment when that is precisely who he or she was conceived to be: the ordinary scientist *in situ*.

C. HINDSIGHT IS...

The final problem observed in the jurisprudence stems from the weight given to the hindsight concern. Courts have frequently recited the risk of hindsight bias when experts espouse opinions as to the obviousness of an invention after the fact. In *Halocarbon*,¹⁴⁴ Justice Pigeon commented:

Practically all research work is done by looking in directions where the "state of the art" points. On that basis and with hindsight, it could be said in most cases that there was no inventive ingenuity in the new development because everyone would then see how the previous accomplishments pointed the way. The discovery of penicillin was, of course, a major development, a great invention. After that, a number of workers went looking for other antibiotics methodically testing whole families of various microorganisms other than *penicillium notatum* ... I cannot imagine patents obtained for antibiotics and for various processes for their production being successfully challenged on the basis that the discovery of penicillin pointed the way and there was no inventive ingenuity in the search for other antibiotics and in the testing and the development of processes.¹⁴⁵

Justice Hugessen, not to be outdone, exclaimed as follows:

Academic Research: The Emerging European Evidence" (2006) 35 Res. Pol'y 790.

143. *Supra* note 9 at 892.

144. *Supra* note 46.

145. *Ibid.* at 944.

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?”¹⁴⁶

This is a legitimate concern.¹⁴⁷ Allowing the hindsight concern to do the bulk of the analytical work nevertheless presents a problem, again, for at least two reasons.

1. THE HYPOTHETICAL FRAME

The accepted protocol for determining whether an invention is obvious requires the court to turn its mind to what Eisenberg calls a “hypothetical frame of reference.”¹⁴⁸ This frame is comprised of two elements: the first relates to what PHOSITA knows and can do—the focus of much of the foregoing—whereas the second requires the court to cast its mind back to the claimed date of invention. While intertwined, these two elements guard against two very different forms of risk. Eisenberg explains:

The risk posed by evaluating obviousness at a later date rather than “at the time the invention was made” is that the bar will be set too high. The risk posed by assigning the evaluation to a decision-maker who does not have ordinary skill in the art is that the bar will be set too low.¹⁴⁹

Fixating on the hindsight concern—which deals with the issue of timing, only without giving adequate consideration to PHOSITA’s skill and knowledge—thus leaves the second risk unguarded against.

2. PHOSITA DECONTEXTUALIZED: PART B

Placing undue weight upon the hindsight concern is problematic for a second reason. In the jurisprudence, the poignant question directed at experts by Justice Hugessen is typically invoked in rhetorical fashion—that is, no “satisfactory answer” is expected. This reveals an assumption on the part of the judiciary: experts and inventors contesting the non-obviousness of an invention against allegations of infringement are presumed to enjoy “freedom to operate.” As one

146. *Beloit*, *supra* note 33 at 295.

147. See *e.g.* Gregory N. Mandel, “Patently Non-Obvious: Empirical Demonstration that the Hindsight Bias Renders Patent Decisions Irrational” (2006) 67 *Ohio St. L.J.* 1391.

148. *Supra* note 9 at 887.

149. *Ibid.* at 888.

justice of the Federal Court recently observed, however, such an assumption may not always be sound:

But was it open to others to experiment with and address the problem while the base patents, all of them held by Pfizer, were still active? ... The capsules came out in 1992, the '071 patent application was filed in 1994. There was not much time to conduct research on the food effect problem. In those circumstances, I find it difficult to accept the argument that if it wasn't novel [*sic*], why didn't someone else do it?¹⁵⁰

True, the *Patent Act* does permit use of a patented product or process in connection with the “development and submission of information required under the law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.”¹⁵¹ A common law experimental use defence to patent infringement may also still apply,¹⁵² even though its underlying rationale is now open to question given that an increasing amount of basic research has commercial implications.¹⁵³

However, without greater scrutiny of (1) the assumption that freedom to operate exists, (2) findings of fact about the industry or technological field in question, and (3) the particular use that the patented invention was being put towards, the notion that would-be users of the technology are free to do as they please may no longer hold. The net effect is that PHOSITA is once again at risk of being decontextualized from the modern scientific environment in which he or she is supposed to reside.

V. CONCLUSIONS: CAUSES AND CHANGES

In the end, it appears Justice Hugessen's colourful depiction of the mythical ordinary skilled technician in *Beloit* has had a tremendous impact. PHOSITA remains very much in the realm of myth: not only detached from reality, but

150. *Pfizer Canada Inc. v. Apotex Inc.*, *supra* note 92 at para. 129. Despite using the word “novelty,” Mosley J. was dealing with the issue of obviousness at this point in his analysis.

151. *Supra* note 31, ss. 55.2(1)-(6).

152. For the decision in which such a defence was found to apply, see *Micro Chemicals Limited et al. v. Smith Kline & French Inter-American Corporation*, [1972] S.C.R. 506.

153. That universities now aim to commercialize much academic research clearly informed the Federal Circuit's decision to restrict the experimental use defense to use of a patented invention “solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.” See *Madey v. Duke University*, 307 F.3d 1351 at 1362 (Fed. Cir. 2002).

also from the legal exercise of determining obviousness. Forces beyond Justice Hugessen's poetic words were, however, involved in bringing this about, including (1) judicial pragmatism, (2) the limitations of expert evidence within an adversarial system, (3) the unintended framing effect of claim construction upon the obviousness inquiry, and (4) an impoverished understanding of the purpose of the non-obviousness test and the relative roles and importance of patents, as well as the public domain, to innovation.

The foregoing has only touched upon the first of these intertwined forces, suggesting that PHOSITA's common sense and tacit knowledge are all but ignored by the court owing to its deeply engrained pragmatic preference for the written record.¹⁵⁴ This pragmatism, in turn, renders consideration of these two capacities a non-event. In contrast, where the capacity in question is less removed from the prior art—for example, PHOSITA's ability to conduct literature reviews—the court's pragmatism becomes a strength: the requirement for evidence that PHOSITA would be able to find the prior art in question means that he or she begins to transcend the line between fiction and fact.

Judicial pragmatism also partially helps to explain negative characterization. However, the limitations of expert evidence and PHOSITA's role in patent claim construction are also critical factors. Careful explanation is needed to illustrate this and further develop the argument as to why the jurisprudence in general, and negative characterization (whether express or implied) in particular, mask a fundamental misunderstanding of innovation.

A. BEHIND DOCTRINE: AN IMPOVERISHED UNDERSTANDING OF INNOVATION

Justice Binnie framed the rationale for PHOSITA's involvement in claim construction as follows:

The involvement in claims construction of the skilled addressee holds out to the patentee the comfort that the claims will be read in light of the knowledge provided to the court by expert evidence on the technical meaning of the terms and concepts used in the claims. The words chosen by the inventor will be read in the sense the inventor is presumed to have intended, and in a way that is sympathetic to accomplishment of the inventor's purpose expressed or implicit in the text of the claims. However, if the inventor has misspoken or otherwise created an unnecessary or troublesome limitation in the claims, it is a self-inflicted wound. The public is entitled to

154. *Patent Act*, *supra* note 31, s. 28.3 (specifically directing the court toward the prior art).

rely on the words used *provided* the words used are interpreted fairly and knowledgeably.¹⁵⁵

Notice the absence of qualifiers such as “ordinary” or “unimaginative” to describe PHOSITA in this oft-quoted principle of interpretation. For the purpose of claim construction, then, PHOSITA assumes the mantle of a skilled reader rather than an ordinary, unimaginative technician. PHOSITA is a person with a “mind willing to understand” or a person who is trying to “achieve success” when he or she is deployed for the purposes of patent claim construction.¹⁵⁶ As a result, the expert witnesses offered by the parties to the litigation are, practically by definition, capable of speaking to what such a skilled reader would deduce from the patent’s claims in the light of the prior art. The issue for the court at the point of claim construction is therefore to determine which expert’s interpretation appears the most persuasive or plausible.

At the point of resolving the issue of obviousness—a step that is necessarily post claim construction¹⁵⁷—the court must instead determine whether the putative invention would be obvious to the unimaginative, ordinary skilled technician. Here, experts, many of whom are likely to have patents of their own, would seem much less proximal to PHOSITA.

PHOSITA’s role in claim construction may thus indirectly set the stage for negative characterization. Sometimes it is explicit, as in *Novopharm*. More often, the court visibly struggles through the awkward exercise of finding a suitable “proxy” for this unimaginative being amongst the experts—the same experts who, a moment ago, purported to supply the perspective of the skilled reader. To the extent the court finds a given expert credible and his or her evidence helpful to claim construction, turning around and dubbing him or her “ordinary” and lacking even a “scintilla of inventiveness”¹⁵⁸ would seem a plain insult.

The Supreme Court of Canada has not contemplated the awkward logistics of this evidentiary issue.¹⁵⁹ And therein lies a window into the Court’s impoverished understanding of innovation.

155. *Free World Trust*, *supra* note 59 at para. 51 [emphasis in original].

156. *Ibid.* at para. 44.

157. *Ibid.* at para. 19; *Whirlpool*, *supra* note 59 at para. 43.

158. This phrase has been used by Canadian courts on several occasions. See *e.g. Diversified Products*, *supra* note 62; *Halocarbon*, *supra* note 46.

159. That the construction of the patent’s claims was not at issue in *Apotex* may partially explain this. See *Apotex* (2008), *supra* note 15 at para. 76.

Justice Binnie's remarks in *Free World Trust* evince a conviction that PHOSITA's place in claim construction is sound because it serves the bargain between the patentee and the public. In a sense, the non-obviousness requirement, where PHOSITA also supposedly plays an integral role, also speaks to the bargain between the patentee and the public by demarcating what is already known (*i.e.*, knowledge in the public domain or previously patented) from that which is not. It is therefore worth asking whether PHOSITA's diminished role in the obviousness inquiry, as a result of negative characterization, is an acceptable trade-off, given his or her newfound prominence in claim construction. Does narrowing the scope of a patent through the eyes of a skilled reader during claim construction essentially achieve the same thing as finding that an invention would be obvious to PHOSITA?

Richard Gold and Karen Durell argue that the purposive construction test espoused in *Free World Trust* and *Whirlpool*, and the renewed emphasis placed upon the skilled reader therein, marks an important shift in Canadian patent law, one which better balances the interests of the public as against those of patentees. They also argue that those judicial holdings ensure that PHOSITA serves as a flexible yet transparent tool to delimit the boundaries of monopoly rights.¹⁶⁰ That may be the case; however, the content analysis performed here shows that PHOSITA is not transparent insofar as courts generally fail to specify his or her level of education or experience, or make any other finding of fact regarding PHOSITA's identity. More fundamentally, it is inaccurate to equate PHOSITA's function in claim construction with his or her function in determining an invention's obviousness.¹⁶¹

During claim construction, PHOSITA translates to the public what is and what is not the property of the patentee. Knowledge that is not the property of the patentee may be the property of someone else, potential property that has yet to be claimed, or knowledge that forms part of the public domain. Note, though, that triaging knowledge outside the instant patent into one of these three categories is of no concern at the claim construction phase.

With respect to obviousness, where PHOSITA is fulfilling a gate-keeping function, triaging is exactly what transpires. If the claimed invention is deter-

160. E. Richard Gold & Karen Lynne Durell, "Innovating the Skilled Reader: Tailoring Patent Law to New Technologies" (2005) 19 I.P.J. 189 at 192.

161. To be fair, Gold and Durell do not equate these two functions.

mined to be obvious, then that means it is already part of the public domain, and, as such, it can never be the subject of a patent monopoly.

Because of this difference in function—translation versus gate-keeping—and the different implications about knowledge associated with each function, the trade-off is not equal. Increasing PHOSITA's role in claim construction may keep some knowledge in the public domain and may temporarily stall the appropriation of knowledge that is as yet unclaimed. But undermining PHOSITA's role in the obviousness inquiry allows knowledge that should, in principle, remain permanently in the public domain to be lost for a twenty-year period of patent protection.

We might still think that this is defensible on balance if we assume that there is a strong relationship between patents and innovation. That is, the loss of knowledge from the public domain should not be of grave concern because patents are the primary driver of innovative activity. This view appears deeply entrenched amongst the judiciary,¹⁶² occasionally manifesting itself in statements of meta-truth.¹⁶³

However, nothing could be further from what we know.¹⁶⁴ To begin, the reality, so far as we can discern it, is that the strength of the relationship between patents and innovation varies depending on the type of technology in question and a host of other market and non-market factors.¹⁶⁵ Save for the pharmaceutical and biotechnology sectors, patents appear to matter very little relative to other types of advantages or assets.¹⁶⁶ And even in the pharmaceutical and biotechnology sectors, some now argue that patents in and of themselves are becoming less integral to a firm's success.¹⁶⁷

162. E. Richard Gold *et al.*, "The Unexamined Assumptions of Intellectual Property: Adopting an Evaluative Approach to Patenting Biotechnological Innovation" (2004) 18 Pub. Aff. Q. 299 at 304ff.

163. See *e.g.* *Harvard College v. Canada (Commissioner of Patents)*, [2002] 4 S.C.R. 45 [*Harvard*]. In *Harvard*, Binnie J. (dissenting) chose the following opening words: "Innovation is said to be the lifeblood of a modern economy. We neglect rewarding it at our peril" (at para. 4).

164. For a detailed summary of the empirical literature about patents and innovation, see Bronwyn H. Hall, "Patents and Patent Policy" (2007) 23 Oxford Rev. Econ. Pol'y 568 at 574-75.

165. See Dan L. Burk & Mark A. Lemley, "Policy Levers in Patent Law" (2003) 89 Va. L. Rev. 1575.

166. See *e.g.* Stuart J.H. Graham *et al.*, "High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey" Berkeley Tech. L.J. [forthcoming], online: <<http://ssrn.com/abstract=1429049>>.

167. This partially stems from the ongoing, tumultuous shift within and across these two sectors,

A necessary corollary to this is that the public domain remains critical to innovation. How critical, again, appears to vary by industry. But the general importance of the public domain cannot be questioned. Studies of the transfer of knowledge from the university research setting to the private sector, for example, consistently demonstrate that patenting and licensing only account for a fraction of total knowledge flows.¹⁶⁸ And all sectors of industry report valuing knowledge—both codified and tacit knowledge—gained from the university through traditional means (*i.e.*, publications, conference presentations, student mentoring and hiring) more than knowledge acquired through patent licences.¹⁶⁹ Put differently, patents rarely teach.¹⁷⁰ On the contrary, empirical evidence shows that academic scientists essentially look everywhere but the patent literature for information about developments in their respective fields of activity.¹⁷¹ Scientists working in firms consult the patent literature more so than their academic peers, but it is by no means the source they most rely upon.¹⁷² And yet courts often appear to ignore the importance of the public domain entirely.

The point here is not whether one realm (proprietary versus non-proprietary) is more important than the other.¹⁷³ Patents clearly do serve as *ex*

from a business model geared towards developing “simple small molecule” pharmaceuticals to one intent on generating “large complex molecule” biopharmaceuticals or “biologics.” In this new age of biopharmaceuticals, first-mover advantage is potentially far more important than patent rights *per se*, although firms do typically seek to pair the two strategies. See Gregory N. Mandel, “The Generic Biologics Debate: Industry’s Unintended Admission that Biotech Patents Fail Enablement” (2006) 11 Va. J.L. & Tech. 1.

168. See Ajay Agrawal & Rebecca Henderson, “Putting Patents in Context: Exploring Knowledge Transfer from MIT” (2002) 48 Mgmt. Sci. 44.

169. See Wesley M. Cohen, Richard R. Nelson & John P. Walsh, “Links and Impacts: The Influence of Public Research on Industrial R&D” (2002) 48 Mgmt. Sci. 1.

170. For an interesting attempt to modify patent law doctrine in the United States so that patents might teach, see Sean B. Seymore, “The Teaching Function of Patents” Notre Dame L. Rev. [forthcoming in 2010], online: <<http://ssrn.com/abstract=1352044>>.

171. John P. Walsh, Wesley M. Cohen & Charlene Cho, “Where Excludability Matters: Material versus Intellectual Property in Academic Biomedical Research” (2007) 36 Res. Pol’y 1184 at 1189.

172. See Wesley M. Cohen *et al.*, “R&D Spillovers, Patents and the Incentives to Innovate in Japan and the United States” (2002) 31 Res. Pol’y 1349 at 1362-64.

173. The findings of one provocative study are worth noting, however:

In perhaps one of the most startling papers on the economics of innovation published in the past few years, Josh Lerner looked at changes in intellectual property law in sixty countries over a period of 150 years. He studied close to three hundred policy changes, and found that,

ante and *ex post* incentives for research and development.¹⁷⁴ Rather, the point is that the relative importance of patents to innovation will always be context-dependent. And by failing to adequately characterize PHOSITA for the purposes of the non-obviousness inquiry, the court is undercutting the primary tool at its disposal for developing a patent law standard that is reflective of the industry-specific nature of innovation.¹⁷⁵

Accordingly, a richer understanding of innovation is needed. The next two sections of this article thus formulate changes that ought to be made at the doctrinal, institutional, and theoretical levels in order to improve the application of the non-obviousness requirement in Canada and restore its purpose in light of our improved understanding of innovation.

B. FIRST ORDER CHANGE: THE DOCTRINE

1. OBVIOUSNESS REALISM

At the doctrinal level, the primary goal should be to create a framework for, or remove barriers to, an “obviousness analysis based in the real world.”¹⁷⁶ In other

both in developing countries and in economically advanced countries that already have patent law, patenting both at home and abroad by domestic firms of the country that made the policy change, a proxy for investment in research and development, decreases when patent law is strengthened!

Yochai Benkler, *The Wealth of Networks: How Social Production Transforms Markets and Freedom* (New Haven: Yale University Press, 2006) at 39, citing Josh Lerner, “Patent Protection and Innovation Over 150 Years” (National Bureau of Economic Research, Working Paper No. 8977, 2002), online: <<http://www.nber.org/papers/w8977>>. Another interesting study that relates more directly to the topic of this article found that “relaxing the standard of nonobviousness creates a tradeoff—raising the probability of obtaining a patent, but decreasing its value. We show that weaker nonobviousness requirements can lead to *less* R&D activity, and this is more likely to occur in industries that rapidly innovate” [emphasis in original]. Robert M. Hunt, “Nonobviousness and the Incentive to Innovate: An Economic Analysis of Intellectual Property Reform” (Federal Reserve Bank of Philadelphia, Working Paper No. 99-3, March 1999), Abstract, online: <<http://www.philadelphiafed.org/research-and-data/publications/working-papers/1999/wp99-3.pdf>>.

174. Neither of these justifications for patent rights is perfect, but firms clearly do see them as such. See Mark A. Lemley, “Ex Ante versus Ex Post Justifications for Intellectual Property” (2004) 71 U. Chicago L. Rev. 129.
175. Burk and Lemley suggest that PHOSITA is perhaps the most “fundamental policy lever” to ensure that patent law is industry-specific. See Burk & Lemley, *supra* note 27 at 114-17.
176. Durie and Lemley have persuasively argued that this is what the US Supreme Court hoped, but failed, to achieve in *KSR*. See Durie & Lemley, *supra* note 107 at 28.

words, the focus should be on enabling the court to decipher, in each case, “whether scientists in *this particular discipline* [or field of research] would believe *this particular invention* to be obvious.”¹⁷⁷ In theory, *Apotex* marks a positive development in this regard. By adopting the UK *Pozzoli*-modified version of the *Windsurfing* test for obviousness,¹⁷⁸ the Supreme Court of Canada has provided a framework for more fact-driven analyses. Identifying PHOSITA and his or her common general knowledge is now the first step in the inquiry, as opposed to simply being one amongst several factors to be considered.¹⁷⁹

Perhaps an even more promising change is that *Apotex* appears to lift the blanket prohibition against routine experimentation.¹⁸⁰ Because the evidence indicated that well-known techniques were used to arrive at the invention,¹⁸¹ one of the key issues in dispute between the parties was whether an “obvious to try” standard should ever be invoked in determining obviousness.¹⁸² Contrary to rulings below, Justice Rothstein opined that an “obvious to try” test for obviousness may be legitimate in certain circumstances—for example, in the pharmaceutical industry, where “there may be many chemically similar structures that can elicit different biological responses and offer the potential for significant therapeutic advances.”¹⁸³ In addition to taking into account the field or context of invention, whether “routine trials” versus “prolonged and arduous” experimentation were necessary may be a helpful factor to consider in deciding whether the “obvious to try” standard is appropriate.¹⁸⁴ Thus, in a convoluted way, the Court implied that routine experimentation can, in some cases, be undertaken.¹⁸⁵

177. *Ibid.* at 12 [emphasis in original].

178. See *Pozzoli*, *supra* note 56 and accompanying text.

179. *Apotex* (2008), *supra* note 15 at para. 67.

180. *Ibid.* at para. 69.

181. *Ibid.* at para. 85.

182. *Ibid.* at para. 82. Ultimately, Rothstein J. held that Shore J. had erred in not allowing such a standard to be used in the case.

183. *Ibid.* at para. 68.

184. *Ibid.* at para. 69.

185. What should matter most, then, is not the “routineness” of the experimentation *per se*, but whether it was routine to conduct such (known, accepted) experiments in arriving at the invention in dispute, taking into account the context in which the research was performed. For example, if the “inventive spark” lay not in the doing of those (routine) tests, but in some prior association or idea, then the fact of having to conduct such experiments should not by itself bar a finding of obviousness. Rather, the inquiry should shift its focus to whether that

However, there are reasons to doubt that this holding will help judicial decision-making beyond cases involving pharmaceutical selection patents—that is, that it will inspire more fact-driven analyses across the board. There remains a risk that the decision will be interpreted as placing the primary emphasis upon determining whether a particular standard (the “worth a try” standard) is appropriate in the pharmaceutical context instead of ensuring that PHOSITA’s ability to engage in experimentation is rooted in an understanding of the practices and techniques of the invention’s field, much less an understanding of PHOSITA’s specific abilities.¹⁸⁶ Further, as shown above, there is a systematic failure to achieve the latter at courts of first instance.¹⁸⁷

This broader problem was not before the Supreme Court of Canada. The identity of PHOSITA—a “trained pharmacist”—was agreed to by the parties and Justice Rothstein simply reiterated Justice Shore’s findings of fact about the different experimental techniques being well-known to the skilled person.¹⁸⁸ Other contested features of PHOSITA (*e.g.*, his or her common sense) as well as the obviousness analysis more generally (*e.g.*, the import of secondary considerations) were simply not at issue in the case. Consequently, *Apotex* leaves much work to be done, even at the doctrinal level.

To begin, there remains a need to re-emphasize that obviousness is a factual inquiry.¹⁸⁹ As such, characterizing PHOSITA through specific findings of fact—determining not only what level of education and experience he or she has, but

prior association or idea was known to someone skilled in the art. The *Pozzoli*-modified *Windsurfing* test builds this insight into its step-by-step obviousness analysis, requiring the court to try to identify the “inventive concept” at the heart of the patent’s claim. In the absence of such a requirement, the Federal Court appears to have turned its mind to identifying the inventive spark or concept only once in connection with obviousness. See *GlaxoSmithKline*, *supra* note 120 at para. 66.

186. Indeed, in one of the first decisions to consider the Supreme Court’s holding in *Apotex* (2008), *supra* note 15, one of the two main issues under appeal was whether the newly adopted “worth a try” standard had been correctly applied. See *Apotex Inc. v. Pfizer Canada Inc.* (2009), 72 C.P.R. (4th) 141 (F.C.A.).

187. One exception is *Mobil Oil Corp. v. Hercules Canada Inc.* (1994), 57 C.P.R. (3d) 488 (F.C.T.D.). In that case, Wetston J. remarked that the idea of PHOSITA representing a “composite” of scientists, researchers, and technicians is “particularly true where the invention relates to a science or art that transcends several scientific disciplines” (at 494).

188. *Apotex* (2008), *supra* note 15 at paras. 74-75.

189. To reiterate, only eight decisions in the pool of fifty-two explicitly framed non-obviousness as a factual inquiry. See Part III, above.

also the specific norms and practices associated with the technological field of the invention and the context in which PHOSITA performs his or her work—is critically important. Is PHOSITA working in a publicly-funded laboratory or private industry? Does the invention transcend several scientific disciplines or does it fit within the confines of a single field? These sorts of contextual factors are highly relevant to the exercise of defining PHOSITA’s capacities. Private industry, as a setting, provides little incentive to publish research relative to an academic institution. At the very least, then, if PHOSITA is found to be working within industry, it should highlight the need to pay special attention to PHOSITA’s tacit knowledge. If PHOSITA is engaged in a transdisciplinary area of research, his or her ability to draw inferences from one scientific field and assess their relevance to another, as well as to synthesize developments from several scientific fields, should by definition be greater than a PHOSITA working in one discipline alone. As science continues to evolve, and more transdisciplinary areas of inquiry or modes of research emerge (such as “bioinformatics,” “nanotechnology,” and “synthetic biology”), it will be increasingly important to take into account the context in which PHOSITA lives, thinks, and acts in order to arrive at accurate characterizations of his or her capacities.

On a related note, PHOSITA’s capacity for common sense and basic reasoning should be reaffirmed. Here, though, the best remedy may be indirect. PHOSITA as “paragon of deduction and dexterity” has all but disappeared since *Beloit*, not because this quality is now lost from the court’s lexicon, but because of the emphasis upon the prior art as naked text, disrobing PHOSITA of his or her ability to research or think about how various texts speak to one another. The flag or mosaic analogy is helpful in distinguishing anticipation from obviousness, but it appears to lead the court to concentrate upon what the prior art, item-by-item, literally says rather than what the prior art *conveys* on an item-by-item, as well as aggregated, basis.¹⁹⁰

To correct this, renewed emphasis needs to be placed upon how (and to what extent) the skilled technician would synthesize *all* of the prior art together in light of his or her skills and knowledge, including his or her tacit knowledge. The mosaic analogy may be retained, but equal attention should be paid to the process of integrating the various prior art elements comprising the mosaic as the elements themselves.

190. This is, perhaps, understandable, given the extremely technical nature of the prior art.

On the other hand, certain holdings and features of the obviousness analysis post-*Beloit* continue to resonate with the real world and should therefore be preserved. Requiring evidence that PHOSITA would have, in fact, been knowledgeable of a particular piece of prior art fits in this category, especially where the prior art in dispute is a patent, because certain scientists may be far less aware of patents than others.¹⁹¹

The relevance of secondary considerations should also be preserved, yet clarified significantly. This prescription may come as a surprise, given that secondary factors have been blamed for marginalizing PHOSITA from the US obviousness test prior to *KSR*¹⁹²—roughly the same harm sought to be avoided here, even though the content analysis did not reveal an over-reliance on secondary factors by Canadian courts. However, when properly understood, these factors can provide a more reliable indicator of an invention's obviousness relative to expert testimony.¹⁹³

All of these factors form part of Canadian jurisprudence, but it is not clear that courts understand why some factors—failure of others and teaching away¹⁹⁴—are in principle more probative than others. Evidence of commercial success is, for instance, dismissed as irrelevant as often as it is accepted as compelling because the court sees it as attributable to marketing instead of true invention. Rarely, if ever, does the court attempt to assess whether the claims of the patented invention are “co-extensive” with the commercially successful product, in which case the evidence should be given some weight notwithstanding marketing efforts.¹⁹⁵ The harder case to decide will be where the nexus between secondary considerations and the invention is strong and thus supports the invention's non-obviousness, but the evidence as to what PHOSITA would know, et cetera, points in the opposite direction. Until the problem of negative characterization is corrected, that sort of difficult choice is one that the court is unlikely to face.

191. See Walsh, Cohen & Cho, *supra* note 171.

192. See *e.g.* Eisenberg, *supra* note 9.

193. One can, for example, “criticize evidence of copying or acquiescence as circular, since patent enforcement can cause the marketplace to fall into line, taking a licence even to patents they believe should never have been issued.” See Durie & Lemley, *supra* note 107 at 18-19.

194. *Ibid.*

195. But see *Samsonite Corp. v. Holiday Luggage Inc.* (1988), 20 C.P.R. (3d) 291 (F.C.T.D.). This case provides the lone example of the court turning its mind to this issue.

2. ADDRESSING NEGATIVE CHARACTERIZATION

As argued above, PHOSITA's involvement in claim construction appears to precipitate both types of negative characterization. A certain degree of conceptual incoherence results, as PHOSITA appears to be "everywhere yet nowhere" in the analysis.¹⁹⁶ The Supreme Court of Canada's decision in *Apotex* may even invite more negative characterization by welcoming evidence about the "history of the invention" in dispute, as well as the knowledge of those involved in bringing it about, such as Mr. Badorc.¹⁹⁷ Ironically, Justice Rothstein noted that the "knowledge of those involved in finding the invention" may be particularly useful where it is "no lower than what would be expected of the skilled person,"¹⁹⁸ when the tendency in the jurisprudence is to hold the inventor(s) in higher regard than PHOSITA. Clearly, the Supreme Court was either not cognizant of this tendency, or it did not grasp that negative characterization is at odds with the *Patent Act* and capable of spawning a PHOSITA with *less* than ordinary skill.

As such, the primary doctrinal change, suggested in the preceding sub-section, of ensuring that PHOSITA be fully characterized in his or her own right may be insufficient to fix the problem. To fully combat negative characterization, whether in its manifest *Novopharm* form, or in its PHOSITA-conflated *Apotex* analog, the *source* of the evidence regarding who PHOSITA is, what he or she knows, and what he or she can accomplish should be altered.

The court should diversify the sources of information that PHOSITA is based upon, depending on the function that he or she is asked to carry out. Instead of having party experts act as the sole supplier of PHOSITA's characteristics for both claim construction and obviousness purposes, the court should also receive evidence from patent examination officials at the Canadian Intellectual Property Office (CIPO) about what the skilled technician would know, et cetera, for the purpose of determining obviousness. Party experts could continue to speak to the boundaries of the patented invention, as interpreted by the skilled reader,¹⁹⁹

196. That PHOSITA plays an identifiable role in several frequently-litigated patent law issues has been the subject of commentary for some time. As regards the United States, see e.g. John O. Tresansky, "PHOSITA – The Ubiquitous and Enigmatic Person in Patent Law" (1991) 73 J. Pat. & Trademark Off. Soc'y 37. That PHOSITA is seldom identified by way of factual findings is, however, an observation that has, until now, never been demonstrated in Canada.

197. *Apotex* (2008), *supra* note 15 at paras. 70-71.

198. *Ibid.* at para. 70 [emphasis added].

199. Doing so would seem appropriate, given PHOSITA's translational function at the claim

as well as to the invention's obviousness. CIPO officials, on the other hand, could provide a disinterested (or at least less-interested) source of information about PHOSITA's knowledge and capacities. Moreover, by opening up the sources of evidence that inform PHOSITA's identity to include not only expert inventors, but also patent examiners—individuals whom, as at least two commentators have contended, are much more legitimate PHOSITA proxies²⁰⁰—the court may be less inclined to fall into either type of negative characterization trap.

In terms of mechanics, patent examiners need not appear in court to be so involved. Rather, institutional reform on the part of CIPO is needed. At the time of examination, the examiner should be permitted to rely on his or her own knowledge, common sense, and experience in the technological field (as opposed to simply the prior art and other evidence provided by the putative patentee) to deem a patent obvious.²⁰¹ The examiner should document in writing his or her reasons for thinking that PHOSITA would or would not be able to come up with the invention under review, and, in the event of determining that the invention is obvious, provide the patent applicant with an opportunity to rebut those reasons (through argument and/or by submitting an affidavit explaining the knowledge or ability of those skilled in the art).²⁰²

Legally, integrating this paper trail (or "file wrapper," as it is known in the United States) into the obviousness determination should not, in principle, be a problem. In *Free World Trust*, the Supreme Court of Canada held that the file wrapper cannot be used as evidence for claim construction, but left the door open for other purposes, including, presumably, obviousness.²⁰³

This solution is admittedly imperfect, if not also potentially artificial. At the judicial level, it may effectively result in two PHOSITAs—the skilled reader

construction stage. This role serves to mediate the interests of patent-holders and the public—interests corresponding directly to the patent-holding party and the alleged infringer in the instant litigation.

200. Eisenberg, *supra* note 9 at 898-99; Durie & Lemley, *supra* note 107 at 24.

201. The current *Manual of Patent Office Practice* lacks a provision allowing an examiner to deny a patent application based upon his or her knowledge, common sense, or experience. See Canadian Intellectual Property Office, *Manual of Patent Office Practice* (Ottawa: Industry Canada), c. 13 at 13-15 ("Examinations of Applications"), online: <[http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/vwapj/chapitre13-chapter13-eng.pdf/\\$file/chapitre13-chapter13-eng.pdf](http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/vwapj/chapitre13-chapter13-eng.pdf/$file/chapitre13-chapter13-eng.pdf)>.

202. Durie & Lemley, *supra* note 107 at 23.

203. See *Free World Trust*, *supra* note 59 at paras. 66-67.

tasked with claim construction and the ordinary technician deployed for obviousness—and it remains to be seen whether two (hypothetical) heads are better than one. From an institutional perspective, CIPO already faces tremendous time and resource constraints: while the backlog of patent applications may be less than in larger markets (such as the United States and Europe), the total time examiners are able to devote to each patent application is presumably not that much greater than, for example, the eighteen or so hours that United States Patent and Trademark Office examiners are able to afford.²⁰⁴

However, this proposal would seem less taxing on the system than integrating review by neutral outside experts into the patent examination process—a proposal being explored in the United States²⁰⁵ and already in place in the United Kingdom.²⁰⁶ At bottom, though, it is important to bolster the obviousness requirement for innovation’s sake, despite these institutional challenges.

C. SECOND ORDER CHANGE: INNOVATION THEORY

Much of the foregoing critique could be construed as a complaint with the uncreative, unimaginative, uninventive, or non-innovative character commonly ascribed to PHOSITA. Some would contend that this defining trait, however termed, is inevitable. If an invention is determined to be within PHOSITA’s power to produce or know, and, therefore, undeserving of the title “invention,” then why not characterize him or her as uninventive? Even if patenting becomes ordinary practice within a particular field, paradoxically relegating PHOSITA—a creature without even a “scintilla of inventiveness”—to the realm of the *extraordinary*, this outcome would still seem to flow inexorably from the language of the *Patent Act* and the very task PHOSITA was conceived to perform. Taking the argument advanced here to its logical extreme, in other words, critics may charge that altering the policy embodied by the *Patent Act* so as to recognize PHOSITA’s creativity is not possible.

204. See Durie & Lemley, *supra* note 107 at 19. The authors describe this eighteen hours as the total time that US patent examiners need in order to do several tasks, including an evaluation of the invention’s obviousness.

205. See Beth Simone Noveck, “‘Peer to Patent’: Collective Intelligence, Open Review, and Patent Reform” (2006) 20 Harv. J.L. & Tech. 123; Eisenberg, *supra* note 9 at 899-905. But see Durie & Lemley, *supra* note 107 at 21 (arguing against this approach).

206. See *Patents Act 1977* (U.K.), 1977, c. 37, s. 21. The Act allows anyone (not simply “neutral experts”) to submit arguments and evidence on the patentability of an invention, including with respect to whether the putative invention involves an inventive step.

That criticism may attach to arguments advanced by others—most notably, Ron Bouchard's efforts to legitimize PHOSITA's inventive abilities within the pharmaceutical context.²⁰⁷ Although grounded in the same understanding of innovation theory as Bouchard's argument, the problem identified in the jurisprudence and the correction called for here is much more basic.

The innovation-related problem in the jurisprudence does not stem from PHOSITA's unrecognized inventiveness, innovativeness, or creativity. Rather, it stems from the fact that the court commonly and casually interchanges these terms. This is a problem, because treating these terms as though they were synonymous—particularly invention and innovation—fundamentally confuses ends and means. The core purpose of the Canadian patent system is to facilitate innovation. But, as explained in the foregoing, the relationship between patents and innovation is not one-to-one. Treating innovative capacity and inventiveness as essentially equivalent therefore flies in the face of this empirical reality. And, significantly, it also necessarily discounts the sphere of knowledge and skill that, according to the statute, PHOSITA has legitimate access to—knowledge in the public domain—which may, in some industries, be more important to innovation than patents.

Arriving at a contextually-characterized PHOSITA is, once again, the primary means within the court's control to guard against this. A second, related tactic is to reframe the purpose of the non-obviousness criterion in view of the dual importance of the public domain and patented knowledge to innovation.²⁰⁸ Such a reframing might read as follows: Non-obviousness serves to identify significant departures from what is already known, recognizing that both patented knowledge and knowledge in the public domain are integral to innovation.

This wording of the purpose arguably muddies the distinction between non-obviousness and novelty. The proposed language may also be interpreted as

207. See Ron A. Bouchard, "Should Scientific Research in the Lead-up to Invention Vitiating Obviousness under the Patented Medicines (Notice of Compliance) Regulations: To Test or Not To Test?" (2007) 6 C.J.L.T. 1; Ron A. Bouchard, "Living Separate and Apart is Never Easy: Inventive Capacity of the PHOSITA as the Tie that Binds Obviousness and Inventiveness in Pharmaceutical Litigation" (2007) 4 U.O.L. & T.J. 1.

208. In this respect, too, the proposal made here is distinguishable from the change suggested by Bouchard, *ibid.* Whereas Bouchard invokes the concept of purposive construction to focus the inquiry on the essence of the invention, the proposal made here would frame the non-obviousness requirement in terms of the function of the doctrine vis-à-vis innovation more broadly.

setting a higher standard for non-obviousness. However, this merely re-illustrates the insufficiency of words in terms of capturing true invention that judges have long expressed. The real purpose of this new purposive frame is to underscore the dual importance of the public domain and patented inventions. This, in turn, helps to encourage future courts to engage in more contextual characterizations of PHOSITA, so as to better position themselves to determine the obviousness of an invention in a manner that reflects the industry-specific nature of innovation.

D. A FINAL WORD ABOUT PHARMACEUTICAL SELECTION PATENTS

Having recently decided *Apotex*, the Supreme Court of Canada may unfortunately not agree that such a reformulation of the obviousness doctrine, infused with a richer understanding of innovation—one which concedes that knowledge in the public domain may be just as crucial to innovation as patented inventions—is needed. As this article has shown, however, the fundamental problem transcending the law of obviousness in Canada was simply not raised. Perhaps the actual outcome in *Apotex* was the correct one, notwithstanding the characterization conflation that occurred: the evidence did seem to suggest that no one—not the pharmaceutical company, not the inventor, and not the skilled person—had previously theorized or predicted which of the two isomers separated out from the racemate would prove effective and safe, notwithstanding that known techniques were used. The company had previously pursued a different path, which had resulted in significant losses of time and money.²⁰⁹ On the other hand, whether the majority of those losses are better traced to the development of the active ingredient in the drug Plavix—as opposed to the various patents covering the drug’s metabolites, extended-release formulations, and enantiomers, all of which are typically tacked on to extend the patent term—is, perhaps, a question that merits more critical scrutiny.²¹⁰ Assuming courts will

209. *Apotex* (2008), *supra* note 15 at para. 91.

210. Recall that the patent at issue in *Apotex* (2008), *ibid.*, was a selection patent. The compound at issue was actually encompassed by a prior, broader patent also held by the same drug manufacturer, Sanofi, but which had expired in 2002. Some commentators argue that such patents provide critical incentives for research and development. Others lament their existence for effectively sanctioning the creation of non-innovative, “me-too” drugs. See Marcia Angell, *The Truth About the Drug Companies: How They Deceive Us and What to Do About It* (New York: Random House, 2004) at 74ff. The more immediate issue for the question of non-obviousness is whether the expenses incurred by Sanofi, which Rothstein J.

always have imperfect information about the true costs of pharmaceutical research and development, finding selection patents valid in principle may well be a defensible patent policy choice. But unless the corrections suggested above are made and the judiciary begins to demythologize PHOSITA by making findings of fact in each case, the current chasm between patent law doctrine and the patent system's central goal of promoting innovation will only widen.

accepted as being tied to the specific patented invention at issue, were actually linked to the research and development of the parent patent.