Living Separate and Apart is Never Easy: Inventive Capacity of the PHOSITA as the Tie That Binds Obviousness and Inventiveness in Pharmaceutical Litigation

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THE PURPOSE OF THIS ARTICLE IS TO GAIN INSIGHT INTO THE RELATIONSHIP between obviousness and inventiveness in pharmaceutical litigation. Canadian jurisprudence and legal commentary stipulate that persons having ordinary skills in the art (PHOSITA) of pharmaceutical drug development possess not even a "mere scintilla" of inventiveness even though the global pharmaceutical industry is one of the most sophisticated, research-intensive and profitable in the world. Because a person lacking in right brain functions would not contemplate, let alone conduct, research during the lead-up to invention, the result is that patentees need only demonstrate a *de minimus* level of testing in order to automatically vitiate a finding of obviousness. Therefore, the current test for obviousness constitutes a binary assessment, with little regard for the realities of contemporary drug development. As such, the identity and inventive capacity of the PHOSITA is critical to the outcome of pharmaceutical litigation. A social sciences construction of the normative identity and inventive capacity of the PHOSITA was undertaken using the tacit and focal knowledge framework of Polanyi and actor-network theory of Latour. Both analyses underscored the inherent creativity and inventiveness of the normative PHOSITA and the ability of the PHOSITA to work under conditions of uncertainty and ambiguity. The normative PHOSITA exists in a milieu that is at once indeterminate and determinate, indicating that the push-pull of obviousness and inventiveness cannot be legitimately explained using binary terminology alone. Consequently, the normative PHOSITA supports a flexible rather than stringent standard for obviousness. The legal nexus between the normative PHOSITA and obviousness is provided by a "purposive construction," which focuses on the essence of an invention rather than on binary distinctions and provides a contextual yet objective and evidence-driven framework for obviousness. Finally, the suggested purposive approach is conducive to a patent policy which facilitates rather than impedes strong innovation in the pharmaceutical sector.

AVEC CET ARTICLE, ON CHERCHE À COMPRENDRE LES LIENS QUI PEUVENT EXISTER entre l'évidence et l'inventivité dans le contexte des litiges en matière pharmaceutique. La jurisprudence canadienne et la doctrine juridique s'accordent pour dire que les personnes versées dans l'art (ou « PHOSITA » pour « persons having ordinary skills in the art ») de l'élaboration des drogues pharmaceutiques ne possèdent même pas une « simple parcelle d'inventivité » bien que l'industrie pharmaceutique soit l'une des plus élaborées, des plus axées sur la recherche et des plus rentables du monde. Étant donné qu'une personne dépourvue des fonctions propres à la partie droite du cerveau ne pourrait envisager, et encore moins diriger, des projets de recherche, à partir de l'étape de la mise en route jusqu'à celle de l'invention, il suffit par conséquent aux titulaires de brevet de satisfaire le test minimum pour automatiquement vicier une conclusion d'évidence. Par conséquent, le critère actuel pour conclure à l'évidence consiste en une évaluation binaire, qui accorde peu d'importance aux réalités du développement moderne de la pharmacopée. Dans cette optique, l'identité et la capacité inventive des PHOSITA sont cruciales pour l'issue des litiges en matière pharmaceutique. Une construction de l'identité normative et de la capacité inventive des PHOSITA, sous l'angle des sciences sociales, a été élaborée à l'aide du cadre des connaissances tacites et focales de Polanyi et de la théorie du réseau d'acteurs (*actor-network theory* ou *ANT*) de Latour. Les deux analyses ont montré la créativité et l'inventivité inhérentes des PHOSITA normatifs et la capacité de ces derniers de travailler dans des conditions d'incertitude et d'ambigüité. Les PHOSITA normatifs vivent dans un milieu qui est à la fois indéterminé et déterminé, ce qui incite à conclure que le rapport entre l'évidence et l'inventivité ne peut légitimement s'expliquer à l'aide de la seule terminologie binaire. Par conséquent, les PHOSITA normatifs suivent un critère souple, et non pas rigoureux, en ce qui a trait à l'évidence. Le lien juridique entre les PHOSITA normatifs et l'évidence découle d'une « interprétation utilitaire » qui met l'accent sur l'essence d'une invention plutôt que sur des distinctions binaires et qui fournit un cadre à la fois contextuel et objectif, fondé sur la recherche, pour prouver l'évidence. Enfin, l'interprétation utilitaire proposée aboutirait à une politique en matière de brevets qui favoriserait, plutôt qu'elle n'empêcherait, un solide élan d'innovation dans le secteur pharmaceutique.

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> Obviousness and inventiveness are antitheses. What is obvious cannot be inventive, and what is inventive cannot be obvious.
>
> –Chief Justice Gleeson, *Aktiebolaget Hässle v Alphapharm*[1]

> When all is said, we are called upon imaginatively to protect this act of discovery against a hypostatized average practitioner, acquainted with all that has been published and all that has been publicly sold. If there be an issue more troublesome, or more apt for litigation than this, we are not aware of it.
>
> –Judge Learned Hand, *Harries v Air King Products Co*[2]

1. INTRODUCTION

THE LAW PERTAINING TO OBVIOUSNESS under the *Patented Medicines (Notice of Compliance) Regulations*[3] ("NOC Regulations") was canvassed and evaluated in earlier work.[4] The NOC Regulations belong to a specific class of legal instruments referred to as "linkage regulations," which tie patent protection for marketed pharmaceuticals to the drug approval process.[5] It was demonstrated that there is substantial uncertainty in Canadian jurisprudence over what constitutes the

1. 2002 HCA 59, <http://www.austlii.edu.au/au/cases/cth/HCA/2002/59.html>, (2002) 212 *Commonwealth Law Reports* 411 at para. 20, citing *Beecham Group Limited's (Amoxycillin) Application* (EW CA, 1979), 1980 *Reports of Patent, Design and Trade Mark Cases* 261 at p. 290.
2. (USA 2d Cir, 1950), 183 *Federal Reporter, 2d ser.* 158 at p. 162.
3. *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, <http://laws.justice.gc.ca/en/cr/SOR-93-133> [*NOC Regulations*].
4. Ron A Bouchard, "Should Scientific Research in the Lead-up to Invention Vitiate Obviousness under the Patented Medicines (Notice of Compliance) Regulations: To Test or Not To Test?," (2007) 6:1 *Canadian Journal of Law & Technology* 1-27, <http://papers.ssrn.com/abstract_id=958870>.
5. As discussed further below (see Part 3.1.1 below), Canada's linkage regime ties patent protection under the *Patent Act*, (1985) *Revised Statutes of Canada* ch. P-4, <http://laws.justice.gc.ca/en/ /cs/P-4> to the requirements for drug approval in the *Food and Drugs Act*, (1985) *Revised Statutes of Canada* ch. F-27, <http://laws.justice.gc.ca/en/cs/F-27> and *Food and Drug Regulations*, (1978) *Consolidated Regulations of Canada* ch. 870, <http://laws.justice.gc.ca/en /cr/C.R.C.-c.870> via the *NOC Regulations*. Prior to the *NOC Regulations* coming into force in 1993, the regulatory systems for drug approval and patenting in Canada were distinct and separate: *AstraZeneca Canada Inc. v Canada (Minister of Health), 2006 SCC* 49, <http://scc.lexum.umontreal.ca/en/2006/2006scc49/2006scc49.html>, 2006:2 *Supreme Court Reports* 49 at para. 12 [*AstraZeneca*].

accepted test for obviousness in the context of pharmaceutical litigation; some cases standing for the proposition that no testing whatsoever is allowed ("stringent standard"), some for the opposite proposition that some testing is allowed without automatically vitiating a finding of obviousness ("flexible standard"), and still others purporting to follow the former standard while actually applying the latter one. The main conclusion of the work was that confusion over the issue of obviousness arises due to a lack of understanding by courts as to what constitutes the appropriate identity and inventive capacity of persons skilled in the art of pharmaceutical sciences. The purpose of the present work is to directly address this issue.

A patent for invention is a grant of property right by government to an inventor. Under Canadian patent law, property rights under a patent include the right to exclude others from making, using or selling an invention in Canada from the date the patent is granted for a period of 20 years after the filing date.[6] In exchange for the grant of patent, inventors must provide a full description of the invention and how it is enabled so that the public can benefit from disclosure and use it as a springboard from which to launch further innovations in that or other fields. This *quid pro quo* between the inventor and public is referred to as the "traditional patent bargain,"[7] which predates the 1623 *Statute of Monopolies*.[8]

Section 2 of the Canadian *Patent Act* (the "Act") defines an invention as 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." An invention must meet three basic requirements in order to be patentable; the subject matter[9] defined in the claims must be new,[10] useful[11] and non-obvious.[12] The first requirement is met where the subject matter of the patent has not yet been disclosed to the public. The second is met where the subject matter provides sufficient utility or benefit to the public and achieves the purpose for which it came into being. The third is met where the

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6. *Patent Act*, *supra* note 5 at ss. 42, 44.
7. *Free World Trust v Électro Santé Inc.*, 2000 SCC 66, <http://scc.lexum.umontreal.ca/en/2000/2000scc66/2000scc66.html>, 2000:2 *Supreme Court Reports* 1024 at para. 13; *Whirlpool Corp. v Camco*, 2000 SCC 67, <http://scc.lexum.umontreal.ca/en/2000/2000scc67/2000scc67.html>, 2000:2 *Supreme Court Reports* 1067 at para. 37; *Hotchkiss v Greenwood* (US SC, 1850), <http://supreme.justia.com/us/52/248/case.html>, 52 *United States Supreme Court Reports* 248; *Graham v John Deere Co.* (US SC, 1966), <http://supreme.justia.com/us/383/1/case.html>, 383 *United States Supreme Court Reports* 1 at pp. 688-689, paras. 3–4, 11–12.
8. *An Act concerning Monopolies and Dispensations with penall Lawes and the Forfeyture thereof*, 21 James I ch 3, <http://www.statutelaw.gov.uk/content.aspx?LegType=All+Primary&PageNumber=7&BrowseLetter=S&NavFrom=1&parentActiveTextDocId=1518308&ActiveTextDocId=1518308&filesize=16503> [*Statute of Monopolies*]. In *Free World Trust*, *supra* note 7 at para. 13, the Court stated that:

   > prior to the *Statute of Monopolies* (1623) "the Crown rewarded an inventor with a limited monopoly in exchange for public disclosure of "a new invention and a new trade within the kingdom...or if a man hath made a new discovery of any thing": *Clothworkers of Ipswich Case* (1653), Godb. 252 [1653 *Godbolt's King's Bench Reports* 252], 78 E.R. 147 [78 *English Reports* 147], at p. 148, where the court went on to say that the effect of an unjustified monopoly was "to take away free-trade, which is the birthright of every subject."

9. Section 27(4) of the *Patent Act*, *supra* note 5, stipulates that the subject matter of the patent must be defined distinctly and explicitly in the claims section of the patent.
10. Under section 28.2(1) of the *Patent Act*, *supra* note 5, the subject matter defined in the claims cannot be disclosed more than one year before the filing date.
11. *Henriksen v Tallon Limited* (UK HL, 1965), 1965 *Reports of Patent, Design and Trade Mark Cases* 434; *Burton Parsons Chemicals Inc. v Hewlett Packard (Canada) Ltd* (CAN SC, 1974), 1976:1 *Supreme Court Reports* 555, 17 *Canadian Patent Reporter, 2d ser.* 97.
12. Under section 28.3 of the *Patent Act*, *supra* note 5, the subject matter defined in the claims cannot have been obvious as of the claim date to a person skilled in the art of that invention.

subject matter constitutes an "inventive step" or manifests sufficient "inventive ingenuity" over the prior art to warrant the traditional patent bargain. Where an inventive step is lacking, a patent is not granted or, if granted, can be later ruled invalid on the grounds that it is "obvious" in light of the prior art, provided that the person skilled in the art would have been led directly and without difficulty to the solution taught by the patent.[13] When the claims at issue are deemed to be obvious or anticipated (for lack of novelty), they are struck down and can no longer be used to prohibit competitors from using the invention.

Under the terms of the Act, the lens through which the court must gaze when deciding the issue of obviousness is that of a person having ordinary skills in the art, also referred to as the PHOSITA. The two terms will be used throughout interchangeably.[14] When assessing the issue of obviousness courts are charged with undertaking a determination of whether the impugned invention represents an inventive step over the prior art, including previously disclosed inventions.[15] One problem that frequently comes up in the obviousness analysis is whether or not experimental research or testing leading to crystallization of the impugned invention constitutes an inventive step from the perspective of the PHOSITA. The issue of "testing" is thus shorthand for whatever scientific experimentation and research was conducted prior to crystallization of the invention. The issue of testing is significant in the context of pharmaceutical inventions because like all biomedical inventions they typically come about as a result of cumulative incremental advances over the prior art; that is, they do not come into being *in vacuo*.

There is considerable "push-pull" between inventiveness and obviousness in determining the validity of a patent. While in one sense there is a zero sum game between the two concepts insofar as the final decision of the court is concerned (the invention is either valid or invalid), in another more subtle sense, there is a broad spectrum of potential research and testing leading up to crystallization of the invention that cannot be seen in a binary fashion and which only the PHOSITA is positioned to judge. For example, assume it was well known to our industrial drug development PHOSITA that ingestion of one of either two known methylxanthine compounds, theophylline or theobromine, yields a mild stimulant effect in humans by raising the levels of cyclic AMP and antagonizing endogenous adenosine. The patentee conducts an array of simple tests in the

13. *Beecham Canada Ltd. et al. v Procter & Gamble Co.* (CAN Fed CA, 1982), 61 *Canadian Patent Reporter, 2d ser.* 7 at p. 27.
14. *Whirlpool*, *supra* note 7. The Court held (at paras. 70–71) that persons skilled in the art have "ordinary" skills in that art. "PHOSITA" is the term of art used in American patent law and scholarship. See for example: Glynn S Lunney, "E-Obviousness," (2001) 7 *Michigan Telecommunications & Technology Law Review* 363–422, <http://www.mttlr.org/volseven/Lunney.pdf>; Rebecca S Eisenberg, "Obvious to Whom? Evaluating Inventions From the Perspective of the PHOSITA," (2004) 19:3 *Berkeley Technology Law Journal* 885–906, <http://btlj.boalt.org/data/articles/19-3_spring-2004_symp_3-eisenberg.pdf>; Dan L Burk and Mark A Lemley, "Biotechnology's Uncertainty Principle," (2004) 54:3 *Case Western Reserve Law Review* 691–742, <http://ssrn.com/abstract=303619>.
15. *Beloit Canada Ltd. v Valmet OY* (CAN Fed CA, 1986), 8 *Canadian Patent Reporter, 3d ser.* 289 at p. 293 [*Beloit*]; *Crosley Radio Corp. v Canadian General Electric Co.* (CAN SC, 1936), 1936 *Canada Law Reports: Supreme Court of Canada* 551 at pp. 555–556; *Beecham*, *supra* note 13 at p. 27; *Samuel Parkes & Co. Ltd. v Crocker Bros. Ltd.* (EW CA, 1929) 46 *Reports of Patent, Design and Trade Mark Cases* 248 at p. 248; *Martinray Industries v Les Fabricants National Dagendor* (CAN Fed Ct Trial Div, 1991), 41 *Canadian Patent Reporter, 3d ser.* 1, p. 30; *Canadian Gypsum Co. Ltd. v Gypsum Lime & Alabastine Canada Ltd.* (Exchequer Ct, 1931), 1931 *Canada Law Reports: Exchequer Court of Canada* 180 at p. 187.

lab using well known methods and equipment, and finds that a small and easy to effect change in the ring structure of either compound produces yet another methylxanthine compound, caffeine, which has a substantially larger stimulant effect via the same two biochemical pathways as theophylline and theobromine. Does the discovery of the stimulant effects of caffeine amount to the exercise of sufficient inventive ingenuity to constitute a patentable invention, or is it obvious in light of the known existence, chemical structure, stimulant effects and mechanism of action of the parent compounds? One could ask the same question under circumstances where all three methylxanthines were known in the art and later testing showed that caffeine had the same or similar stimulant effects as previously documented for theophylline and theobromine. The potential combinations are endless. On the one hand, it might be said that only very minor or "routine" (e.g., non-inventive) testing was needed in order to simply confirm caffeine had properties similar to those of other known methylxanthines. On the other hand, it might be said that there is sufficient uncertainty involved in *any* testing that the mere act of undertaking it is an expression of sufficient inventive ingenuity to warrant a patent. Thus, obviousness and inventiveness represent divergent positions on the continuum of potential inventive activity undertaken by patentees as well as that contemplated by the PHOSITA in the *post-hoc* obviousness analysis. It is the overlapping grey zone between the two poles that has presented the greatest challenge to courts grappling with the issue.

While obviousness and inventiveness are opposite ends of the spectrum of activity leading up to invention, the roof under which they co-inhabit, however uncomfortably, is that of human agency. Notwithstanding the PHOSITA represents at once the metric for the obviousness analysis undertaken by the courts, the class of persons most likely to be actual inventors in reality, and the societal medium through which all pharmaceutical inventions emanate and are vetted, rejected and put into practice, Canadian patent jurisprudence[16] and legal commentary[17] nevertheless stipulates that for an invention to be obvious, no "experimenting or serious thought, or research, whether the research be in the laboratory or amongst literature" can be conducted in the lead-up to invention.[18] Judicial reasoning underpinning this approach hinges on the current legal fiction of the PHOSITA, who is said to possess not even a "mere scintilla" of inventiveness or creativity.[19] This is true independent of whether the obviousness analysis is couched as (a) an express injunction against testing or (b) the "worth a try" approach to testing or (c) whether the PHOSITA "would have" versus "could have" arrived at the impugned invention.[20] The approach taken by Canadian

16. *Beloit, supra* note 15; *Bayer Aktiengesellschaft v Apotex Inc.* (ON CJ (Gen Div), 1995), 60 *Canadian Patent Reporter, 3d ser.* 58; affirmed (ON CA, 2002), <http://www.ontariocourts.on.ca/decisions/2002/january/bayerC35755.pdf>, 16 *Canadian Patent Reporter, 4th ser.* 417 (leave to appeal denied (CAN SC, 1998), <http://scc.lexum.umontreal.ca/en/bulletin/1999/99-04-16.bul/99-04-16.bul.html>, [1998] SCCA No 563 (SCC)) [*Bayer (ON CJ)* (cited to *Canadian Patent Reporter*)].
17. Harold G Fox, *The Canadian Law and Practice Relating to Letters Patent for Inventions*, 4th ed. (Carswell Company Limited, 1969); George Francis Takach, *Patents: A Canadian Compendium of Law and Practice* (Juriliber, 1993).
18. Fox, *supra* note 17 at pp. 70–71
19. *Beloit, supra* note 15 at p. 294; *Bayer(ON CJ), supra* note 16 at p. 79.
20. Bouchard, "Scientific Research," *supra* note 4.

courts on the issue is highly binary in nature, which contrasts sharply with the spectrum of inventive activity engaged in by both actual patentees or more generally by persons skilled in the art of pharmaceutical research and development.

As alluded to above, it is not surprising that differing parties to litigation seek differing standards. On the one hand, patentees (typically brand-name pharmaceutical firms) and advocates of broad patent scope and the innovation agenda desire a stringent obviousness standard such that any amount of research or testing undertaken to arrive at an invention will result in a patent monopoly. Here, parties attacking a patent on grounds of obviousness face the fact that if evidence of testing is put before the court by the patentee then its attack on patent validity must *automatically* fail. By contrast, parties alleging invalidity based on obviousness (typically generic pharmaceutical firms) and advocates of narrower patent scope and a higher threshold for innovation desire a more flexible, objective and evidence-based obviousness standard, which operates such that some testing in the lead-up to invention can be contemplated without necessarily vitiating a finding of obviousness. Under these circumstances a monopoly would be justified only where testing is inventive in nature. The issue of inventiveness is a particular concern in the case of pharmaceuticals owing to the considerable public interest at stake in the commoditization of essential medicines. For this reason, pharmaceutical patents should be scrutinized carefully in order to determine if they merit the grant of a monopoly privilege.[21] This raises the question of whether a broad social sciences analysis of the descriptive and prescriptive norms of the pharmaceutical PHOSITA supports the contention that a *de minimus* level of testing during the lead-up to invention should vitiate a finding of obviousness.

The analysis is split up into four parts. Part 3 canvasses leading case law on the relationship between testing and the inventive capacity of the PHOSITA. It is concluded that there is no clear and unambiguous line of jurisprudence supporting either position. Part 4 is a social sciences analysis of the identity and inventive capacity of the pharmaceutical PHOSITA. It is concluded that there is no evidence to support the legal myth that such persons are completely devoid of creativity and inventiveness. To the contrary, there is ample evidence that the pharmaceutical PHOSITA is inherently inventive and able to work successfully in an environment characterized by uncertainty and ambiguity. This is supported by an analysis of the tacit and focal knowledge bases[22] unique to pharmaceutical research and an actor-network theory[23] perspective of persons skilled in the art of pharmaceutical research and how these individuals are both integrated into and integral to the drug development cycle. In Part 4, the legal nexus between the test for obviousness and the normative PHOSITA is located in Supreme Court of Canada jurisprudence requiring patents to be construed purposively rather than in a binary or rigid fashion. A purposive test allows for some testing without automatically vitiating a finding of obviousness, provided that the testing is non-

21. *Commissioner of Patents v Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning* (CAN, SC, 1964), 1964 *Canada Law Reports: Supreme Court of Canada* 49 at p. 50 [*Farbwerke*]. See also Michael Walzer, *Spheres of Justice: A Defense of Pluralism and Equality* (Basic Books, 1983) at pp. 78–122.
22. Michael Polanyi, *The Tacit Dimension* (Anchor Books, 1967).
23. Bruno Latour, *Science in Action* (Harvard University Press, 1987).

inventive in nature. The proposed test would bring Canada in line with leading patent jurisprudence in the United States and United Kingdom, particularly given the recent US Supreme Court decision in *KSR v Teleflex*. Finally, in Part 5 the disparate effects of the two standards on innovation and invention are analysed, with particular focus on the life sciences industry. It is concluded that a purposive standard for obviousness would support strong innovation and efficient patenting in the pharmaceutical and biotechnology sectors, the former of which is currently plagued by weak patents, line extension and "me-too" products, and other minor variations of products where the patent on the original new chemical entity has long since expired.

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2. SETTING THE STAGE: THE CASE LAW

2.1. Routine Research

SECTION 28.3 OF THE ACT[24] requires that courts must look to the PHOSITA for guidance when making a determination of obviousness. However, the Act does not define the creative, or indeed any other intellectual or cognitive, qualities of the PHOSITA other than that they are a "person" who is "skilled" in the relevant "art." While it appears that the accepted approach to obviousness is to assume implicitly that the PHOSITA should have not even a scintilla of inventiveness,[25] a review of historical case law reveals this is hardly settled law. Indeed, there are many decisions that have addressed the issue directly and have come down on both sides of the dividing line, including Supreme Court and other appellate jurisprudence. The intent of this Part is to review case law pertaining to obviousness that deals directly with the creative capacity and ability of the PHOSITA.

Many of the decisions in which a certain degree of testing has been allowed without vitiating a finding of obviousness rely to some degree on the finding that non-inventive testing is not outside the ken of the PHOSITA. An early example of this reasoning is the Exchequer Court of Canada decision in *Burns & Russell Canada v Day & Campbell Ltd.*[26] The case is notable for the following passage by Justice Gibson:

> [T]he Courts have applied a standard for this hypothetical person in determining whether or not an invention exists by saying that it is or is not "*beyond the expected skill of the calling*" or "*beyond the skill of the routineer.*"[27]

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24. Section 28.3 of the *Patent Act*, *supra* note 5, provides that 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.
25. *Beloit*, *supra* note 15; *Bayer (ON CJ)*, *supra* note 16.
26. *Burns & Russell v Day & Campbell* (Exchequer Ct, 1965), 1966 *Canada Law Reports: Exchequer Court of Canada* 673, 48 *Canadian Patent Reporter* 207 [*Burns & Russell* (cited to *Canadian Patent Reporter*)].
27. *Burns & Russell*, *supra* note 26 at p. 219 (emphasis added).

The court held that that "routine" or work-shop testing is within the ability of persons skilled in the art. Note that Gibson J. makes no mention of the absence of a scintilla or any other measure of creativity or inventiveness. Rather, the court focused on the skills of the PHOSITA relative to the context at hand. This reasoning was adopted more recently by Justice Wetston in the leading AZT trial decision when he said "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."[28] Similar reasoning was adopted by Justice Reed in the *Apotex v Hoffmann-La Roche*[29] trimethoprim decision, where the adduced evidence demonstrated that Hoffman-La Roche undertook substantial and lengthy non-inventive testing on the road to invention. In each of these cases the court grappled explicitly with the context of the invention, focussing particularly on the state of the prior art at the time of the claim date and the knowledge and skills of persons skilled in that art. The objective was to ask whether the PHOSITA would have come "directly and without difficulty" to the impugned invention in the obviousness analysis. The court therefore dealt with the issue of the creativity of the skilled technician indirectly, as part of its contextual analysis of inventive step.

There are some historical cases where the issue of testing was grappled with directly, including by appellate courts. For example in *Lightning Fastener v Colonial Fastener*,[30] Rinfret J of the Supreme Court of Canada held that inventions brought about through the exercise of mechanical skill do not involve an exercise of inventive ingenuity. The court noted specifically (at p. 377) that it "is not the object of the *Patent Act* to dignify by the name of invention every slight advance in the domain of mechanism." A similar distinction was made by Chief Justice Duff of the Supreme Court of Canada in *Vanity Fair Silk Mills v Canada*[31] and in an earlier Exchequer Court decision in *Pope Alliance v Spanish River*.[32] The distinction between patent-worthy and non patent-worthy research has been confirmed and upheld by the Supreme Court of Canada in its more recent

28. *Apotex Inc. v Wellcome Foundation Ltd.* (CAN FC Trial Div, 1998), <http://decisions.fct-cf.gc.ca/en/1998/t-3197-90/t-3197-90.html>, 79 *Canadian Patent Reporter, 3d ser.* 193 at para. 243 [*Apotex v Wellcome (FCTD)* cited to *Canadian Patent Reporter*]; affirmed (CAN Fed CA, 2001), <http://decisions.fca-caf.gc.ca/en/2000/a-211-98/a-211-98.html>, 1 *Federal Court Reports* 495 [*Apotex v Wellcome (FCA)*]; affirmed, 2002 SCC 77, <http://scc.lexum.umontreal.ca/en/2002/2002scc77/2002scc77.html>, 2002:4 *Supreme Court Reports* 153 [*Apotex v Wellcome (SCC)*].
29. *Apotex Inc. v Hoffmann-La Roche Ltd.* (CAN FC Trial Div, 1987), 15 *Canadian Patent Reporter, 3d ser.* 217 at p. 224.
30. *Lightning Fastener Co. v Colonial Fastener Co.* (CAN SC, 1933) 1933 *Canada Law Reports: Supreme Court of Canada* 371 at p. 377.
31. *Vanity Fair Silk Mills v Canada* (CAN SC, 1939), 1939 *Canada Law Reports: Supreme Court of Canada* 245 at p. 246: "An invention is not patentable where "anybody familiar with and skilled in the art might be expected to arrive at without the exercise of invention in the sense of the patent law."
32. "To apply to calendar rolls what Pope had already applied to other rolls in a paper machine, to transform Smith, Schulte, or Imray to Pope, did not I think require that amount of skill and ingenuity which might be called invention, but only experiment and ordinary mechanical skill"; and p. 41: "The patent in question looks too much like an effort to limit the use of inventions already given to the public, and to control at every turn in a continuous manufacturing process by patenting not improvements or freshly invented means, but only alterations in the form and size of well known methods and appliances, and which fall within the field of the mechanic rather than that of the inventor." *Pope Appliance Corp. v Spanish River Pulp and Paper Mills Ltd* (Exchequer Ct, 1927), 1927 *Canada Law Reports: Exchequer Court of Canada* 28 at p. 41, upheld on appeal (CAN SC, 1928), 1928 *Canada Law Reports: Supreme Court of Canada* 20.

leading patent jurisprudence.[33] Analogous pronouncements in the context of obviousness have been made by appeal courts in the United Kingdom[34] and United States.[35] In addition to obviousness, Canadian courts have also allowed routine trial and error testing by the PHOSITA in the sufficiency analysis,[36] provided that such testing is non-inventive.

The push-pull between inventiveness and obviousness in setting the threshold for patentability and its relation to competition has been the topic of significant debate in the United States.[37] One of the leading United States Supreme Court cases on obviousness is *Graham v John Deere*,[38] where it was alleged that the statutory requirement for obviousness under section 103 of the United States *Patent Act* overruled previous judicial deliberations of what constitutes "the flash of inventive genius" and lowered the bar for obviousness.[39] The *Graham* court rejected this claim, holding that language to this effect in its previous *Cuno*[40] decision was nothing other than "rhetorical embellishment" and did not create a differing standard. Rather, *Cuno* stood for the abiding proposition that non-obvious subject matter is subject matter that extends "beyond the skill of the calling." This distinction was recently picked up by both the Solicitor General and a group of patent law professors in their respective *amici* briefs in *KSR v Teleflex*.[41] As discussed in detail below, *KSR* is notable as it is the first substantial decision by the United States Supreme Court on obviousness since *Graham*. In their *amici* brief, the law professors extended the concept of non-inventive research specifically to litigation involving biomedical

33. *Apotex v Wellcome (SCC)*, *supra* note 28; *Free World Trust*, *supra* note 7.
34. *Technograph Printed Circuits Limited v Mills & Rockley (Electronics) Limited* (UK HL, 1971), 1972 *Reports of Patent, Design and Trade Mark Cases* 346; *The General Tire & Rubber Company v The Firestone Tyre and Rubber Company Limited* (EW CA, 1971), 1972 *Reports of Patent, Design and Trade Mark Cases* 457 at pp. 497–498: The test for obviousness includes an analysis of "whether what had to be done to achieve the step was truly a matter of inventive experiment or merely a matter of that type of trial and error which forms part of the normal industrial function of such an addressee," *Samuel Parkes*, *supra* note 15 at p. 248: To be patentable, an invention must display that "characteristic or quality the presence of which distinguishes invention from a workshop improvement," *London General Omnibus Company v Bonnard* (UK HL, 1920), 38 *Reports of Patent, Design and Trade Mark Cases* 1 at p. 15: An invention cannot be properly patentable where it "might well have occurred to an intelligent person without any exercise of that invention which is necessary as the ground of a patent." See also discussion of *Genentech Inc.'s Patent* (EW CA, 1989), 1989 *Reports of Patent, Design and Trade Mark Cases* 147 in Bouchard, "Scientific Research," *supra* note 4.
35. In *Hotchkiss*, *supra* note 7 at p. 267, United States Supreme Court held: "[U]nless more ingenuity and skill... were required...than were possessed by an ordinary mechanic acquainted with the business, there was an absence of that degree of skill and ingenuity which constitute essential elements of every invention. *In other words, the improvement is the work of the skilful mechanic, not that of the inventor.*" (Emphasis added.) *Hotchkiss* was upheld on this point in the context of obviousness in *Cuno Corporation v Automatic Devices Corporation* (US SC, 1941), <http://supreme.justia.com/us/314/84/case.html>, 314 *Supreme Court Reports* 84; and *Graham*, *supra* note 7.
36. *Cabot Corp. v 318602 Ont. Ltd.* (CAN FC Trial Div, 1988), 20 *Canadian Patent Reporter, 3d ser.* 132 at p. 146; *Airseal Control Inc. v M&I Heat Transfer Products Ltd.* (CAN FC Trial Div, 1993) 72 *Federal Trial Reporter* 196, 53 *Canadian Patent Reporter, 3d ser.* 259 at para. 40 [*Airseal Control* (cited to *Federal Trial Reporter*)].
37. See generally, Lunney, "E-Obviousness," *supra* note 14; Eisenberg, "Obvious to Whom?", *supra* note 14; and Burk and Lemley, "Biotechnology," *supra* note 14.
38. *Graham*, *supra* note 7.
39. *Graham*, *supra* note 7 at p. 692–693.
40. *Cuno Corporation*, *supra* note 35 at para. 91.
41. Brief for the United States as Amicus Curiae Supporting Petitioner (August 2006), <http://www.usdoj.gov/osg/briefs/2006/3mer/1ami/2004-1350.mer.ami.pdf> at p. 3 [United States Solicitory General *KSR* Brief], submitted to *KSR v Teleflex* (US SC, 2007), <http://www.supremecourtus.gov/opinions/06pdf/04-1350.pdf>, 550 *United States Reports* 398 [*KSR*];127 S.Ct. 1727; Brief of Twenty-Four Intellectual Property Law Professors as *Amici Curiae* In Support of Petitioner (August 2006), available at PatentlyO: Patent Law Blog, <http://patentlaw.typepad.com/patent/ksramicus.pdf> at p. 12 [IP Law Professors *KSR* Brief], submitted to *KSR v Teleflex* (US SC, 2007), <http://www.supremecourtus.gov/opinions/06pdf/04-1350.pdf>, 550 *United States Reports* 398;127 S.Ct. 1727.

technologies. They claimed that methodological advances provided an obvious path to new results that should not themselves be patentable. They also claimed the Federal Circuit had, prior to *KSR*, sufficiently "marginalized" the role of the PHOSITA through its relatively rigid "teaching, suggestion, motivation" test such that patents were routinely granted even though the prior art demonstrated a clear and unencumbered path toward the invention. The U.S. Supreme Court, grounding its decision in *Graham*, agreed that research construed by an ordinarily creative PHOSITA to be routine was not patentable, and that marginalizing the PHOSITA through an overabundance of caution relating to hindsight is an error of law where it denies factfinders recourse to common sense interpretations of the context surrounding the invention.

Thus, while the need for caution in distinguishing between inventive and non-inventive testing in the *a posteriori* analysis had been acknowledged by the courts,[42] there can be little question that by the mid-1960s there was a well-developed line of appellate jurisprudence in Canada, the United States, and the United Kingdom distinguishing routine, ordinary or workshop-type testing from inventive testing done on the road to a patentable invention.

2.2. Scintilla of Inventiveness

There are two distinct lines of cases supporting the "no testing approach." The first can be linked to Fox's per se injunction against allowing any type of research or testing on the road to a patentable invention:

> In order that a thing shall be 'obvious', it must be something that would directly occur to someone who was searching for something novel, a new manufacture, or whatever it might be, *without the necessity of his having to do any experimenting or serious thought, or research, whether the research be in the laboratory or amongst literature*.[43]

This passage has a rich history in Canadian obviousness jurisprudence. As discussed elsewhere,[44] it has resulted in many decisions supporting a finding of non-obviousness under circumstances where some degree of testing was carried out on the road to invention.

The second, dealt with here, is a line of cases where a fundamental link is drawn between persons skilled in the art having no "scintilla of inventiveness" and the degree of consequent activity allowed to be properly contemplated by the PHOSITA in the *post-hoc* obviousness analysis. As touched on above, the gist of these cases is that, because the PHOSITA possesses not even a modicum of creativity or inventiveness, evidence demonstrating that significant research took place in the lead-up to invention has the potential to automatically vitiate a finding of obviousness. For example, in *Bayer v Apotex*, Justice Lederman of the Ontario Court reviewed the prohibition against testing by Fox and the

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42. *Ernest Scragg & Sons Ltd. v Leesona Corp.* (Exchequer Ct, 1964), *Canada Law Reports: Exchequer Court of Canada Reports* 649, at paras. 189–191; *Samuel Parkes*, *supra* note 15 at p. 248.
43. Fox, *Canadian Law and Practice*, *supra* note 17 at pp.70–71 (emphasis added).
44. See Bouchard, "Scientific Research," *supra* note 4.

acceptance of this view by the Federal Court in *Cabot Corp. v 318602 Ontario,*[45] and went on to say:

> Thus, although one would normally imagine that this mythical person's laboratory is filled with mythical test tubes and Petri dishes and that his or her daily life is spent in experimentation, for the purposes of this legal exercise, no research of any kind can be contemplated. *So, although it may have been logical to an actual skilled person at the time, based on the state of the art, to conduct certain testing, that is not open to the mythical skilled technician.* The mythical researcher cannot have an inquiring or thinking mind which ultimately would lead him or her to the answer but rather he or she is expected to instantly and spontaneously exclaim, without more, "I already know the answer and it is obvious." Nor is it appropriate to say that there were significant telltales which pointed the way for the mythical expert….[46]

The locus of Justice Lederman's caricature of the mythical PHOSITA is derived from the Federal Court of Appeal decision in *Beloit v Valmet*.[47] In *Beloit*, Justice Hugessen stated that the test for obviousness is "not to ask what competent inventors did or would have done to solve the problem." Rather, 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 court, continued Hugessen J, must therefore ask whether this mythical PHOSITA "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." As noted in *Beecham*, the test is not whether an unimaginative PHOSITA in the drug formulation field "could have" achieved the same result as the patentee but rather whether they "would have" derived it under the same conditions.[48] Clearly, under such conditions no testing in the lead-up to invention could be contemplated by the mythical PHOSITA, first because trial and error is equivalent to "could" rather than "would" and second because it would involve more that a scintilla or *de minimus* level of inventiveness.

It is noteworthy that despite the pedigree of *Beloit* in subsequent obviousness decisions, Justice Hugessen did not provide detailed reasons in support of his claim that the Canadian PHOSITA possesses not even a scintilla of inventiveness. This did not go unnoticed by Justice Lederman in *Bayer*, who commented that there appears to be "a significant difference in the abilities of the English hypothetical skilled technician and the Canadian one" and that "making inquiries or testing, seems to be something outside the ken of the notional Canadian skilled technician."[49]

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45. *Cabot Corp.*, *supra* note 36.
46. *Bayer (ON CJ)*, *supra* note 16 at p. 81 (emphasis added).
47. *Beloit*, *supra* note 15 at p. 294.
48. *Beecham*, *supra* note 13 at p. 27.
49. *Bayer (ON CJ)*, *supra* note 16 at p. 80.

Nevertheless, in *Tye-Sil v Diversified Products* decision,[50] the Federal Court of Appeal revisited the issue and held that it was apparently "well established that a mere 'scintilla of invention' is sufficient to support the validity of a patent." In rendering this statement, Décary JA cited the 1929 English Court of Appeal decision in *Samuel Parkes v Cocker Bros*.[51] and the 1952 Supreme Court of Canada decision in *Canada v Uhlemann Optical*.[52] However, in neither of these cases was it said explicitly that when assessing obviousness the PHOSITA *cannot* contemplate that testing be reasonably undertaken in order to arrive at the impugned invention. Nor was it claimed that the PHOSITA *does not* possess even a mere scintilla of inventiveness. Rather, the decisions stand for the different proposition that for an invention to be patentable, the exercise of at least a mere scintilla of inventiveness is required.

In *Pope Appliance v Spanish River*[53] Viscount Dunedin stated that an invention is simply "finding out something which has not been found out by other people." This was true even under circumstances where someone other than the inventor might have "experimented" and derived the invention. The fact that the invention may have been contemplated by another "does not prevent the one who first applies and gets a patent from having a good patent." The reasoning of the court was adopted by Justice Pigeon in *Farbwerke v Halocarbon*.[54] However, no mention was made by Viscount Dunedin or Justice Pigeon in their respective reasons of whether or not there was a direct relationship between experimenting and exercising more than a scintilla of inventiveness. Indeed a legal nexus between the PHOSITA possessing not even a scintilla of inventiveness and the issue of testing can only be found in *Beloit* and *Bayer*, and even then, the link is implicit rather than being the subject of detailed judicial examination.

Even in cases that accept the prohibition against the exercise of more than a mere scintilla of inventiveness, the issue is far from straightforward. For example, in *Farbwerke v Halocarbon,* Pigeon J attempted to define what exactly constitutes a "scintilla" of inventiveness and it is clear from the cases cited by him that one person's measure of a scintilla will not apply equally in all situations to all judges. For example, the Privy Council decision in *General Electric v Fada*[55] is cited for the proposition that for an invention to warrant the patent monopoly "there must be a substantial exercise of the inventive power or inventive genius" even though later in the decision it was stated that in certain cases "it may be very slight." Even when a "slight" amount of inventiveness will do, it must still nevertheless produce important results and disclose great inventive ingenuity; "if the invention requires independent thought, ingenuity and skill, producing in a distinctive form a more efficient result, converting a comparatively defective apparatus into a useful and efficient one, rejecting what is bad and useless in

50. *Tye-Sil Corp. Ltd. v Diversified Products Corp.* (CAN Fed CA, 1991), 35 *Canadian Patent Reporter, 3d ser.* 350.
51. *Samuel Parkes*, *supra* note 15.
52. *Canada v Uhlemann Optical Co.* (CAN SC, 1952), 1 *Canada Law Reports: Supreme Court of Canada* 143.
53. *Pope Appliance Corp. v Spanish River Pulp & Paper Mills, Ltd.* (PC), 1929: 1 *Dominion Law Reports* 209, at 216. For discussion in the context of biomedical litigation, see *Pfizer Canada Inc. v Canada (Minister of Health)* 2006 FCA 214 at para. 23.
54. *Farbwerke Hoescht Aktiengesellschaft Vormals Meister Lucius & Bruning v Halocarbon (Ontario) Ltd et al* (CAN SC, 1979), 42 *Canadian Patent Reporter 2d ser.* 145.
55. *Canadian General Electric Co. Ltd. v Fada Radio Ltd.* (SCC, 1930), 1 *Dominion Law Reports* 449.

former attempts and retaining what is useful, and uniting them all into an apparatus which, taken as a whole, is novel, there is subject-matter." Thus, depending on the circumstances, the definition of "mere" is well beyond a *de minimus* level of inventiveness and can clearly encompass routine or workshop-type testing: the scintilla can be more like a shard. Many other cases contain similar language when the discussion comes around to what actually constitutes the minimal threshold level of inventiveness required to support patentability. Despite confusion over the quantitative standard for inventive ingenuity, a substantial number of decisions have been reported[56] where a finding of obviousness is vitiated based on either a simple per se injunction against testing or the exercise of more than a *de minimus* level of inventiveness.

2.3. Clarifying the Binary Standard

The discussion thus far underscores the tension in attempting to measure or quantify the degree of inventiveness attaching to an invention and the difficulty in applying a binary standard for obviousness. This tension can be seen clearly in the recent Federal Court of Appeal *Q'Max*[57] decision. Stone JA, referring to *Lightening Fastener* and *Apotex v Wellcome*, held that "where all that is required of an inventor is the application of mechanical skill, inventive ingenuity is lacking." The court went on in the same paragraph, however, to hold that the trial judge was properly guided by the decision of Lederman J in *Bayer v Apotex*[58] to the effect that, "unlike in England, a notional skilled technician in Canada is not required to make enquiries or testing."

Unusually, the *Q'Max* panel seems to be saying that the Ontario Court of Justice's decision in *Bayer* trumps those to the contrary by courts with considerably more experience in patent matters, including the Supreme Court of Canada,[59] the Exchequer Court,[60] the Federal Court of Canada,[61] the English Court of Appeal,[62] the United States Supreme Court[63] and the Federal Court of Appeal's own previous pronouncements on the matter.[64] The majority found that the trial judge would not have found the invention to be non-obvious if it "had been brought about by the mere application of mechanical skill."[65] As such, *Q'Max* is similar to many decisions involving pharmaceutical patents in which courts appear to be applying one standard for obviousness but actually

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56. See Tables 1 and 3 in Bouchard, "Scientific Research," *supra* note 4.
57. *671905 Alberta Inc. v Q'Max Solutions Inc,*. 2003 FCA 241, <http://decisions.fca-caf.gc.ca/en/2003/2003fca241/2003fca241.html>, 2003:4 *Federal Court Reports* 713 at para. 47.
58. *Bayer (ON CJ)*, *supra* note 16.
59. *Lightning Fastener*, *supra* note 30; *Pope Appliance*, *supra* note 32 ; *Vanity Fair supra* note 31; *Apotex v Wellcome (SCC)*, *supra* note 28; *Free World Trust*, *supra* note 7.
60. *Burns & Russell*, *supra* note 26; *Pope Appliance*, *supra* note 32.
61. *Glaxosmithkline v Canada (Minister of Health)*, 2003 FC 899, <http://decisions.fct-cf.gc.ca/en/2003/2003fc899/2003fc899.html>; *Pfizer Canada Inc. v Apotex* (FC Trial Div., 2002) 22 *Canadian Patent Reporter, 4th ser.* 466; *Novartis v Apotex* (FC Trial Div., 2001) 2001 FCT 1129, <http://decisions.fct-cf.gc.ca/en/2001/2001fct1129/2001fct1129.html>; *Apotex v Hoffmann La-Roche*, *supra* note 29.
62. *C. Van Der Lely v Bramfords Ltd.* (HL, 1963) *Reports of Patent, Design and Trade Mark Cases*, *4th ser.* 61; *Genentech*, *supra* note 34.
63. *Graham*, *supra* note 7; *Hotchkiss*, *supra* note 7; *Cuno*, *supra* note 35; *KSR, supra* note 41.
64. *Apotex v Wellcome (SCC)*, *supra* note 28; *SmithKline Beecham Pharma Inc. v Apotex*, 2002 FCA 216, <http://decisions.fca-caf.gc.ca/en/2002/2002fca216/2002fca216.html>, 21 *Canadian Patent Reporter, 4th ser.* 129 at paras. 14 & 19 [*SmithKline (FCA)*].
65. *Q'Max, supra* note 57 at para. 47.

go on to apply a completely different standard.[66] In *Q'Max*, the court first appeared to allow some testing in the obviousness rubric and then reversed, stipulating that no testing can be undertaken in this context. This type of dilemma recently led two judges dealing with the same patentee, the same drug (azithromycin), the same listed patents, the same prior art, the same or similar evidence and legal argument, and purporting to apply the same legal precedents, to arrive at opposite conclusions on the question of obviousness within two weeks of one another.[67]

Given the nuances of the clinical, scientific, legal and economic web in which inventions in the life sciences are developed, it is perhaps not surprising that over the years many judges have expressed caution over trying to use such a bright dividing line in assessing the relationship between inventiveness and obviousness. For example, in an earlier Exchequer Court decision,[68] President Thorson stated that "the court should keep in mind the fact that it has never been possible to define with precision, apart from the statutory definition, what constitutes an invention" and that some of the attempts to do so "have verged on the ludicrous."[69] Speaking to the issue at hand, he noted that "[one] of the reasons for the difficulty is the lack of a standard for differentiating an invention from a workshop improvement." Similarly, in *Canada v Uhlemann,*[70] Rinfret CJ of the Supreme Court of Canada looked to the English law on inventiveness[71] for guidance on the issue of the standard for inventiveness in the context of validity, holding that:

> It would seem to be necessary to fix upon some definition of invention, but this has never been done, and *in my opinion no definition of invention can be found which is of the slightest assistance to anyone in a case of difficulty.... When you approach the dividing line it is so impossible to get a test that it becomes, more or less, a matter of personal opinion....*[72]

Similar concerns have been expressed in the United Kingdom,[73] where the issue was addressed directly through inclusion of an obviousness requirement

66. Bouchard, "Scientific Research," *supra* note 4.
67. *Pfizer Canada Inc. v Novopharm Limited*, 2005 FC 1299, <http://decisions.fct-cf.gc.ca/en/2005/2005fc1299/2005fc1299.html> at paras. 118-119; *Pfizer Canada Inc. v Apotex Inc.,* 2005 FC 1421 <http://decisions.fct-cf.gc.ca/en/2005/2005fc1421/2005fc1421.html> at paras. 128–131.
68. *Ernest Scragg*, *supra* note 42.
69. *Ernest Scragg*, *supra* note 42, at para. 190.
70. *Canada v Uhlemann Optical*, *supra* note 52. See also *Janssen-Ortho Inc. v Novopharm Limited,* 2006 FC 1234, <http://decisions.fct-cf.gc.ca/en/2006/2006fc1234/2006fc1234.html> at para. 113.
71. *Terrell on the Law of Patents*, 7th edition, at page 71.
72. *Canada v Uhlemann Optical*, *supra* note 52 at p. 151(emphasis added).
73. The word "obvious" was apparently first used by Lord Herschell in *Thomson v The American Braided Wire Company* (UK HL, 1889), 6 *Reports on Patent, Design, and Trade Mark Cases* 518. See also *Vickers, Sons and Co., Limited v Siddell* (UK HL, 1890), 7 *Reports on Patent, Design, and Trade Mark Cases* 292. *Longbottom v Shaw* (UK HL, 1891), 8 *Reports on Patent, Design, and Trade Mark Cases* 333. The leading United Kingdom case on obviousness is *Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd* (UK HL,1985), 1985:4 *Reports on Patent, Design, and Trade Mark Cases* 59 at pp. 73–74. The test provides: (1) First the court identifies the inventive concept embodied in the patent in suit; (2) Next, the court will assume the mantle of the normally skilled but unimaginative addressee in the art at the relevant date and will impute to him what was at that date, common general knowledge in the art in question; (3) The court should then identify what, if any, differences exist between the matters cited as being "known or used" and the alleged invention; (4) Finally, the court has to decide 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 required any degree of invention.

in the *Patents Act* in 1977.[74] As noted in *Monlycke v Procter & Gamble*[75] and more recently in *Conor Medsystems v Angiotech Pharmaceuticals*,[76] the effect of the amendment is that the criterion for deciding if the claimed invention involves an inventive step is to be assessed in a wholly objective manner rather than subjectively.[77] The task of the court is to decide whether the impugned step would be obvious to the PHOSITA in light of the prior art at the time of the claim date and the sum of the skills, experience and abilities of the PHOSITA. The court is not assisted by judges asking whether the patent discloses something sufficiently inventive to deserve the grant of a monopoly nor to extract from older judgments expressions such as whether a "scintilla of invention" is necessary to support a patent. In this regard the *Monlycke* court heeded previous cautions articulated by the Court of Appeal[78] regarding judicial reliance on the coining of literal phrases and undue reliance in the obviousness analysis on whether or not the judge has correctly paraphrased the words of the relevant patent legislation in some particular verbal formula rather than addressing the essence of the invention on the facts before them.[79] In *Angiotech*, Pumfrey JA

74. TA Blanco White, *Patents For Inventions and the Protection of Industrial Design*, 5th ed. (Stevens & Sons Ltd, 1983) at s. 4-209, footnote 52; see also *Société Technique v Emson Europe* (EW CA, 1993), 1993 *Reports on Patent, Design, and Trade Mark Cases* 513 at p. 519; *Cairnstores Limited v Aktiebolaget Hassle*, 2002 EWHC 308 (Ch), <http://www.bailii.org/ew/cases/EWHC/Ch/2002/309.html> at para. 94.
75. *Monlycke AB v Procter & Gamble Ltd*, (EW CA, 1994) 1994 *Reports on Patent, Design, and Trade Mark Cases* 49 at 112:

> Under the statutory code (which is further confirmed in its completeness by sections 74 and 72) the criterion for deciding whether or not the claimed invention involves an inventive step is wholly objective. It is an objective criterion defined in statutory terms, that is to say whether the step was obvious to a person skilled in the art having regard to any matter which forms part of the state of the art as defined in section 2(2). We do not consider that it assists to ask whether the patent discloses something sufficiently inventive to deserve the grant of a monopoly. Nor is it useful to extract from older judgments expressions such as "that scintilla of invention necessary to support a patent." The statute has laid down what the criterion is to be: it is a qualitative not a quantitative test. The warning against coining phrases given by the Court of Appeal in General Tire Rubber Co ... is even more apt under the l977 Act.

See also the rejection of semantic arguments by the Court of Appeal in *Hallen v Brabantia* (EW CA, 1991), 1991 *Reports on Patent, Design, and Trade Mark Cases* 195 at pp. 211–212.
76. *Conor Medsystems Inc. v Angiotech Pharmaceuticals Inc.*, 2006 EWHC 260 (Pat), <http://www.bailii.org/ew/cases/EWHC/Patents/2006/260.html> at para. 33, citing *Monlycke*, *supra* note 75.
77. In *General Tire v Firestone*, (EW CA, 1972) 1972 *Reports on Patent, Design, and Trade Mark Cases* 457 at p. 498 the Court of Appeal stated:

> It is as well in relation to the evidence in the instant case at this point to refer to the need for objective as opposed to subjective test. The question is whether the step was obvious to a normally qualified skilled addressee in 1950 -- as opposed to the person who in fact claims to be the inventor or to any particular rival of his. Indeed, it is not infrequent that the inventor is not himself called as a witness in a patent action. That, however, does not rule out evidence as to how the problems were in fact approached at the relevant time by the patentee, by his rivals, or by others. What they did may provide significant signposts leading to the answer to the objective test.

78. *General Tire v Firestone*, *supra* note 77 at pp. 497–498; *Hallen v Brabantia*, *supra* note 75.
79. *Johns-Manville Corporation's Patent* (EW CA, 1967) , *Reports on Patent, Design, and Trade Mark Cases* 479 at pp. 493-494. Per Lord Diplock:

> I have endeavoured to refrain from coining a definition of 'obviousness' which counsel may be tempted to cite in subsequent cases relating to different types of claims. Patent law can too easily be bedevilled by linguistics, and the citation of a plethora of cases about other inventions of different kinds. The correctness of a decision upon an issue of obviousness does not depend upon whether or not the decider has paraphrased the words of the Act in some particular verbal formula. I doubt whether there is any verbal formula which is appropriate to all classes of claims. (Emphasis added)

See also Lord Diplock in *Catnic v Hill and Smith* (UK HL, 1980), 1982 *Reports on Patent, Design, and Trade Mark Cases* 183 at p. 243: warning against "the kind of meticulous verbal analysis which lawyers are too often tempted by their training to indulge" and stating further that "pedantry and patents are incompatible."

held that the obviousness provision of the relevant patent legislation[80] requires courts to make a finding of fact as to what was, at the priority date, included in the state of the art and then to find again as a fact whether, having regard to that state of the art, the alleged inventive step would be obvious to the relevant PHOSITA.[81] Hence, the determinative issue is not whether testing is routine or workshop in nature, or whether more than a scintilla of invention has been exercised, but whether the PHOSITA would be led directly and without difficulty to the invention.[82] The court is obliged to determine whether the invention, including any steps taken to get there from the perspective of the PHOSITA, is obvious in light of the prior art.[83]

Codification of the obviousness requirement in the United States had a similar effect,[84] underscoring the analysis of whether or not the step taken towards the invention was inventive in nature from the perspective of the PHOSITA rather than focusing on judicial interpretation of narrow phrases such as whether or not the invention manifested a "flash of genius." This includes the recent rejection by the US Supreme Court in *KSR* of the Federal Circuit's narrow TSM test in favour of the broader "functional and flexible" contextual approach laid out by the court previously in *Graham*. However, as underscored in *Bayer*,[85] unlike their English and American counterparts, Canadian courts have *not* assumed the mantle of an objective evidence-driven and contextual test from the perspective of the PHOSITA, notwithstanding codification of obviousness in 1996.[86]

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80. *Patents Act* 1977 ch. 37, <http://www.statutelaw.gov.uk/legResults.aspx?LegType=All%20Primary&PageNumber=2&BrowseLetter=P&NavFrom=1&activeTextDocId=1344006>at s. 3 defines inventiveness (following Article 56 of the *European Patent Convention 2000 (EPC 2000* (as adopted by decision of the Administrative Council of 28 June 2001), <http://documents.epo.org/projects/babylon/eponet.nsf/0/0A16F3934268E871C12572BC00597957/$File/special_edition_1_epc_2000.pdf#page=7>):"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…."
81. For example, in *Pharmacia Corp. v Merck & Co. Inc.*(EW CA, 2002) 2002 *Reports on Patent, Design, and Trade Mark Cases* 775 at para. 818, it was stated that "all courses of action which present themselves without the exercise of invention are obvious." *Brugger v Medicaid*, 1996 *Reports on Patent, Design, and Trade Mark Cases* 635.
82. *Beecham*, *supra* note 13; *Beloit*, *supra* note 15 at p. 294.
83. Per Lord Aldous, in *Pharmacia Corporation & Ors v Merck & Co Inc & Anor,* 2001 EWCA Civ 1610, <http://www.bailii.org/ew/cases/EWCA/Civ/2001/1610.html> at para. 124:

> A step from the prior art, albeit made without reason, can still be obvious. The [trial] judge categorises such as step as workshop modifications and, in so doing, introduces a test not in the statute, namely whether the step from the prior art was a workshop modification. The statutory test is obviousness and any modification which is obvious will not be patentable, whereas one which is not obvious will be. The true test, as made clear in *Windsurfing*, is to ask whether the invention was obvious. Whether or not there is a reason for taking the step from the prior art may well be an important consideration, but that does not mean that it is an essential requirement of a conclusion of obviousness. In any case the [trial] judge in these proceedings did consider whether there was a reason for taking the step from the prior art and concluded that there was, namely a natural desire to investigate the analogs and the structural activity relationship of such compounds.

84. *Graham*, *supra* note 7 at pp. 691–692, where the court described the phrase "flash of creative genius" as a "rhetorical embellishment of language going back to 1833." See also *Cuno*, *supra* note 35.
85. *Bayer (ON CJ)*, *supra* note 16 at p. 80.
86. *Canamould Extrusions Ltd. v Driangle Inc.,* 2003 FCT 244, <http://decisions.fct-cf.gc.ca/en/2003/2003fct244/2003fct244.html> at para. 61; Roger T Hughes and John H Woodley, *Hughes & Woodley on Patents*, 2d ed. (Butterworths, 2005) at s. 12.

2.4. Summary

From the above, it is apparent that there is no clear consensus in Canadian case law regarding several key points in the obviousness analysis as they relate to the issue of testing and the creative capacity of the PHOSITA in the *post hoc* obviousness analysis. The cases reviewed demonstrate that this is true notwithstanding that *Beloit* is often described as the "accepted approach to obviousness" in Canada. The first area of confusion is whether or not there is a legally legitimate prohibition against testing in the lead-up to invention. This has been expressed in the case law either as Fox's "per se" prohibition against *any* serious thought, research or experimentation or based on the ground that the PHOSITA cannot exercise even a mere scintilla of inventiveness in his or her contemplation of the problem before them. The answer to this question in turn informs several "binary" (all or nothing) determinations relating to obviousness such as whether the PHOSITA may properly consider routine, work-shop or otherwise "ordinary" testing in the lead up to invention, whether the PHOSITA may properly consider the impugned invention "obvious to try," and whether in his or her determination on obviousness the PHOSITA "would have" v. "could have" arrived at the invention. As discussed below, it is proposed that all of these questions revolve around judicial misconceptions regarding the normative identity and inventive capacity of actual persons skilled in the relevant art—in this case, that of research and product development in the medical sciences.

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3. WHO IS THE PHOSITA?

3.1. Normative Construction

3.1.1. Introduction

THE BINARY APPROACH TO OBVIOUSNESS taken by Canadian courts encompasses notions of testing/no testing, scintilla/no scintilla of inventiveness, whether the PHOSITA did/did not consider the invention "worth a try," and whether he or she would/could have arrived at the invention. It is argued here and elsewhere[87] that binary propositions of this nature not only marginalize the PHOSITA in the obviousness analysis but result in a test that is inherently and thus unfairly biased towards patentees. An important outcome of this situation, as recently argued before the Federal Court of Appeal,[88] is that it strips the notational skilled

87. Bouchard, "Scientific Research," *supra* note 4. Use of the term "marginalization" of the PHOSITA in the context of obviousness was coined by Eisenberg, "Obvious to Whom?" *supra* note 14.

88. Appellant's Factum at paras. 4, 36, 47, submission to *Apotex Inc. v Sanofi-Synthelabo Canada Inc.*, 2006 FCA 421,<http://decisions.fca-caf.gc.ca/en/2006/2006fca421/2006fca421.html>. As noted in the factum (at para. 36), in the pharmaceutical field workshop-type testing would include, but not be limited to synthesizing compounds using known techniques, making salts and formulations, and ascertaining the properties of such compounds and formulations through ordinary testing: *SmithKline,(FCA), supra* note 64 at paras. 17–21; *ApotexInc. v Merck & Co. Inc. et al.* (CAN Fed CA,1995), 60 *Canadian Patent Reporter, 3d ser.* 556; *Mobil Oil Corp v Hercules Canada Inc.* (CAN Fed CA, 1995), 63 *Canadian Patent Reporter, 3d ser.* 473. pp. 484 – 486; *Airseal Controls Inc. v M & I Heat Transfer Products* (FC TD, 1993), 53 *Canadian Patent Reporter, 3d ser.* 259 at p. 274; affirmed (FC CA, 1997) 77 *Canadian Patent Reporter, 3d ser.* 126; *Stonehouse v Batco Manufacturing Ltd.* (FC TD, 2004), 38 *Canadian Patent Reporter, 4th ser.* 105, para 143; *Commissioner of Patents v Farbwerke Hoechst* (CAN SC, 1963), 41 *Canadian Patent Reporter,* 9 at pp. 13–14; *Bayer Inc. v Canada* (FC TD, 1998), 82 *Canadian Patent Reporter, 3d ser.* 359, paras. 27–28; affirmed (CAN Fed CA, 2000), 6 *Canadian Patent Reporter, 4th ser.* 285.

technician of the ability to conduct routine testing or other workshop-type activities in a manner that would never occur in reality.[89] This contravenes section 28.3 of the Act, which explicitly states that the determination of obviousness is to be made through the lens of the PHOSITA contextually and in an evidenced-based manner (at the time of the claim date and in light of all relevant prior art) not by the judiciary on narrowly defined grounds. Over time, and particularly in the context of pharmaceutical litigation before the Federal Court of Canada, the test for obviousness has become progressively more rigid, subjective and less evidence-based compared with other jurisdictions with similar statutory and common law obviousness requirements. Concerns over the impact of a rigid test for obviousness innovation in technology-intensive industries have been expressed frequently in the United States,[90] culminating in the recent decision by the United States Supreme Court directly on point in *KSR*.[91]

The primary cause for marginalization of the skilled technician in Canada is the insistence by many courts that the PHOSITA cannot bring even a mere scintilla of inventiveness to the analysis of the impugned invention. This creates two substantial and interrelated legal problems. That is, neither persons skilled in the art at the time of the invention nor those acting as experts in the *post-hoc* obviousness analysis are devoid of inventive capacity. If this were true, how could either PHOSITA be a proper benchmark for the obviousness analysis as required by the Act? This would be particularly troubling where the descriptive and prescriptive norms of pharmaceutical research and development support rather than refute the notion that the PHOSITA employs more than a *de minimus* level of inventiveness in their professional activities. Consequently, while the notational or mythical technician was created to render the test for obviousness (and other issues in patent litigation, including anticipation, utility, enablement, sound prediction, ambiguity, lack of novelty, improper subject matter, and claims broader than disclosure) objective rather than subjective, a legal fiction of this type cannot be workable when it does not, indeed *can not*, represent the average, or "ordinary" technician. At best it is a hybrid objective-subjective metric. This raises the question of who is the ordinary PHOSITA in the pharmaceutical industry and what are the norms governing their behaviour that relate to the issue of obviousness?

Critical to understanding how the PHOSITA in pharmaceutical research and development would arrive at an invention is the nature of the tacit and focal knowledge in the art.[92] As noted by Snider J in a case involving crystalline forms of azithromycin,[93] pharmaceutical companies are sophisticated multinational firms, capable of rapidly and efficiently conducting all necessary research relating

89. *Apotex Inc. v Sanofi-Synthelabo Canada Inc.*, 2006 FCA 421, <http://decisions.fca-caf.gc.ca/en/2006/2006fca421/2006fca421.html>, affirming *Sanofi-Synthelabo Canada Inc. v Apotex Inc.*, 2005 FC 390, <http://decisions.fct-cf.gc.ca/en/2005/2005fc390/2005fc390.html>.
90. See for example, Lunney, "E-obviousness," *supra* note 14; Eisenberg, "Obvious to Whom?", *supra* note 14; Burk and Lemley, "Biotechnology," *supra* note 14.; United States Solicitor General *KSR* Brief and IP Law Professors *KSR* Brief, *supra* note 41.
91. The decision of the United States Supreme Court in *KSR v Teleflex*, *supra* note 41, was rendered at the time this article went to press.
92. Polanyi, *supra* note 23. A more full discussion of tacit and focal knowledge with regards to obviousness is found in Part 3.1.3 below.
93. *Pfizer Canada Inc. v Apotex Inc.,* 2003 FC 1428, <http://decisions.fct-cf.gc.ca/en/2004/2003fc1428/2003fc1428.html> at para. 30.

to the rational design, medical chemistry, formulation, dosage forms, manufacturing, and storage of pharmaceutical products. Indeed, David Wolfe and colleagues[94] proposed in the context of innovation clusters that the life sciences industry is heavily dependent on forms of knowledge they refer to as synthetic and analytical knowledge. "Synthetic knowledge" is knowledge directed to finding technical solutions to specific problems, and is particularly important for product development. "Analytical knowledge" refers to intellectual skills underpinning analysing and synthesizing information, for example, those required for constructing rational and/or cognitive models. As discussed in detail below, Wolfe's articulation of knowledge forms in the life sciences encompasses and is informed by the concepts of tacit and focal knowledge described earlier by Polanyi and is highly relevant to a purposive analysis of obviousness. Applied to the issue at hand, a deeper understanding of the nature of the types of knowledge possessed, applied, advanced and *ingrained within* the skilled technician would suggest that the normative pharmaceutical PHOSITA is highly creative, intuitive and discovery-oriented. This can be contrasted to the Canadian legal fiction of persons skilled in the art, who possess not even a "mere scintilla" of inventiveness. Unfortunately, while the nature, scope and depth of knowledge forms used by relevant persons skilled in the art have been understood within the pharmaceutical industry for years, very few judges, particularly at the appellate level, positioned on the outside of the art have made an effort to understand the normative nature of the "persons," "skills," or "art" in the context of pharmaceutical litigation.

There has been much written on "law and norms," and a detailed analysis of this topic is beyond the scope of this paper. I will confine my comments to literature aimed at understanding scientific norms as they apply to biomedical patenting and litigation.[95] In fact there is precious little scholarly work aimed at the pharmaceutical PHOSITA, let alone scientific norms in this industry. This is because most recent law and norms work has focused on the relatively new field of biotechnology and the role therein of intellectual property and regulatory rights. Nowhere is this more true than the debate in the United States, where Vanevar Bush's ground-breaking *Science: The Endless Frontier*[96] privileged university-based scientific research as never before and where investments in basic research were later translated for the first time *en masse* into the commercialization sphere via the *Bayh-Dole Act*[97]and *Stevenson-Wydler Act*[98] of

94. David A Wolfe, Charles H Davis, and Matthew Lucas, "Global Networks and Local Linkages: An Introduction," in David A Wolfe and Matthew Lucas, eds., *Global Networks and Local Linkages: The Paradox of Cluster Development in an Open Economy* (McGill-Queens' University Press, 2005) at pp. 8–9.
95. Rebecca S Eisenberg, "Proprietary Rights and the Norms of Science in Biotechnology Research," (1987) 97:2 *Yale Law Journal* 177–231; Arti Kaur Rai, "Regulating Scientific Research: Intellectual Property Rights and the Norms of Science." (1999) 94:1 *Northwestern University Law Review* 77–152, <http://ssrn.com/abstract=172032>; see also Anita Varma and David Abraham, "DNA is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market," (1996) 9:1 *Harvard Journal of Law and Technology* 53, <http://jolt.law.harvard.edu/articles/pdf/v09/09HarvJLTech053.pdf>; and Lunney, "E-Obviousness," *supra* note 14; Eisenberg, "Obvious to Whom?", *supra* note 14; Burk and Lemley "Biotechnology," *supra* note 14.
96. Vannevar Bush, *Science: The Endless Frontier*, Report (Government Printing Office, 1945), <http://www1.umn.edu/scitech/VBush1945.html>.
97. *Bayh-Dole Act*, (2000) 35 *United States Code* ss. 200–212, <http://www.access.gpo.gov/uscode/title35/partii_chapter18_.html>. The stated purpose of the Act (s. 200) is to "use the patent system to promote the utilization of inventions arising from federally-funded research or development…."
98. *Stevenson-Wydler Technology Innovation Act*, (2000) 15 *United States Code* ss. 3701-3712, <http://www.access.gpo.gov/uscode/title15/chapter63_.html>.

1980, the establishment of the patent-specific Court of Appeals for the Federal Circuit in 1982[99] and the 1980 United States Supreme Court decision in *Chakrabarty.*[100] Indeed it has been claimed that together these legal events are responsible for underwriting the global biotechnology boom.[101]

Scientific norms may refer to either observed behaviours engaged in by the scientific community towards scientific discovery or other private behaviours engaged in out of a sense of commitment and communal understanding of how scientists should approach certain types of problems.[102] As such, scientific norms can be both descriptive and prescriptive.[103] This is relevant to the present work in so far as descriptive and prescriptive norms are strongly interrelated and influence not only how norms are perceived within science but also how they are used by other fields of knowledge such as law. For example, descriptive norms operate to make scientists responsive to prescriptive norms and *vice versa,*[104] but can also serve as a motor for the evolution of prescriptive norms as the rules of the game change. Norms apply equally to individuals and industrial sectors, both of which benefit by a uniform base of tacit and focal knowledge as well as the resulting knowledge spillovers. These considerations are particularly important to biomedical research, including that conducted in university and hospital labs, technology clusters, and more conventional industrial sectors, as both sets of norms have evolved substantially following what Ravetz referred to as "the industrialization of science."[105] The issue is complicated further in the North America pharmaceutical context, where patent rights associated with product development are protected under the umbrella of so-called linkage regimes rather than through conventional patent infringement and validity provisions. For these reasons, descriptive and prescriptive norms can be legitimately collapsed into a single category for the purpose of the obviousness analysis, as both relate to the *identity* and inventive *capacity* of the PHOSITA and thus the "person" and "skills" relevant to section 28.3 of the Act.

Scientific norms up to the time of the biotechnology revolution have been described in detail by, among others, Barber, Kuhn, Hagstrom, and

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99. The United States Court of Appeals for the Federal Circuit was established under Article III of the United States Constitution on 1 October 1982: *Federal Courts Improvement Act* 1982, (2000) 28 *United States Code* ss.41–49, <http://www.access.gpo.gov/uscode/title28/parti_chapter3_.html>.
100. *Diamond v Chakrabarty* (US SC, 1980), <http://supreme.justia.com/us/447/303/case.html>, 447 *United States Reports* 303.
101. Sheila Jasanoff, "The Life Sciences and the Rule of Law," (2002) 319 *Journal of Molecular Biology* 891–899 at p. 893.
102. Rai, "Regulating Scientific Research," *supra* note 95 at p. 6, notes 15, 16.
103. Eisenberg, "Proprietary Rights," *supra* note 95; Rai, "Regulating Scientific Research," *supra* note 95; F Scott Kieff, "Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science—A Response To Rai and Eisenberg," (2001) 95:2 *Northwestern University Law Review* 691–705, <http://ssrn.com/abstract=240955>.
104. Robert C Ellickson, "Law and Economics Discovers Social Norms," (1998) 27:2 *Journal of Legal Studies* 537–552; Kieff, "Facilitating Scientific Research," *supra* note 103.
105. Jerome T Ravetz, *Scientific Knowledge and Its Social Problems* at p. 245 (Transaction Publishers, 1995).

Merton,[106] with particular attention being paid to the norms of universalism, communalism, disinterestedness and organized scepticism. In her analysis of how increased emphasis on commercialization impacts scientific norms following establishment of the biotechnology sector, Eisenberg[107] suggested that heavy emphasis on patentability in biological research can frustrate these norms and cause disharmony by "commercializing" the scientific community.[108] Nevertheless, while some legal commentators and scientists have cast a skeptical eye on the push by many national governments towards an emphasis on technology transfer and translational research, it appears that a strong focus by the global medical research enterprise on commercialization is here to stay. Rai[109] discussed two other norms relevant to the obviousness enquiry: independence and invention.[110] As discussed in detail below, the norms of independence and inventiveness are fundamental to the identity and inherent inventive capacity of a normative PHOSITA embedded within the current global pharmaceutical innovation ecology.

While it has been argued that the biotechnology industry will converge and eventually merge with its older multinational pharmaceutical sibling,[111] there

106. Bernard Barber, *Science and the Social Order* (Collier Books, 1953); Thomas Kuhn, *The Structure of Scientific Revolutions* (Chicago University Press, 1962); Warren O Hagstrom, *The Scientific Community* (Southern Illinois University Press, 1965); Robert K Merton, *The Sociology of Science: Theoretical and Empirical Investigations* (Chicago University Press, 1973). As noted by Kieff, *supra* note 103 at p. 693:

> Universalism means that the veracity of claimed scientific observations should be determined by universal criteria without regard to the particular attributes of the claimant, such as reputation, institutional affiliation, or nationality. Communalism means that scientific advances should be product of the community and for the benefit of the community. Disinterestedness means that scientific effort should be expended for the purpose of seeking generally applicable scientific truth, rather than some personal interest. Organized skepticism means that claimed scientific observations should be subject to empirical scrutiny.

107. Eisenberg, "Proprietary Rights," *supra* note 95 at p. 194.
108. See also, Donald Stokes, "Completing the Bush Model: Pasteur's Quadrant," presented at *Science the Endless Frontier 1945–95: Learning from the Past, Designing for the Future* (Center for Science, Policy, and Outcomes, Columbia University, New York, 9 December 1994), <http://www.cspo.org/products/conferences/bush/Stokes.pdf>at p. 9; Nicholas S Argyres and Julia Porter Liebeskind, "Privatizing the Intellectual Commons: Universities and the Commercialization of Biotechnology," (1998) 35 *Journal of Economic Behaviour and Organization* 427–454; RR Nelson, "The Advance of Technology and the Scientific Common," (2003) 361 *Philosophical Transactions of the Royal Society of London* 1691–1708.; Arti Kaur Rai and Rebecca S Eisenberg, "Bayh-Dole Reform and the Progress of Biomedicine,"(2003) 66:1–2 *Law and Contemporary Problems* 298–314, <http://www.law.duke.edu/shell/cite.pl?66+Law+&+Contemp.+Probs.+289+(WinterSpring+2003)>;. Royal Society Working Group on Intellectual Property, "Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science," (2003), <http://www.royalsoc.ac.uk/displaypagedoc.asp?id=11403> at pp. 1–38; Adame B Jaffe and Josh Lerner, *Innovation and its Discontents: How our Broken Patent System is Endangering Innovation and Progress, and What to do About It* (Princeton University Press, 2004); David J Triggle, "Patenting the Sun: Enclosing the Scientific Commons and Transforming the University—Ethical Concerns," (2005) 63:3 *Drug Development Research* 139–149; Sarah Boettiger and Alan B Bennett "Bayh-Dole: If We Knew Then What We Know Now," (2006) 24:3 *Nature and Biotechnology* 320–323.
109. Rai, "Proprietary Rights," *supra* note 95 at p. 17.
110. Rai, "Proprietary Rights," *supra* note 95 at pp. 17–24; see also Kieff, "Facilitating Scientific Research," *supra* note 103 at p. 693: "Independence means that scientists should be 'free to set their own research agendas and criticize the work of others.' Invention means that scientists should 'make original contributions to the common stock of knowledge.'"
111. "Small is beautiful for biotech bellwethers," (12 January 2004) *Drug Researcher.com*, <http://www.drugresearcher.com/news/ng.asp?id=48975-small-is-beautiful>; "'Big Pharma' Turns to Biologics for Growth to 2010: Financial and strategic segmentation of the 'Big Pharma' sector by drug technology," (4 May 2006) *Datamonitor Report*, <http://www.the-infoshop.com/study/dc38343-big-pharma.html>; Adis International Limited, "Billion Dollar Baby: Convergence Between Biotech and Pharma May Lead To Integrated Sector," (May 2005) 3:6 *Pharmaceutical & Diagnostic Innovation* 3–5; John Rhodes, "Convergence of Opportunities and Interests in Pharmaceuticals and Biotechnology," Report, (May 2006) , <http://www.deloitte.com/dtt/article/0,1002,sid%3D2218%26cid%3D115931,00.html>; Lisa M Jarvis, "Losing Their Religion: Biotechs Take a More 'Agnostic Approach' to Drug Discovery by Expanding Into Small Molecules," (30 October 2006) 84:44 *Chemical and Engineering* News 14–20, <http://pubs.acs.org/cen/coverstory/84/8444cover.html>; Trevor Stokes, "Small Molecule Drugs: Avoiding Roadblocks in Development," (1 November 2006) 26:19 *Genetic Engineering News*, <http://www.genengnews.com/articles/chitem.aspx?aid=1934>; Michael Bernstein, "Biotechs Expand Into Small Molecules For Drug Discovery," (November 3, 2006*) Medical News Today*, <http://www.medicalnewstoday.com/medicalnews.php?newsid=55491>.

remain significant patenting issues affecting pharmaceutical norms that are unique to the industry. As noted above, this situation comes about in North America largely due to linkage regulations governing the regulatory approval, marketing and patenting of drugs. Canada's linkage regulations are coupled with the drug approval through operation of the *Food and Drugs Act* and associated regulations.[112] Prior to the NOC Regulations coming into force, the regulatory systems for drug approval, marketing and patenting were kept distinct and separate.[113] The NOC Regulations came in at the time Canada's compulsory licensing provisions were repealed, and were based in both substance and procedure on analogous legislation in the United States known as the *Hatch Waxman Act*.[114] To date Canada and the United States are the only two jurisdictions with this type of hybrid intellectual property-regulatory regime.

Under the NOC Regulations, parties are allowed to list unlimited patents on a patent register, provided they are relevant to an already marketed product.[115] When a party wishes to contest that product, it must prove in a judicial review proceeding that each patent listed on the register is either not infringed or invalid.[116] This has led to evergreening[117] of the original patented product through a proliferation of line extension patents under circumstances where the original patent on the new chemical entity has expired, leading to the charge that innovation in the pharmaceutical sector has stagnated.[118] While significant and persistent concern has been expressed over the public health and economic consequences of evergreening, Justice Binnie noted in *AstraZeneca*[119] that it "is entirely understandable" that brand-name pharmaceutical firms avail themselves of NOC Regulations allowing evergreening by "adding bells and whistles to a pioneering product" after the original patent has expired. As will be

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112. *Food and Drugs Act, supra* note 5; *Food and Drug Regulations, supra* note 5; Gunar K Gaikis, "Pharmaceutical Patents in Canada: An Update on Compulsory Licensing," (1992) 42 *Patent World* 19; Edward Hore, "A Comparison of United States and Canadian Laws as they Affect Generic Pharmaceutical Drug Entry," (1992) 55 *Food and Drug Law Journal* 373; Donald G McFetridge, "Intellectual Property Rights and the Location of Innovative Activity: The Canadian experience with Compulsory Licensing of Patented Pharmaceuticals,"working paper, (1997) *National Bureau of Economic Research Summer Institute*; Andrew A Caffrey, III and Jonathan M Rotter, "Consumer Protection, patents and Procedure: Generic Drug Market Entry and the Need to Reform Hatch-Waxman," (2004) 9:1 *Virginia Journal of Law and Technology* 1–44, <http://www.vjolt.net/vol9/issue1/v9i1_a01-Caffrey.pdf>.
113. *AstraZeneca*, *supra* note 5 at para. 12.
114. *Drug Price Competition and Patent Restoration Act 1984*, (2000) 21 *United States Code* s. 355, <http://www.access.gpo.gov/uscode/title21/chapter9_subchapterv_parta_.html>, commonly known as *Hatch Waxman*.
115. *NOC Regulations*, *supra* note 3 at ss. 3, 4; *Regulatory Impact Analysis Statement: Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*, (2006) 140:24 *Canada Gazette*.
116. *NOC Regulations*, *supra* note 3 at s. 5.
117. "Evergreening" refers to undue extension of the statutory monopoly attached to drug product by means of listing on the patent register multiple patents with obvious or uninventive modifications. Under such circumstances, the patentee prolongs its monopoly beyond what the public has agreed to pay: *Whirlpool*, *supra* note 7 at para. 37; *Bristol-Myers Squibb Co. v Canada (Attorney General)*, 2005 SCC 26, <http://scc.lexum.umontreal.ca/en/2005/2005scc26/2005scc26.html> , 2005:1 *Supreme Court Reports* 533 at para. 66 [*Bristol-Myers Squibb Co (SCC)*]; *AstraZeneca*, *supra* note 5 at para. 39. According to the Roy J Romanow, *Building on Values: The Future of Health Care in Canada*, Final Report (2002), <http://www.hc-sc.gc.ca/english/pdf/romanow/pdfs/HCC_Final_Report.pdf> at pp. 208-209, 253 [Romanow Report]:

    > A particular concern with current pharmaceutical industry practice is the process of "evergreening," where manufacturers of brand name drugs make variations to existing drugs in order to extend their patent coverage. This delays the ability of generic manufacturers to develop cheaper products for the marketplace and it is a questionable outcome of Canada's patent law.

118. Romanow Report, *supra* note 117, as discussed in detail in Part 5, below. See also note 251 *infra* and accompanying text.
119. *AstraZeneca*, *supra* note 5, para. 39.

discussed in Part 6 below, considerably less inventive ingenuity and innovative activity are required to derive line extension and me too patents as opposed to those on truly breakthrough products. Analogous concerns have been expressed in the United States where the regime originated.[120] Thus, the issue of inventiveness in the pharmaceutical industry has important implications not only for the PHOSITA in the legal analysis of obviousness, but also more broadly for North American patent policy and its effects on domestic and international innovation policies, competition between brand-name and generic pharmaceutical firms, and access to affordable drugs for consumers.

Finally, the issue of the identity and inventive capacity of the PHOSITA is a particularly important consideration for the legal legitimacy of the obviousness test. As stated by the Supreme Court in *Whirlpool,*[121] a patent is to be interpreted by persons skilled in the art in possession of knowledge that is incidental to that particular trade. "Rocket science patents may only be comprehensible to rocket scientists."[122] The actual skills possessed by such persons, and the capacity to use them in the context of practicing the relevant art, are normative in that they are contingent not only on norms reflecting the broad project of science but also as they are parsed relative to the more narrow subject matter of the patent at issue and how the courts should interpret these skills legally. The question arises therefore as to whether the cases standing for the proposition that no testing can be done on the road to invention under the obviousness attack or that the PHOSITA should possess not even a scintilla of inventiveness adequately reflect these norms. It is submitted that much of the confusion in the cases reviewed stems from a lack of judicial understanding regarding the nature of the scientific endeavor generally, and the specific manner in which a typical PHOSITA in the global pharmaceutical sector would approach the project of drug development. For the sake of simplicity the terms "persons" "skilled" in the "art" will be dealt with in reverse order.

3.1.2. The "Art"

The art at issue is that which begins with pharmaceutical sciences, extended to the context of commercial drug development under the auspices of relevant regulatory authorities. The point of departure for an analysis of a person skilled in the art of pharmaceutical sciences is therefore the discipline known as pharmacology. Pharmacology encompasses all of the basic and medical sciences pertaining to drugs, and in particular how specific chemical substances interact with both healthy and non-healthy living systems and tissues. When substances of this type have medicinal properties they are called pharmaceuticals, or drugs. Drugs are often referred to as small molecule therapeutics in that they typically

120. See, for example, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (United States Federal Trade Commission, 2002), <www.ftc.gov/os/2002/07/genericdrugstudy.pdf>; Caffrey and Rotter, "Consumer protection, Patents and Procedure," *supra* note 112. Ironically, following the FTC study in the United States, President Bush made significant procedural amendments to Hatch Waxman such that only one automatic stay is allowed per drug. Canada has not followed suit despite similar calls for amendment to the NOC Regulations for the same reasons.
121. *Whirlpool*, *supra* note 7 at para. 70.
122. *Whirlpool*, *supra* note 7 at para. 71, citing Dickson J in *Consolboard*, *infra* note 200.

comprise small molecular weight entities with discrete agonist (stimulant) or antagonist (inhibitory) properties at specific receptors or other molecular targets.

The field of pharmaceuticals is broad; it encompasses the interaction of chemical substances (organic, medicinal and biochemical) in the context of normal bodily functions (physiology) and various disease states (pathosphysiology). It also encompasses the detailed pharmaceutical sciences of drug composition, properties, metabolism, formulation, interactions, safety, efficacy, toxicology, as well as the various uses of such compounds in the therapy of disease. Each of these disciplines typically warrants an entire department within a Faculty of Medicine or research institute, and is the subject of numerous textbooks and literature aimed variously at undergraduate, graduate and postgraduate level audiences. Biomedical products can be at the level of small molecules such as for pharmaceutical inventions or can also include biotechnological inventions, which refer to technological applications that use biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use. For the purposes of the present discussion only the former is assumed, though there are obvious parallels to biotechnology and other life sciences litigation.

When the issue of legally constructing relevant persons skilled in the art in the context of drug patents arises, the case law typically focuses on the complexity of pharmaceutical sciences. However, there is a critical difference between persons skilled in the art of *any* patentable subject matter and one working in the pharmaceutical sciences from a rent-seeking global drug development perspective where intellectual property and regulatory rights are seen to be paramount and to drive drug development activities. In an international environment where property and regulatory rights, political lobbying, and drug marketing are a multi-jurisdictional effort, there can be no question that the commercial and regulatory path to drug development is relevant to understanding the knowledge base and best practices of persons skilled in the art of pharmaceutical research. For courts to avoid this level of factual sophistication when construing patents amounts to blind justice.

As a potential drug candidate nears the clinical trial phase, the technology evolves from that which is diffuse and unfocussed to that which is discrete and targeted, and thus comes within the regulatory reach of governments through the application of relevant food and drugs legislation and regulations. Regulation of pharmaceuticals in Canada begins when a New Drug Submission is made under the *Food and Drugs Act* and associated regulations.[123] In addition to regulatory approval, drug candidates are typically subject to patent protection through the provisions of patent legislation and data and marketing exclusivity through operation of the *Food and Drugs Act* and regulations. As noted above, the nexus connecting drug approval to patent protection is extended further in Canada through operation of the NOC Regulations, which specifically allow for relatively simple changes to drug formulation through the Supplementary New Drug Submission process, which nevertheless can significantly extend market monpolies on drugs that otherwise would have come off patent protection.[124]

123. Trudo Lemmens and Ron A Bouchard, "Regulation of Pharmaceuticals in Canada," in Jocelyn Downie, Timothy Caulfield, and Colleen M Flood, eds., *Canadian Health Law and Policy,* 3d ed. (Butterworths, 2007) 318–387, <http://ssrn.com/abstract=958929>.

124. Lemmens and Bouchard, "Regulation of Pharmaceuticals in Canada," *supra* note 123.

Consequently, contemporary industrial drug development is grounded in the fundamentals of science, law, policy and economics. It is therefore not surprising that the number of activities related to drug discovery taught to undergraduate, graduate and professional audiences has expanded over the years beyond the more conventional specialties such as clinical pharmacology, medicine and epidemiology to include patent law, regulatory affairs, international regulation, marketing, competitive intelligence, finance and pharmacoeconomics.[125]

Based on the discussion above it is reasonable to say that decisions regarding a firm's global drug development efforts (also referred to as a drug's "therapeutic product profile" or "therapeutic product development") are not made based on scientific considerations alone. A therapeutic product profile is a function of commercial market research into unmet needs, competitive intelligence, therapeutic strategies and scientific development and opportunities.[126] Each of these broad categories is deliberated before and during the entire drug development cycle. Only if a drug is seen to offer an efficient and effective competitive advantage over other existing products or those in development elsewhere does development proceed through completion of clinical trials. As such, the drug development process involves numerous levels of business decisions that hinge on issues as diverse as patent and regulatory strategies, market attractiveness, competitive intelligence, risk-benefit analyses and strength weakness opportunity threat (SWOT) analyses, as well as other corporate considerations relating to commercialization and marketing of drugs. Thus, while the pharmaceutical sciences should and do dominate the analysis of the "art" in which persons are skilled, the art encompassed by the obviousness analysis is complex, sophisticated and extends well beyond considerations of scientific and therapeutic advantages and characteristics of a potential drug candidate. As discussed below, if one wants to look to how scientific truths became that way, one needs to look far beyond the bench scientists, not only to unpack how opinion is converted into scientific fact, but also to understand *who* those at the bench are, *what* they do, and *why* they do it.

3.1.3. The "Skills"

The next component of the term at hand represents the "skills" of the PHOSITA. These are assumed to encompass the basket of cognitive and physical proficiencies, facilities, and dexterities acquired and/or developed by persons skilled in the art through training and experience relevant to the scientific, medical, marketing, intellectual property, regulatory and business issues relevant to commercialization of biomedical products.

I will use as a template for analysis the concept of tacit and focal knowledge first put forward by the scientist and philosopher Michael Polanyi.[127] One of the most important elements of Polanyi's body of work for the present

125. For example, see William Wardell, Susan Toland, and Anthony W Fox "What Pharmaceutical Medicine Is and Who Does It," in Andrew J Fletcher, Lionel D Edwards, Anthony W Fox, and Peter Stonier, eds. *Principles and Practice of Pharmaceutical Medicine* (John Wiley and Sons, 2002) 13–15 at p. 14.
126. Warren Kaplan and Richard Laing, "Priority Medicines for Europe and the World," Report, World Health Organization, Department of Essential Drugs and Medicines Policy, (November 2004), <http://mednet3.who.int/prioritymeds/report/final18october.pdf>.
127. Polanyi, *The Tacit Dimension*, *supra* note 22.

purposes is that while knowledge is generally assumed to be public, it is to a very great extent personal, and thus subject to a significant "tacit" dimension. This tacit dimension is the great filter through which all external, or focal, knowledge must pass in order to become useful in the world. For Polanyi, focal knowledge, or that knowledge about an object or phenomenon that is "in focus" in the objective realm, for example the knowledge that converting a particular drug from a neutral chemical form into a besylate acid addition salt will increase its bioavailability, must be converted to tacit personal knowledge in order to be used pragmatically as a tool to understand or improve on what is in focus. That which is tacit is complimentary to that which is focal, yet both can vary from one context to another, for example just because one besylate salt form is more bioavailable than its neutral form does not mean it is so for all drugs. From an obviousness perspective, the relevant information or knowledge about how to solve a particular pharmaceutical problem comprises traditional prior art sources such as textbooks, literature, conference proceedings but also more practical and intuitive details of how such information is put into practice in an actual laboratory and how that knowledge is passed on from one person to the next in a personal sense. Because tacit knowledge is transferred from one person to another rather than through focal vectors of communication such as books and journal articles, the accumulation and evolution of such knowledge is "personal" and thus is contingent on the cumulative and interactive cognitive processing abilities of all individuals composing the art.

Another element of Polanyi's thesis relevant to the present analysis is that knowledge is *applied*. The cognitive mechanisms by which those skilled in the art acquire and use knowledge are critical to the epistemological nature of that knowledge. Knowledge is not a static body of material waiting to be discovered. For Polanyi, knowledge is an activity best described as a "dynamic process of knowing." In this sense, the "facts" represented by focal knowledge are subsidiary to the PHOSITA's tacit understanding and application thereof. By applying the facts encompassed by the prior art, the PHOSITA necessarily emphasizes the functional aspect of knowledge through his or her normative tacit filter.

And what of the perceptual and analytical skills and capacity of the ordinary pharmaceutical scientist? The definition of science found in most encyclopedias refers not only to the knowledge possessed by a person skilled in the sciences but also the methods and processes by which scientific knowledge is formed. A scientist is a person whose profession is to *investigate* the natural sciences using such methods and processes. Therefore, science is both a particular kind of activity (verb) and the results of that activity (noun).

Generally speaking, from an intellectual processing perspective, a scientist represents a combination of traditional right and left brain skills, or functions, aimed at elucidating solutions to the problems before them. The contribution of each function will depend, to varying degrees in varying people at varying times, on the specific function the PHOSITA is fulfilling in their job description at the time. For example, scientists read the literature, think of experiments, conduct and analyze them. These skills aggregate into a statistical average comprising the "ordinary" level of skill in a given field. Scientists then

undertake many other activities related to this analysis such as contributing to various therapeutic product profiles, writing proposals, presenting data and other information to senior management, participating in scientific and corporate meetings, writing papers, patent applications and the like. The fact that such activities require not an insignificant level of skill(s) is evidenced by the fact that persons skilled in the art offering expert opinion before the court usually have a PhD, an MD or both. As anyone who has sought an expert in the context of pharmaceutical litigation knows it is rare for an expert to have qualifications other than at the terminal level of education plus 10-20 years of industry experience. Indeed, from the perspective of the obviousness analysis, a person skilled in the art is more often that not an entire team of such persons.[128]

On the one hand, the average PHOSITA will be trained to emphasize the logical, sequential, rational, and analytical functions of the brain when engaged in what could be called the "methodological phase of investigation." The methodological phase of investigation follows, though not exclusively so, the designing phase and precedes the analysis of data and may or may not involve troubleshooting difficulties, depending on the degree of creative input necessary to surmount technical problems. On the other hand, the PHOSITA also engages in a range of creative, intuitive, processing, and synthesizing functions, in what may be termed the "contemplative phase of investigation." The contemplative phase of investigation involves, though again not exclusively so, conceptualization of the problem at hand and analysis of which methods(s) might be best used to solve it. The contemplative phase of investigation would also include those intellectual perceptions and judgments brought to bear on choosing the best courses of action and interpretation in the context of, for example, trouble-shooting problems which arise during the methodological phase of investigation as well as intuitively understanding non-rational (serendipitous) experimental signs and signals relating to various forms of scientific observations. Central to the contemplative stage is that scientists are working within a context of ambiguity, where the focus is on creating new knowledge within a universe of potential solutions from which they must choose in order to move forward. The contemplative phase of investigation is process-oriented whereas the methodological phase of investigation is product-oriented. In light of the large amount of in-house firm research conducted by pharmaceutical firms and their ultimate goal to produce new products, clearly both are relevant to the pharmaceutical PHOSITA.

Emphasis is placed in this analysis on science as a creative and personal process, consistent with Polanyi's notion of tacit knowledge and the contemplative phase of investigation described above. The analysis therefore privileges the moment and process of individual decision-making as central to the activity of science. This is consistent with the etymology of science, where the latin *scire* refers to the act of deciding in order to arrive at *scientia*, or knowledge.[129]

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128. *Apotex v Hoffmann-La Roche*, *supra* note 29; *Canadian Industries Ltd. v Sherwin-Williams Co. of Canada* (CAN Exchequer Ct, 1946), 1946 *Exchequer Court of Canada Reports* 65; *Apotex v Wellcome (FCTD)*, *supra* note 28; *SmithKline Beecham Pharma Inc. et al. v Apotex and The Minister of Health*, 2001 FCT 770, <http://decisions.fct-cf.gc.ca/en/2001/2001fct770/2001fct770.html>, 2001:4 *Federal Court Reporter* 518 [*SmithKline (FCTD)*]; *Genentech*, *supra* note 34.
129. Eric Partridge, *Origins: A Short Etymological Dictionary of Modern English* (Routledge & Kegan Paul, 1966) at p. 594.

3.1.4. The "Person"

Finally, who is the relevant "person" skilled in the art? It is worthwhile to re-state here the so-called "classic test" for obviousness articulated by Hugessen JA in *Beloit v Valmet*:[130]

> 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.

As indicated by the passage above, there are but two perspectives in Canadian law from which to view a patent: that of an inventor and that of the PHOSITA. This interpretation constitutes an unfortunate proposition for purposes of the obviousness analysis: Inventors are inventive by nature while the inventor's contemporary, the PHOSITA, possess not even a mere scintilla of inventiveness. Thus, from a judicial perspective, persons relative to the analysis of a patent are either completely inventive (1) or not inventive at all (0). As there is no middle ground in this analysis, it constitutes a binary proposition. Following on the previous discussion of right and left brain functions, the PHOSITA is to be construed under Canadian law entirely in terms of their unilateral left brain function.

According to Canadian jurisprudence this split in intellectual function exists even though the mythical PHOSITA is called upon broadly to provide the lens for courts to analyse many aspects of patent law, including the doctrines of sound prediction, utility, enablement, anticipation and obviousness, which to varying degrees are representative of what may be seen as more traditional left-brain type or rational functions. In addition, the court asks our bifurcated PHOSITA to provide the benchmark for more ambiguous and less rational right-brain functions such as the doctrines of ambiguity, lack of inventiveness (novelty), improper subject matter and claims broader than disclosure. Indeed, one assumes that both patent counsel and the judiciary routinely use both left and right brain functions to analyse these issues in relation to questions of both law and fact.

In light of the importance of tacit knowledge in the pharmaceutical industry, with its emphasis on "knowing," intuition, process, and decision-making, it can be argued that the difference between the judicial construction of persons skilled in the art of pharmaceutical sciences and those who invent under identical circumstances is thin indeed and does not warrant the sharp binary dividing line between obviousness and non-obviousness. From a normative

130. *Beloit, supra* note 15 at pp. 294–298. See also *Whirlpool, supra* note 7 at para. 33.

perspective, these "persons" can easily be seen to be, and indeed often are, one and the same, with the same level of skill in the art and the same level of training, separated by an arbitrary wall. It is submitted that this arbitrary wall can not and *should* not be used to predict with any consistency or reliability whether an invention would, or for that matter could, be obvious. In this formulation, the knowing process is not a static linear accumulation of precise findings and results, but more of a dynamic trial and error process encompassing several starts and stops. All knowledge is accumulated by skilled technicians, along with the attendant personal risk, by venturing into the unknown.

This dilemma has not escaped judicial notice. Even in *Bayer*, representing the high watermark for the binary proposition in pharmaceutical litigation, Lederman J noted:

> *What seems paradoxical is that this hydra-headed technician is well-versed in the relevant sciences and yet totally unimaginative. It is difficult to think of such a person as a complete dullard.* Presumably this prompted John Bochnovic in a chapter entitled, "Invention Inventive Step/Obviousness" in *Patent Law of Canada* (Toronto: Carswell), to state (without the support of any judicial authority) at p. 48: "The suggestion that the skilled technician should be unimaginative should not strip that technician of the ability to pursue reasonable and logical inquiries."[131]

It is consistent with the creative nature of scientists working to advance knowledge in their field, whether dramatically or incrementally, to infer that the PHOSITA possesses more than a *de minimus* level of inventiveness. The statistically average PHOSITA may not possess the flowing torrent of inventiveness assumed by some judiciary to attach to theoretical inventors. Nevertheless, in technology-heavy sectors, the PHOSITA, by virtue of their job description, is in possession not only of a great deal of focal knowledge but also the *capacity* and *ability* to apply this knowledge aggressively in pursuit of advances in his or her art. Indeed, not only is the amount of knowledge possessed by the ordinary PHOSITA considerable, courts have said that such persons have a mind willing to understand solving the problem before them successfully.[132] This accords with the notion that the ability to make scientific decisions and exert judgement in pursuit of scientific knowledge in an environment characterized by ambiguity represents the fundamental essence of science. The *raison d'etre* of the typical scientist, pharmaceutical or otherwise, is to plan and conduct original experiments in an environment of uncertainty.[133] In other words, the base level of activity of an experimental scientist is to invent, *not* the opposite. This will be true no matter if the inventive act produces something completely novel or moves a field forward incrementally: the common denominator is one of invention or creation under conditions of ambiguity.

131. *Bayer (ON CJ)*, *supra* note 16 at p. 79 (emphasis added). John Bochnovic is a senior IP partner at the highly regarded firm of Smart & Biggar and, even at the time of his 1994 article, had more than 15 years experience in prosecuting and litigating intellectual property matters.
132. *Baldwin International Radio Co. of Canada v Western Electric Co.* (CAN SC, 1933), 1934 *Canada Law Reports: Supreme Court of Canada* 94; *Ernest Scragg*, *supra* note 42 at pp. 55–56; *Burton Parsons Chemicals*, *supra* note 11.
133. See discussion of the norms of science in Rai, "Regulating Scientific Research," *supra* note 95 at pp. 16–17.

Based on the above, to say that the PHOSITA can possess no scintilla of inventiveness is to say that a scientist cannot be a scientist. To impose a standard of no scintilla on a pharmaceutical scientist working in one of the largest, most sophisticated, profitable and competitive industries in the world is either completely irrational or simply far too low a rational standard when one constructs the nature of the PHOSITA in the relevant context.[134] Thus, it comes as no surprise that some commentators have labeled the PHOSITA having no scintilla of inventiveness "wrong as a matter of science."[135] To this, I would add that the mythical PHOSITA is wrong as a matter of law.

The obviousness question should not be binary. Rather it should be a graded enquiry answered by those best positioned to judge from experience. Contrary to the ghost PHOSITA,[136] assessment of the entire range of inventive activity falls *within* rather than *outside* the experience of the normative PHOSITA. Indeed, according to Rai the norm of invention is the strongest norm there is in the biomedical community.[137] In the academic branch of the scientific community "kudos" are reserved for those making the most original contributions to the common stock of knowledge.[138] However, in the multinational pharmaceutical industry kudos would be reserved for those deriving patentable subject matter. Thus, inventiveness with an eye to commercial application and patentability is the most highly prized norm in this sector. As discussed by Eisenberg, if the point of the obviousness requirement is to distinguish patent-worthy invention from non patent-worthy research (the latter exemplified by routine advances in the field), then the normative PHOSITA is a reasonable point of reference.[139] The result of moving away from this metric is that judges must logically be obliged to consult persons with *less than* ordinary skill in the art, in order to maintain the illusion that the PHOSITA has no scintilla of invention. The following passage is instructive with regard to the circular nature of the reasoning required to maintain this façade:

> This interpretation is in considerable tension with the statutory language. At best, it is circular, defining nonobviousness (and therefore patentability) by reference to the skill level of PHOSITA, and then defining PHOSITA's skill level by reference to capacity to make patentable (that is, nonobvious) inventions. At worst, it 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. [140]

134. *Bristol-Myers Squibb Canada Co. v Novopharm Ltd.*, 2005 FC 1458, <http://decisions.fct-cf.gc.ca/en/2005/2005fc1458/2005fc1458.html>, 43 *Canadian Patent Reporter, 4th ser.* 433 [*Bristol-Myers Squibb Canada Co. v Novopharm Ltd.*].
135. Burk and Lemley, "Biotechnology," *supra* note 14; see also Varma and Abraham, "DNA is Different," *supra* note 95; Arti Kaur Rai, "Intellectual Property Rights in Biotechnology: Addressing New Technology," (1999) 34:3 *Wake Forest Law Review* 827–847, <http://www.law.wfu.edu/prebuilt/LR_v34n3_Rai.pdf>; Arti Kaur Rai, "Addressing the Patent Gold Rush: The Role of Deference to PTO Patent Denials," (2000) 2 *Washington University Journal of Law & Policy* 199–227, <http://law.wustl.edu/journal/2/p199rai.pdf>.
136. Burk and Lemley, "Biotechnology," *supra* note 14, footnotes 76-77.
137. Rai, "Regulating Scientific Research," *supra* note 95 at pp. 20-21.
138. Rai, "Regulating Scientific Research," *supra* note 95 at p. 21; Hagstrom, *The Scientific Community*, *supra* note 106 at p. 13 and pp. 23–42.
139. Eisenberg, "Obvious to Whom?" *supra* note 14 at p. 886.
140. Eisenberg, "Obvious to Whom?" *supra* note 14 at p. 892.

The shortcomings of a rigid binary interpretation of nonobviousness have been recognized by courts in other jurisdictions. In *Genentech Inc's Patent,* Lord Mustill construed persons skilled in the art of biomedical research as those for whom the processes of advanced reasoning and decision-making were paramount, particularly given that the act of solving problems was central to the art of research and development.[141] Lord Mustill went on to characterise the PHOSITA as those persons working in a "discovery" capacity who, "but for" their inherent inventive capacity, would never have been included as part of the relevant team of skilled scientists in the first place.

A normative construction comports with certain judicial articulations relating to the identity and inventive capacity of the PHOSITA. For example, the PHOSITA has been described as having read and understood *all* of the relevant prior art available and is endowed with *all* of the common knowledge pertinent to the field and all skills required to practice the invention.[142] Moreover, the skilled technician is cognitively equipped to make *all* necessary logical and rational deductions required in order to understand and arrive at the invention,[143] including conducting, analyzing and interpreting the results of mechanical, routine or workshop-type testing.[144] Moreover, the PHOSITA is recognized as a "paragon" of dexterity in undertaking those activities.[145] Indeed, the PHOSITA is presumed to be enabled by *all* relevant knowledge, best-practices and prior art in the industry at the time of the claim date,[146] and is employed in a state of the art research facility equipped with *all* relevant equipment and technology to derive or at least understand the invention. If that is not enough, the PHOSITA is deemed to spend his or her daily life in experimentation in pursuit of these goals.[147] It is not surprising, given these acknowledged cognitive and behavioural traits, that some judges have reasoned that the PHOSITA has a mind willing to understand[148] everything that is necessary in order to successfully solve the problem before them[149] and is not looking to fail in their research and development endeavors.[150] This understanding led Justice Gibson in a recent case involving gatifloxacin to hold that it is appropriate for the court, depending on evidence adduced, to cast the definition of the PHOSITA "well above the concept of an individual having no scintilla of inventiveness or imagination."[151] This is consistent with the fact that the PHOSITA provides the legal benchmark

141. *Genentech*, *supra* note 34 at pp. 108–115; Bouchard, "Scientific Research," *supra* note 4.
142. *Whirlpool*, *supra* note 7; *Free World Trust*, *supra* note 7, para. 26 and 44; *Beloit*, *supra* note 15 at pp. 293 and 294; *Apotex Inc. v Syntex Pharmaceuticals International Inc.* (FC Trial Div, 1999), <http://decisions.fct-cf.gc.ca/en/1999/t-2870-96/t-2870-96.html>, 1 *Canadian Patent Reporter*, *4th ser.* 22, paras. 38 and 40.
143. *Canadian Industries*, *supra* note 128; *Apotex v Hoffmann-La Roche*, *supra* note 29; *Apotex* v *Wellcome (FCTD)*, *supra* note 28; *SmithKline (FCTD)*, *supra* note 128; *Genentech*, *supra* note 34.
144. *Canadian Industries*, *supra* note 128; *Apotex v Hoffmann-La Roche*, *supra* note 29; *Apotex v Wellcome (FCTD)*, *supra* note 28; *SmithKline (FCTD)*, *supra* note 128; *Genentech*, *supra* note 34.
145. *Beloit*, *supra* note 15 at p. 294; *Procter & Gamble Pharmaceuticals Canada Inc. v Canada (Minister of Health)*, 2004 FCA 393, <http://decisions.fca-caf.gc.ca/en/2004/2004fca393/2004fca393.html>, 248 *Dominion Law Reports*, *4th ser.* 674 at p. 44.
146. *Beecham*, *supra* note 13; *Free World Trust*, *supra* note 7; *Genentech*, *supra* note 34.
147. *Bayer (ON CJ)*, *supra* note 16 at p. 61.
148. *Baldwin*, *supra* note 132; *Ernest Scragg*, *supra* note 42 pp. 55–56; *Burton Parsons Chemicals*, *supra* note 11.
149. *SmithKline (FCTD)*, *supra* note 128 at para. 20.
150. *Lister v Norton Brothers and Co.* (EW High CJ Ch, 1886), 3 *Reports of Patent, Design and Trade Mark Cases* 199 at p. 203; *Free World Trust*, *supra* note 7, para. 44, quoting from Fox, *Canadian Law and Practice*, *supra* note 17 at p. 184.
151. *Bristol-Myers Squibb Canada v. Canada Co. v Novopharm Ltd*, *supra* note 134 at paras. 70-74.

not just for obviousness in patent law, but also for the doctrines of anticipation, utility, enablement, sound prediction, ambiguity, lack of novelty, improper subject matter, and claims broader than disclosure.

Finally, basing the analysis of obviousness on skills possessed by the normative PHOSITA is legitimate given the relationship between law and the scientific subject matter at hand. First, the law of obviousness is strongly contingent on a highly sophisticated body of knowledge that is external to law. Thus, in the absence of guidance from the normative PHOSITA equipped to appreciate the full range of inventive ingenuity at stake, it is difficult for judges to adequately understand the mechanisms by which this knowledge evolved and solidified into focal knowledge in the form of pharmaceutical products. Second, from a public policy perspective,[152] persons skilled in the art are, and indeed should be, the standard on which analysis of the prior art is based due to the fact that such persons comprise the population that most needs to understand the art and to which the art is directed. As noted above, this is a particularly important consideration in the case of pharmaceutical patents given the interdisciplinary and complex nature of the relevant art. Third, basing the analysis on knowledge possessed by the normative PHOSITA would allow courts to take a flexible approach to the evidence before them on a case by case basis. In this light, the nuances of pharmaceutical litigation, particularly that under the *NOC Regulations* and *Hatch Waxman* linkage regimes, are consistent with the contextual claim that patent law is "technology-specific."[153] A factually accurate and legally relevant construction of the PHOSITA provides an important benchmark for the courts to gauge whether and to what degree the public will benefit from the *quid pro quo* of the patent bargain. This is discussed in more detail in Part 5 of the Analysis below.

3.2. An Actor-Network Theory Perspective

3.2.1. Introduction

It was suggested above that the relevant knowledge base pertaining to a generalized pharmaceutical problem-solution set is comprised of both focal and tacit knowledge. An additional layer of interpretation relative to the inventive skills and capacity of persons skilled in the art of pharmaceutical can be introduced at this point, that of actor-network theory (ANT). For the present purposes, ANT represents a temporally evolving marriage and synergy of tacit and focal knowledge bases. Many definitions for ANT abound. It is generally acknowledged to comprise a theory, or analytical method, in the area of science, technology and society (STS) studies. ANT differs from many other network theories in that an "actor-network" contains not merely individuals, represented in the present work by the PHOSITA, but also several types of non-human network nodes, for example knowledge, data, equipment used to generate and analyse data, animals, natural systems as well as various "allies" and organisations

152. See Burk and Lemley, "Biotechnology," *supra* note 14 and Varma and Abraham, "DNA is Different," *supra* note 95.
153. Burk and Lemley, "Biotechnology," *supra* note 14.

required for the crystallization of knowledge into dogma and products. These entities are referred to individually as "actors". According to the International Society for Complexity, Information and Design, ANT is an interdisciplinary approach to STS studies, and is amenable to the study of scientific research due to parallels between ANT and the sciences of complexity, locality, activity theory, and systems theory.[154] ANT attempts to explain and interpret social and technological evolution without using technical-material or social reductionism alone. Rather, it utilizes the principle of "symmetry," referring to the notion that human and non-human actors can and should be integrated into the same conceptual field and to have equal roles in its evolution. Important for the present discussion of obviousness, ANT aims to refute modernist binary notions such as natural/cultural, physical/moral and determinism/indeterminism. This is critical to understanding how far the binary proposition embedded in the law of obviousness is from the practices of actual persons skilled in the art of pharmaceutical sciences and what that implies for litigants and drug-purchasing consumers.

3.2.2. Opening the Black Box

The thrust of the proposed ANT approach is to undertake what is referred to as "opening up the black box."[155] A so-called black box exists when a thing comprising the box (a hypothesis, theory, product or, as in the within instance, a social construct) is no longer questioned. Once it becomes dogma, it is referred to as "ready-made science." In the present context this would equate to "ready made law". By contrast, "science in action" or "science in the making" refers to a situation when the black box is laid open, either before it has had a chance to originally close or afterwards. Because there is always considerable controversy in the creation of a black box, involving many actors with varying agendas and interests, there will always be controversy when the box is opened up: hence its portrayal as more of a "Pandora's box" than an inert cube.[156] With regard to the present thesis, "law in action" would refer to leaving aside the judicially accepted notion of the mythical PHOSITA having no scintilla of inventiveness to peer behind the walls of pharmaceutical firms and decide for ourselves just how much inventiveness the normative PHOSITA possesses and *how* he or she would typically arrive at a biomedical invention in light of what has come before.

There are several elements of the ANT methodology that are particularly useful in the legal analysis of the PHOSITA. First, science in action is indeterminate, confrontational, political and typically characterized by strong ambiguity right up until (and often after) the black box has closed.[157] Consequently, strong creativity, inventiveness and decision-making skills are required on the part of its practitioners as are the necessary allies to bring the process to a close.[158] In the

154. International Society for Complexity, Information, and Design, "Actor-Network Theory," in *ISCID Encyclopedia of Science and Philosophy*, 2007 <http://www.iscid.org/encyclopedia/Actor-Network_Theory>.
155. Latour, *Science in Action*, *supra* note 23.
156. Latour, *Science in Action*, *supra* note 23.
157. Latour, *Science in Action*, *supra* note 23 at pp. 7, 15, 221.
158. Latour, *Science in Action*, *supra* note 23 at pp. 8, 142, 176, 200, 221.

ANT framework, how one gains knowledge is as important as knowledge itself.[159] This clearly supports the tacit/focal analysis of persons skilled in the art of pharmaceutical research undertaken in Part 4.1, both with respect to the multiple spheres of "art" entailed in bringing a pharmaceutical invention to market and the strong cognitive and decision-making skills possessed by actual "persons" skilled in pharmaceutical sciences. Second, discovery in the pharmaceutical industry is characterized more by the innovation process rather than invention per se. This reinforces the multiple spheres model, and the role of intellectual property and regulatory law generally as drivers of the construction and production of scientific knowledge. In this sense, inventors are but one small node in the network of "strong interests" required to bring a product to market or achieve scientific acceptance of the underlying discovery.

Latour specifically addressed the health care sector in the ANT context, second only to military in the research and development funds flowing from government. Strong interests in the art of biomedical research and development include the relevant board of directors of corporations, intellectual property and regulatory counsel, shareholders, private and public policy-makers and other political, commercial and technical allies arranged on the opposite side of the fence from their competitors, or "dissenters."[160] Importantly, this analysis applies not just to the commercial dissemination of an invention in the marketplace, but also to its construction as a scientific truth (black box).[161] In other words, it is not just pharmaceutical scientists that construct the relevant pharmaceutical art and distillations thereof in the form of biomedical products, but a myriad of actors all of whom share a strong interest in the outcome of the relevant discovery or product (or indeed, in maintaining or expanding the relevant marketplace or intellectual property/regulatory landscape). The extension of the "art" in this sense, from a marketable product to its underlying (patentable) truth, is therefore crucial to the judicial construction of an invention as obvious or not, as is the involvement of persons skilled in the art in the analysis.

Marginalization of the PHOSITA in the obviousness analysis in favour of a binary, rigid or otherwise narrow judicial interpretation[162] can only lead to grave difficulty, because judges sitting on the bench are far removed from the relevant network, with its corresponding intricacies and subtleties, and thus can only be outsiders, lacking almost entirely in the necessary resources of a qualified dissenter. As discussed above in Part 3, numerous jurisdictions including the United States, the United Kingdom and Canada codified obviousness precisely to move away from a subjective to an objective standard. Unfortunately, the jurisprudence in Canada moved only part way to an objective standard, instead adopting a hybrid standard of the mythical PHOSITA. Friction between these constructions has produced considerable confusion in Canadian case law regarding the accepted approach to obviousness,[163] as there is little if any consistency in the method by which judges appear to be choosing the degree of

159. Latour, *Science in Action*, *supra* note 23 at p. 220.
160. Latour, *Science in Action*, *supra* note 23 at pp.163–164.
161. Latour, *Science in Action*, *supra* note 23 at pp. 28–29.
162. Eisenberg, "Obvious to whom?", *supra* note 14; Bouchard, "Scientific Research", *supra* note 4.
163. Bouchard, "Scientific Research," *supra* note 4. See also cases discussed in Part 2 above.

inventiveness possessed by persons skilled in the art (and hence the amount of allowable testing).

ANT is a legitimate method for a legal study of persons skilled in the art in the context of the obviousness analysis because, as noted by Mariane Valverde,[164] the purpose of ANT, indeed that of the entirety of law-and-society scholarship, is to map how knowledge external to the law is introduced and processed into legal norms by legal actors. This is particularly true of the obviousness analysis, as the courts, and by extension the Patent and Trademark Office when granting patents and the lawyers who draft and litigate them, are epistemologically dependent (and their analyses strongly contingent) upon external knowledge content and processes in the pharmaceutical sciences. In this sense, relevant actors within the obviousness network would include persons skilled in the art as the most obvious nodes, but also other experts and sources of expertise with whom they interact. This group includes scientific, technical, medical, business, marketing, regulatory and other professionals involved in the drug development process, the prior art at the time of the claim date, schools of medicine and basic sciences responsible for teaching this art, schools of business responsible for teaching how to commercialize and market biomedical technologies, faculties of communication responsible for publicizing it, and all of the animals and people participating in pre-clinical and clinical studies. Rounding out the network are the judges, lawyers and legislators who internalize and operationalize this knowledge base from a legal perspective. Importantly, as suggested in Part 3.1.2., each of these spheres of influence exerts a significant impact on the drug development project as an apparently independent "activity-in-itself." That is not to say each of these nodes should be recognized explicitly in the legal determination of obviousness. Rather, that they be enfolded into the PHOSITA's consideration of the impugned invention "as a whole" when determining whether or not it represents a sufficient inventive step over the prior art to be patentable.

3.2.3. The PHOSITA is Embedded Within and Informed by a Complex Network

One important characteristic of the ANT model is that it underscores the web of nodes and interfaces necessary for the evolution of knowledge. Therefore, acts of scientific discovery must be considered in context of all prevailing forces impacting on them. From the perspective of a factually accurate construction of a PHOSITA, this means highlighting not only traditional sources of focal knowledge that courts typically focus on in the obviousness analysis, but also *how* and *why* persons skilled in the art arrived at that knowledge. That numerous acts are required to form a network of any substance, let alone one involving basic and clinical sciences, as well as business, marketing, legal and regulatory spheres, places due emphasis on creative acts of discovery, decision-making and intellectual ingenuity by individual persons skilled in the art. It is these individual acts that sum together to form the relevant network.

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164. Mariana Valverde, "Authorizing the Production of Urban Moral Order: Appellate Courts and Their Knowledge Games," (2005) 39:2 *Law & Society Review* 419–455, <http://repositories.cdlib.org/csls/lss/14> at p. 419.

According to the ANT model, discrete nodes of interconnectivity can be comprised of both technical and non-technical elements. For this reason ANT is said to be "heterogeneous" with regard to knowledge sources. It is reasonable on this basis to conclude that when taken as a whole, an ANT network relevant to obviousness encompasses Polanyi's focal and tacit knowledge bases and both "right brain" and "left brain" functions necessary for the production and construction of scientific knowledge. In so far as the non-technical elements properly include right brain functions, as well as tacit "knowing" and the processes of scientific investigation and discovery, a legitimate legal analysis of the PHOSITA would encompass inventive and non-inventive, creative and non-creative, and determinate and indeterminate approaches to producing pharmaceutical subject matter and the processes involved in legally construing it. According to Valverde, epistemological heterogeneity is particularly relevant when courts assume the burden of analyzing and constructing external forms of knowledge, which are often treated in evidence with the same weight as purely legal forms of knowledge.[165] This is applicable to the obviousness analysis, as courts depend determinatively on the opinions of persons skilled in the art of pharmaceutical research as well as the prior art as of the claim date for their legal conclusions.

Indeed, the Supreme Court of Canada has clearly stated that the court is to purposively construct patent claims and specifications in light of a considered analysis of the prior art and other forms of scientific knowledge that would be possessed by persons skilled in the art at the time of the invention.[166] It is argued here that this should include persons positioned in a spectrum of inventive-to-non-inventive based on the facts before the court rather than on a binary distinction between 0% and 100% (or 0-1) inventiveness. This is consistent with the notion in ANT studies that constituent actors are inherently unstable and evolving, operating as they do in environments of ambiguity and uncertainty. The ability of persons skilled in the art to analyse the facts before them using both left and right brain functions is no different than that of judges seeing the relevant art through their eyes. This is supported by the relational epistemology of relevant knowledge bases in ANT studies, in which the character of the scientific knowledge captured in a given moment (the prior art of patent law) has no passive identity or existence outside of the synergy of the network and creative inputs of the actors involved - including both judges and persons skilled in the art. In this sense, judges and persons skilled in the art are two aspects, or expressions, of the same network, or system.

3.2.4. Relation to Binary Law

Fundamental to a factually accurate and legally relevant construction of a PHOSITA engaged in global pharmaceutical research and development is that ANT specifically rejects operating in a framework of opposite poles of nature-culture. Proponents of ANT and other network theories reject this type of dualism in favour of a more contextual and nuanced framing of nature-culture, physical-moral, and determinism-indeterminism. Encompassing a spectrum of

165. Valverde, "Authorizing the Production," *supra* note 164 at p. 423.
166. *Free World Trust, supra* note 7.

activity along these lines is viewed by many network scholars and scientists as necessary to stabilize strong complex networks. ANT constructs complex social realities as inherently unpredictable (or at least incompletely predictable) or as transitional and becoming, involving "trajectories of creation" in an environment in which ambiguity is more the rule than the exception. As with many other philosophies and conceptual models of science, notions of continual change and process are central to ANT.

Valverde has taken this argument one step further, claiming generally that because of the relatively greater weight placed on epistemological heterogeneity in law, that law defies the modern binary dichotomy of subject matter encompassed by the natural sciences and the social sciences. I would argue that any such resistance by law to purity-seeking should be even greater in the obviousness analysis given the contingent nature of the law on scientific knowledge and analytical frameworks. In reality, be it constructed through the eyes of ANT, Polanyi, or any other analytical lens, there is no such thing as a person relevant to the contextual operation of law who is 100% left brain function and 0% right brain function or *vice versa*. The legal binary fiction does not apply to any person let alone one skilled in the art of creating knowledge under highly ambiguous circumstances, however controlled and determinative in nature the tools involved. The analytical elements characteristic of so-called left brain function embedded in the obviousness analysis should not, and indeed never do, "drive out" the so-called right brain functions from the mind of the PHOSITA faced with a problem.

That is not to say that science, and in particular a pharmaceutical science driven by legal-regulatory concerns, does not involve "closing" the box in order to arrive at a discrete view of a physical product, process or use. Indeed, temporarily closing the "black box" is seen to be necessary to allow people to leverage the work of others and move the network forward. Hence knowledge flows in a network rather than is produced.[167] This is analogous conceptually to the continual cycling of focal-tacit-focal knowledge described by Polanyi, whereby every conjunction of actors/acts at a tacit "node" serves to change the scope and depth of the network. In patent parlance this would amount to advancing the prior art over time, sometimes in a stepwise or "line extension" manner and sometimes in a "breakthrough" manner. Whether a particular advance of the prior art produces a patentable invention should depend on whether that advance is deemed by the court as inventive (non-obvious) or not (obvious) in light of the relevant facts, not on a model that precludes such analysis.

A final point arguing against a binary construction of obviousness is the argument against[168] complete and unidirectional absorption of external forms of knowledge into a discrete legal view.[169] Indeed, on this point an ANT analysis would generally resist divorcing "scientific" obviousness from "legal" obviousness,

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167. Latour, *Science in Action*, *supra* note 23; see also Bruno Latour, *We Have Never Been Modern* (Harvard University Press, 1993).
168. Valverde, "Authorizing the Production," s*upra* note 164 at p. 425.
169. Gunther Tuebner, "How the Law Thinks: Toward a Constructivist Epistemology of Law," (1989) 23:5 *Law & Society Review* 727–757, <http://ssrn.com/abstract=896502>.

as one finds in Canadian patent law. In other words, the legal construction of obviousness can not and should not be divorced from the underlying scientific reality of whether the PHOSITA would consider an invention to be obvious or not in the laboratory. To do so does violence to actual persons skilled in the art. The intersection between these two concepts, or network nodes in the parlance of ANT, means that by necessity they are interdependent and cannot be divorced or interpreted in a binary fashion.

To say that it can be scientifically obvious to arrive at an invention in practice but that this need not be equivalent to legally obvious, as did Blanchard J in the recent *Pfizer v Novopharm* azithromycin "food effects" case,[170] runs afoul of the descriptive and prescriptive norms at stake, but also against the approach of analyzing a patented invention purposively.[171] It is also contrary to the statutory and accepted common law principles of patent law that a patent must be seen contextually through the eyes of a PHOSITA,[172] who is enabled by all the relevant knowledge, best-practices and prior art in the industry at the time of the claim date[173] and has a mind willing to understand[174] all that is necessary in order to successfully solve the problem before them.[175] Indeed, based on this argument, no one is better placed than the normative PHOSITA to understand the various forces at play in the closing (or not) of a black box or, in patent parlance, whether the box is inventive over the prior art.

3.2.5. Summary

A summary of ANT factors relevant to a legal determination of obviousness from the perspective of a normative PHOSITA is given in Table 1. The factors in the left column represent a range of interpretive departure points and considerations used in the ANT framework to open, or understand prior to opening, a scientific black box. The application of these factors to the obviousness analysis is provided in the right column. In each case, the factor applies to the role of the normative PHOSITA in the obviousness determination as informed by section 28.3 of the Act.

170. *Pfizer Canada Inc. v. Novopharm Ltd.*, 2005 FC 1299, <http://decisions.fct-cf.gc.ca/en/2005/2005fc1299/2005fc1299.html>, 41 *Canadian Patent Reporter, 4th ser.* 502 at para. 119.
171. *Free World Trust, supra* note 7 at paras. 15,19.
172. *Apotex Inc. v Hoffmann-La Roche*, *supra* note 29.
173. *Beecham*, *supra* note 13; *Free World Trust*, *supra* note 7; *Genentech*, *supra* note 34.
174. *Baldwin*, *supra* note 132; *Ernest Scragg*, *supra* note 42 at pp. 55–56; *Burton Parsons Chemicals*, *supra* note 11.
175. *SmithKline (FCTD)*, *supra* note 128 at para. 20.

Table 1. Application of ANT to the Normative PHOSITA

Black Box Factor	Role of Normative PHOSITA
Resources (texts, documents, files, articles, etc.) are turned from opinion to facts or artifacts,[176] in part through the use of positive and negative modalities[177] (information that either leads the reader towards or away from the condition of its production) via the sources responsible for disseminating those modalities.	Assist the court in distinguishing between scientific opinion and fact and between scientific facts and artifacts, as alleged by the parties. Assist the court in understanding positive and negative modalities and how they evolved to that status.
Opinion can be turned into fact in the face of dissenters, even those proposed by relatively weak actors, through the use of important supporters or "allies."[178] This gives rise to the "argument from authority" which becomes accepted dogma.	Assist the court in assessment of allies of those asserting scientific truths, how and why they became allies, and what they have to gain or lose in litigation with regard to the alleged scientific truth at issue.
A document becomes "scientific" when its claims stop being isolated and the allies disseminating it are many and explicit.[179] Fact construction is a collective process; isolated people can only render propositions, assertions and claims, not facts.	Assist the court in assessing how and why to isolate certain claims from the scientific and cultural milieu in which they were developed, and how those claims became accepted as part of the collective relevant art.
When an actor desirous of converting an opinion into a scientific fact is faced with antecedent knowledge and literature, it is necessary to do whatever is required to render that knowledge and literature as amenable as possible to the claims made by that actor.[180]	Assist the court in interpreting specific pieces of prior art as dismissive or supportive of the claims at issue from the perspective of both allies and dissenters. This includes helping the court to determine whether the research or experiments leading to the impugned invention were inventive.
The conversion of an opinion into a scientific fact can be "mapped" by tracking all of the layers of scientific documentation in time and space that transforms both the opinion into fact and the earlier literature into "supporting" documentation.[181]	Assist the court in mapping out the timing and nature of the contribution of the relevant prior art to an invention and the role of allies and dissenters in the transformation.
Scientists speak in the name of themselves and the allies they have shaped and enrolled to tip the balance of force in their favour.[182] An ever increasing number of scientists advocating for a new fact employ "inscriptions" of this truth (papers, journals, data, machinery and other equipment used to obtain data) to support their claims.	Assist the court in assessing the history and validity of inscriptions offered by those asserting or alleging scientific truths, and how inscriptions were employed through frequent and routine use to transform the naming of an actant (scientific fact or thing) into a common name or the conversion of opinion into fact.
Rhetoric is used powerfully to make dissenters isolated and lonely.[183]	Assist the court in unpacking the kinds of rhetoric used in the art to isolate dissenters.

176. Latour, *Science in Action*, *supra* note 23 at pp. 25, 30.
177. Latour, *Science in Action*, *supra* note 23 at pp. 23, 25.
178. Latour, *Science in Action*, *supra* note 23 at at p. 31.
179. Latour, *Science in Action*, *supra* note 23 at pp. 33, 41.
180. Latour, *Science in Action*, *supra* note 23 at at p. 37.
181. Latour, *Science in Action*, *supra* note 23 at pp. 39–40.
182. Latour, *Science in Action*, *supra* note 23 pp. 68–69 and 90.
183. Latour, *Science in Action*, *supra* note 23 at p. 40

A network is composed of nodes of actors with specific and often disparate "interests" connecting them. The size and sum of these interests and the interactions between the actors is what transforms a claim into a fact.[184] Combined, the network acts such that the whole is greater than the sum of its parts and control is dispersed rather than localized. It is the strengths and weaknesses of the associations between actors that are critical. Thus, understanding the nature of a scientific fact is the same as understanding the people (and the whole) that gave birth to the fact.	Assist the court to understand the nature, necessity and range of interests (scientific, political, legal, economic, regulatory, etc.) of scientific and non-scientific actors (pharmaceutical firms, spillover targets, government, business lobbies, investors, employees, consumers, etc.) involved in the construction of scientific truth, the network in which these claims, facts and actors are embedded, and the interests of the various actors in the desired outcome.

3.3. A Deterministic Attack on the "Worth a Try" Approach

Based on the two analytical frameworks described above, I have argued that the normative PHOSITA engaged in the activity of industrial pharmaceutical research and development exhibits considerable inventiveness in the day-to-day discharging of their scientific duties and responsibilities, and that the act of simply *being* a scientist entails considerable creativity and an ability to work with significant levels of ambiguity and indeterminism. I further argued that the binary propositions inherent in *Beloit* (testing/no testing; scintilla/no scintilla; not/worth a try; and could have/would have) were insupportable in so far as normative descriptions of actual persons skilled in the art of pharmaceutical research are concerned. To some degree this is because of a rejection of binary notions of determinism-indeterminism found in most "modern" frameworks for understanding knowledge, particularly in the realm of science and technology. In this sense, the binary propositions encoded within *Beloit* are strongly determinate in nature rather than indeterminate. The approach advocated throughout the present work is more in line with what has been speculated to be the next dominant "paradigm"[185] of science, complex adaptive systems (complexity for short).[186]

A detailed description of a general complex adaptive system ("CAS") is beyond the scope of this work. However, there are several elements of a CAS that are relevant to the discussion of obviousness and the normative PHOSITA. First, a CAS is an open nonlinear dynamic system that is constantly changing and has the capacity to learn from experience and incorporate new information in order to enhance its own fitness. This adaptation occurs spontaneously, using whatever combination of agents is best suited to learn and adapt. For this reason, complexity has been amenable to use in business organizations.[187]

184. Latour, *Science in Action*, *supra* note 23 at pp. 108–109, 120–130, 140–143, 163–164, 180, 222–223.

185. I use the term acknowledging that Thomas Kuhn himself expressed regret over its attribution to him and the many related misunderstandings of his treatise, *The Structure of Scientific Revolutions* (University Of Chicago Press. 1962); see John Horgan, *The End of Science* (Bantam Doubleday Dell, 1996) at pp. 41–47.

186. James Gleick, *Chaos: Making a New Science* (Penguin Books, 1987); Grégoire Nicolis and Ilya Prigogine, *Exploring Complexity* (WH Freeman and Company, 1989); M Mitchell Waldrop, *Complexity: The Emerging Science at the Edge of Order and Chaos* (Simon and Schuster, 1992); Stuart Kauffman, *At Home in the Universe: The Search for the Laws of Self-Organization and Complexity* (Oxford University Press, 1995); Stuart Kauffman, *Investigations* (Oxford University Press, 2000); Albert-László Barabási, *Linked* (Perseus Press, 2002). Note that the work of Kuhn and Latour is, to varying degrees of express acknowledgement by the authors, consistent with the broad generic rules governing complexity.

187. For example see Robert Axelrod, *The Evolution of Cooperation* (Basic Books, 1984); Peter M Senge, *The Fifth Discipline: The Art and Practice of the Learning Organization* (Doubleday, 1990).

Another major feature of a CAS is that it has emergent properties. Emergence refers to the fact that in a system or network of numerous interconnected agents, lower level agents interact together to influence the behaviour of higher level agents, and so on. The behaviour of the entire system is not a reflection of individual agents acting in and of themselves, but rather is the sum of the *interactions* of multiple agents acting on multiple levels of organization. Power in a CAS is decentralized among the nodes making up the network and therefore local interactions produce discernable macrobehaviour. Consequently, in a CAS the "whole is greater than the sum of its parts." A final feature of a CAS relevant to the present discussion is that it operates in an environment characterized by uncertainty and ambiguity. Indeed, not only is the system *faced with* uncertainty, but uncertainty is both *inherent to* the system and *necessary for* its success at the local level, operating as it does "on the edge of chaos." This parallels the discussion above where the PHOSITA was seen to be acting creatively under conditions of ambiguity in order to produce advances within, and with the help of, a web of related spheres of influence such as those of science, medicine, business, politics and economics.

The inherent uncertainty in a CAS, and its contribution towards local stability resulting from competition and cooperation among rivals, is echoed to some degree in models of bounded rationality in game theory and the new field of neuroeconomics, where the existence of uncertainty in the decision-making process is required for agents to win competitions under conditions of ambiguity.[188] While uncertainty can be leveraged by individual agents, in a CAS the behaviour of the system cannot be predicted or controlled with certainty in the broad sense. What order exists in a CAS is that found at the edge of chaos (between structure and surprise) as a result of the balancing forces of competition and cooperativity among agents. This stems largely from the fact that complex systems behave as "self-organized criticalities," with large and small dramas playing out continually under circumstances in which either could be significant in a positive or negative capacity where it is not possible to know which until the event itself happens. A CAS is also exquisitely sensitive to initial or "starting conditions," which due to inherent uncertainty at both the macro and quantum levels are largely unknown to its own agents. Hence, the typical example of a CAS is that of apparently chaotic behaviour (ants, traffic, stock price fluctuations, internet networks) which nevertheless can be described in quantitative terms. From this brief outline, it can be seen that the notion of complex adaptive systems embraces rather than disadvantages uncertainty and ambiguity. As such a CAS differs in many important respects from closed linear equilibrium-based deterministic systems, the study of which began in earnest with Newton and Descartes and has continued uninterrupted right up until the mid-twentieth century.[189] The parallels between complexity and the normative PHOSITA viewed through the twin prisms of Latour and Polanyi are therefore significant and relevant to the current debate on obviousness. This parallel is underscored by the data provided in Table 1 above.

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188. Paul W Glimcher, *Decision, Uncertainty and the Brain: The Science of Neuroeconomics* (MIT Press, 2003).
189. Glimcher, *Decisions, Uncertainty*, *supra* note 188. Many scientists claim the deterministic framework of science continues to dominate to this day.

However, even if one sets aside discussions of tacit and focal knowledge, ANT, and complexity a strong argument can be made that a PHOSITA guided by purely deterministic reasoning would still reject the "worth a try" approach advocated by Justice Lederman in *Bayer*.[190] The same is true for the related "would versus could" distinction, which rests on the same fragile assumption. This is because both approaches stand in stark contrast to the generally accepted scientific principles and tools underpinning current best practices in rational drug design. It is submitted that consideration of the issues discussed above, when analyzed using a fairly rigorous and pragmatic deterministic framework, can only lead to rejection of the worth a try and could v. would articulations of the obviousness test (referred to together as the "worth a try" approach to obviousness for simplicity).

An important aspect of historical pharmaceutical practice and newer rational drug design programs that supports rejection of Justice Lederman's "worth a try" approach to obviousness is that the latter approach is characterized by a degree of uncertainty and unpredictability that persons skilled in the art would, in reality, deem to be unacceptable for reasons of scientific *and* economic inefficiencies. This can be compared with the "next logical step" approach to testing advocated by Justice Gibson in his construction of the obviousness attack, particularly in the gatifloxacin case under the NOC Regulations.[191]

While the "worth a try" approach is not exactly analogous to flipping a coin, it retains many of the features of a more indeterminate system of analysis than does the "next logical step" approach. The "worth a try" approach, says in effect "what the hell, let's give it a try." Each time a new "try" is undertaken, both deterministic and nondeterministic forces are strongly at play in generating the result. This is as true for empirical experiments conducted by the PHOSITA as it would be in a simple mathematical model. While each new try is influenced mathematically to some degree by the last one, the significant role of indeterminism embedded in the "worth a try" process renders it more dependent on what is referred to commonly at the macro level as chance.[192] In other words, each try is less dependent on antecedent or historical events, less influenced by rational or logical planning of the sort dependent on contextual facts, and less incremental in nature than the next logical step approach. Based on this, one can say that the cause and effect relationship of the "worth a try" approach is comparitively weak, particularly given the relative independence of each try from cumulative antecedent, rational and incremental contextual events. For this reason, the causal chain of events in the "worth a try" approach can also be

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190. In *Bayer (ON CJ)*, *supra* note 16, Lederman J rephrased the routine experimentation approach advocated by Apotex as "you try one thing and if not successful you try a few other well known tests to deal with the problem."
191. *Bristol-Myers Squibb Canada and Kyorin Pharmaceutical Co. v Novopharm Ltd. and the Minister of Health*, 2005 FC 1458, <.http://decisions.fct-cf.gc.ca/en/2005/2005fc1458/2005fc1458.html>.
192. Glimcher, *Decisions, Uncertainty*, *supra* note 188:

> The level of indeterminism and uncertainty found at the quantum level is "smoothed over" statistically as more and more particles are added to the event matrix as one moves from the micro-quantum level to the macro/every day level. However, as shown by results of experiments in the field of neuroeconomics, both determinate and indeterminate forces are at play and indeed necessary for success of a competitor to maximize the likelihood of success when competing for scarce resources in an uncertain playing field.

deemed weak. The probability of success is therefore weak to moderate, depending on the degree of chance applicable at the macro level. Given the comparatively strong roles of chance and indeterminism and the relatively weak roles of cause and effect, antecedent events, rational/logical design attributes, and incremental progress, there is a relatively high value set for the degree of legal arbitrariness and uncertainty embedded in the worth a try approach. A summary of the analysis can be found in the left column of Table 2.

By contrast, the "next logical step" approach is just that. It represents an incremental step forward in experimental science that is strongly dependent on the preceding rationally designed steps. This next step may be inventive or non-inventive, depending on the scientific context. But, whether it is routine or not, the process of experimentation in the "next logical step" model reflects a much more deterministic approach to testing in that it is based strongly on the principle of cause and effect and thus represents a logical and rational framework for incremental and empirical progress in understanding a given art. Accordingly, chance, compared with the "worth a try" approach, is comparatively reduced and the probability of success comparatively strong. Consequently, the "next logical step" approach is considerably more efficient than the "worth a try" approach, both scientifically and economically.

For example, when a competent industrial scientist does decide to take a chance on performing an experiment, it is the calculated rational chance of the skilled practitioner, not the type of highly speculative chance embodied by the "worth a try" approach. This is because of the scientific and economic transaction costs involved. No science is done for free, including that in laboratories where experiments are underwritten by public funds. This is particularly true of industry laboratories where funding funnelled into projects is subject to risk-benefit and SWOT analyses in the context of the therapeutic product program for a given drug. Even for bench work, chemicals and other reagents need to be bought, equipment bought or rented, animals sacrificed, people recruited and employed, buildings and other infrastructure acquired and/or built, overhead paid, and licenses for the use or purchase of any relevant patented technologies acquired. In addition to economic costs, the decision to go ahead with a project will consume enormous time on the part of the drug development team and this decision will privilege that project over others with less favourable risk-benefit profiles. These decisions are not taken lightly by senior management and when the decision is made to go ahead on a particular drug development project, that decision is made as rationally, and with as much supporting data, as possible.

Finally, given the comparatively weak roles of chance and indeterminism and the strong roles of cause and effect, antecedent events, rational/logical design attributes, and incremental progress, there is a comparatively low value set for the degree of legal arbitrariness and uncertainty for the "next logical step" approach compared with the "worth a try" approach. A summary of this limb of the analysis is provided in the right column of Table 2.

Table 2. Comparison of estimated certainty and predictability indices in the "worth a try" and "next logical step" approaches to obviousness from the perspective of a modernist PHOSITA

Parameter	Worth a Try	Next Logical Step
SCIENTIFIC		
Chance- Macro/"Real"	Moderate-Strong	Weak
Determinism	Weak	Strong
Historical/Antecedent	Weak	Strong
Cause and Effect	Weak-Moderate	Strong
Rational, Logical	Weak	Strong
Incremental	Weak	Strong
Probability of Success	Weak-Moderate	Strong
LEGAL		
Arbitrariness	High	Low
Uncertainty	High	Low

Based on the Supreme Court of Canada's direction to provide a fair, unequivocal and predictable test for limiting the scope of the patent monopoly,[193] it is submitted that even if one was obliged to stay within a modern binary framework for a critique of the current test for obviousness, the "worth a try" approach to testing would not be favoured by actual persons skilled in the art of pharmaceutical research and development. As noted by Justice Binnie in the Supreme Court's AZT decision, a wide gulf separates speculation from prediction, and other manifestations of what he referred to as "exact science" in the pharmaceutical sciences.[194] Given the requirement in section 28.3 of the Act to view a patent contextually through the eyes of skilled technicians informed by the relevant prior art, the "worth a try" test advocated by Justice Lederman in *Bayer* is unworkable and thus should not provide the proper template for analysis of obviousness—at least not in the context of industrial pharmaceutical research and development.

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4. PURPOSIVE CONSTRUCTION OF OBVIOUSNESS

A USEFUL STARTING POINT FOR DISCUSSION of a coherent and fair test for obviousness which respects norms in the pharmaceutical sector is by way of analogy to the issue of claim construction,[195] which according to the Supreme Court must be made in a pragmatic and informed way.[196] Following the Federal Court of Appeal in *O'Hara v Eli Lilly*[197] and the House of Lords in *Catnic v Hill &*

193. Bouchard, "Scientific Research," *supra* note 4; see also *R v Nova Scotia Pharmaceutical Society* (CAN SC, 1992), <http://scc.lexum.umontreal.ca/en/1992/1992rcs2-606/1992rcs2-606.html>, 1992: 2 *Supreme Court Reports* 606; *Free World Trust*, *supra* note 7.
194. *Apotex Inc* v *Wellcome Foundation (SCC)*, *supra* note 28 at p 193.
195. Bouchard, "Scientific Research," *supra* note 4.
196. *Whirlpool*, *supra* note 7 at paras. 42-50; *Free World Trust*, *supra* note 7 at paras. 44-51.
197. *O'Hara Manufacturing v Eli Lilly* (CAN Fed CA, 1989), 26 *Canadian Patent Reporter*, *3d ser.* 1.

Smith,[198] the court's *Whirlpool* decision stands for the proposition that patent claims should be construed "purposively," whereby emphasis is placed on locating the essence of an invention with the aid of persons skilled in the art (rather than interpreting the words of the inventor literally). There are several good reasons to extend this analytical framework to obviousness.

In *Whirlpool*, the Supreme Court stipulated that courts must take a purposive approach not only to infringement but also validity.[199] Otherwise, claims would be construed differently for these purposes within the context of the same patent and prior art, which the court specifically rejected. Similar reasoning applies to differences between claim construction and obviousness within the validity rubric. A purposive approach to patent construction was seen to predate *Catnic* by virtue of Justice Dickson's statement in *Consolboard*[200] "to the effect that when construing the meaning of a patent it is necessary to look to the whole of the document to ascertain the nature of the invention and methods of its performance." Thus, the purposive approach is not limited to a narrow test or narrow portion of a patent, but rather should be extended to analysis of all aspects of patentability which depend on an objective assessment of the essence of the invention by the PHOSITA in order to justify the traditional patent monopoly.

Obviousness has in common with claim construction an emphasis on the "essential nature" of the invention and how it came to be. In the case of claim construction this refers to distinguishing between essential and non-essential elements of the claim in order to arrive at the essence or "pith and marrow" of the invention, whereas in the obviousness analysis it is the determination of whether the act of arriving at an invention crosses the line between inventive and non-inventive activity. Both assessments are to be made in an objective manner, yet contextually.[201] A purposive construction imports the notion of the normative PHOSITA, because it focuses on the essence of the invention and the steps taken to get there from the perspective of the PHOSITA. Clearly, someone with no inventive ingenuity whatsoever could hardly be in a position to judge whether activity leading up to an invention is inventive, nor could they assess whether any type of testing, let alone routine workshop-type testing, be reasonably contemplated in the lead-up to invention. The normative PHOSITA is and should be in a better, not worse, position than judges or competent patent counsel to assess the legal obviousness of an invention. The normative PHOSITA is thus a legitimate legal nexus between obviousness and inventiveness. This conclusion is supported by the case law review in Part 3, where emphasis is placed not on binary notions of testing/no testing, scintilla/no scintilla, not/worth a try or would/could, but rather whether in light of the prior art the PHOSITA, acting in their normative capacity, would have come directly and without difficulty to the impugned invention at the time of the claim date.[202]

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198. *Catnic v Hill & Smith*, *supra* note 79.
199. *Whirlpool*, *supra* note 7 at para. 49.
200. *Consolboard Inc. v MacMillan Bloedel (Saskatchewan) Ltd.*, (CAN SC, 1981), 1981:1 *Supreme Court Reports* 504 at p. 520, citing *Noranda Mines Limited v Minerals Separation North American Corporation* (CAN SC, 1950), 1950 *Supreme Court Reports* 36.
201. *Whirlpool*, *supra* note 7 at para. 49(d).
202. *Beecham*, *supra* note 13.

Taking a purposive approach to obviousness also satisfies the important interpretive objective in patent law of being reasonable and fair to the patentee and the public[203] as well as respecting the public notice function of law.[204] This is because by focussing on the essence of the activity underpinning the patent, the purposive stance is balanced between taking too narrow (binary) or too broad (subjective) an approach to obviousness, and thus is neither substantively nor procedurally inherently unfair to any particular party.[205] It creates a fairly circumscribed risk zone for the public and potential litigants by respecting the norms in the pharmaceutical sector that underpin all of the inventions produced by pharmaceutical firms.[206] It also avoids society being burdened and the patent landscape being littered by potentially invalid or weak patents, which remain "*in terrorem* of the art"[207] and serve as the basis for extracting unwarranted license fees or monopoly rents from those who would otherwise pay nothing for such disclosures.[208] Indeed, the Supreme Court has held that fairness to the public is a crucial policy consideration when patents involving pharmaceuticals are involved. In *Commissioner of Patents v Farbwerke Hoechst*[209] for example, the court emphasized the considerable public interest at stake under such circumstances, holding that courts must scrutinize pharmaceutical patents carefully in order to determine if they properly merit the grant of a monopoly privilege. This view rejects construction of patents as "simply property"[210] and is consistent with the court's later jurisprudence to the effect that a patent of uncertain scope is tantamount to a public nuisance and that it is the proper policy of patent law to keep the high economic and other costs attaching to poorly circumscribed patents to a minimum.[211]

A purposive approach to obviousness also fulfills the broad goals of patent policy by taking an evidence-based and objective approach to inventiveness. In doing so, it satisfies the requirement to construe section 28.3 of the Act in accordance with the purpose of the enabling legislation and its context. As noted by Binnie J in *Whirlpool,*[212] patents are to be interpreted according to section 12 of the *Interpretation Act* "as best ensures the attainment of its objects."[213] Indeed, the mischief which the original English *Statute of Monopolies*[214] was intended to rectify was precisely the excess grant of monopoly and the untoward effects of unwarranted monopolies on the public. As noted by the United States Supreme Court in *Graham,* the underlying policy of patent systems based on the *Statute of Monopolies* is that "the things which are worth to the public the embarrassment of an exclusive patent must outweigh the

203. *Whirlpool, supra* note 7 at para. 49(g); *Consolboard supra* note 200 at p. 520
204. *Whirlpool, supra* note 7 at para. 49(h).
205. Bouchard, "Scientific Research," *supra* note 4.
206. *Nova Scotia Pharmaceutical, supra* note 193 at para. 43; *Free World Trust, supra* note 7 at para. 41.
207. *Royal Typewriter Co. v Remington Rand* (USA 2d Cir, 1948), 168 *Federal Reporter, 2d ser.* 691 at p. 1.
208. Lunney, "E-Obviousness," *supra* note 14 at p. 384.
209. *Farbwerke, supra* note 21.
210. Lunney, "E-Obviousness," *supra* note 14 at pp. 381–388.
211. *Free World Trust, supra* note 7 at para. 42; see also *RCA Photophone LD. v Gaumont-British Picture Corporation LD. And British Acoustic Films Ltd.* (EW CA, 1936) 53 *Reports of Patent, Design, Trade Mark, and Other Cases* 167 p. 195 [*RCA*].
212. *Whirlpool, supra* note 7 at para. 49(e).
213. *Interpretation Act,* (1985) *Revised Statutes of Canada* ch. I-21, <http://laws.justice.gc.ca/en/i-21/text.html>.
214. *Statute of Monopolies, supra* note 8.

restrictive effect of the limited patent monopoly."[215] The court noted that the inherent problem was to develop some means of weeding out those inventions that would not be disclosed or devised but for the inducement of a patent. The court's view of the standard for obviousness in *Graham* is consistent with the claim by Varma and Abraham that obviousness is the gate by which patent law minimizes inefficient transfers of wealth under conditions where a patentee obtains a right to exclude others from making or using their invention yet does not add to the store of public knowledge when a patent is granted on obvious subject matter.[216]

Important to the issue at hand is that a purposive construction would achieve "flexibility and fairness" in law by focusing on the essence of an invention.[217] This can be contrasted, for example, to a more narrow focus on *either* a literal interpretation *or* analysis of the "pith and marrow" of an invention (which *Catnic* overruled by collapsing the two standards) or closer to home the narrow focus on literal notions of testing/no testing, scintilla of inventiveness/no scintilla, and whether the PHOSITA would have/could have arrived at the invention. For that matter, the same reasoning applies to whether testing is routine/not routine. Rather, a purposive approach to obviousness involves an enquiry into the *nature* of the research or testing leading up to the invention, the focal point being a determination of whether or not the testing was *inventive*. As such, it is consistent with a fundamental principle of patent law that a patent must be read by a mind willing to understand and trying to achieve success, not by a one desirous of misunderstanding or looking for failure.[218] As noted in *Whirlpool,* a "mind willing to understand" necessarily pays close attention to the purpose and intent of the author.[219] The term "purposive" need not be used; any term connoting a functional and pragmatic approach aimed at identifying the essence of inventive activity[220] from the perspective of the normative PHOSITA in light of all relevant prior art as of the claim date would suffice.

Finally, a purposive approach to obviousness would be consistent with the direction by the Supreme Court of Canada in *Pushpanathan* to construct legislation in cases involving significant dependence by tribunals on complex evidence and factual expertise in a "functional and pragmatic" manner. While this approach was set out in an administrative context,[221] it has clear ramifications for analysis of pharmaceutical subject matter under the Act. When assessing how much deference a decision is entitled to, the reviewing court must determine the legislative intent behind the statute creating the tribunal.[222] This includes analysis of the essence and purpose of the specific provision and the legislation as a whole, and is therefore analogous to the patent-specific purposive construction outlined by the court in *Whirlpool* and *Free World Trust*. With regard to obviousness, a

215. *Graham*, *supra* note 7 at p. 690, citing Thomas Jefferson.
216. Varma and Abraham, "DNA is Different," *supra* note 95 at p. 55.
217. *Whirlpool*, *supra* note 7 at para. 48; *Catnic*, *supra* note 79 at p. 243.
218. Per Chitty J in *Lister v Norton Brothers and Co.* (EW High CJ Ch., 1886), 3 *Reports of Patent Cases* 199 at p. 203; see also *Free World Trust*, *supra* note 7, para. 44, quoting from *Fox, Canadian Law and Practice*, *supra* note 18 at p. 184.
219. *Whirpool*, *supra* note 7, para. 49(c); see also *Free World Trust*, *supra* note 7 at para. 44.
220. Or in the pre-*Catnic* sense, the "pith and marrow."
221. *Pushpanathan v Canada (Minister of Citizenship and Immigration)* (CAN SC, 1998), <http://scc.lexum.umontreal.ca/en/1998/1998rcs1-1222/1998rcs1-1222.html>, 1998: 1 *Supreme Court Reports* 982.
222. *Pushpanathan*, *supra* note 221 at para. 26.

functional and pragmatic approach would apply to the analysis of section 28 of the Act as it is embedded within the context of the *Patent Act* generally.

Two important developments have occurred since *Pushpanathan* that merit special attention regarding obviousness.[223] The first is the extension of the functional and pragmatic approach to all types of discretionary administrative decisions,[224] and the second is the increased deference owed to tribunals on questions of mixed fact and law.[225] The former applies to obviousness specifically through the decision-making processes of the Patent and Trademark Office, the methods, legal principles and jurisprudence of which are also applied by the courts and *vice versa*, and more generally through application of the functional and pragmatic approach to statutory interpretation by trial and appellate courts. The second applies through a heightened importance of the availability of a clear, unequivocal and fair test for obviousness[226] which respects the normative PHOSITA at the evidence-laden trial stage, given the strongly contingent nature of patent decisions on forms of knowledge and expert testimony that are external to law.[227] In addition, many pharmaceutical cases before the Federal Court are heard under the NOC Regulations and therefore are judicial review proceedings[228] rather than formal infringement or validity proceedings. The object of litigation under the NOC Regulations is solely to prohibit the issuance of a NOC under the *Food and Drug Regulations*;[229] if a party desires a formal decision on the issue of invalidity, they must avail themselves of remedies under the Act.[230]

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5. DIFFERENTIAL IMPACT ON INVENTION & INNOVATION

THERE IS A WELL DEFINED YET DIFFERENTIAL RELATIONSHIP between the standard for obviousness and that for innovation and invention. To start with, the lower the standard for inventiveness, the more patents will be issued and the more patents will be found non-obvious in pharmaceutical cases.[231] Indeed, there is empirical evidence to suggest that a lower threshold for inventiveness supported by patent policies arguing in favour of this strategy[232] correlate positively with the number of inventions deemed patentable by both the Patent and Trademark

223. John D Richard, , "Reaction and Reality, The Future of Tribunals in Canada," keynote address at *A Judicial Perspective on the Recent Developments and Future Challenges Facing Canada's Administrative Decision-Makers* (Château Laurier, Ottawa, 22 November 2002), <http://www.fca-caf.gc.ca/bulletins/speeches/keynote-nov22_e.shtml>.
224. *Baker v Canada (Minister of Employment and Immigration)* (CAN SC, 1999), <http://scc.lexum.umontreal.ca/en/1999/1999rcs2-817/1999rcs2-817.html>, 1999: 2 *Supreme Court Reports* 817.
225. *Housen v Nikolaisen,* 2002 SCC 33,<http://scc.lexum.umontreal.ca/en/2002/2002scc33/2002scc33.html>, 2002:2 *Supreme Court Reports* 235; *Telus Advanced Communications v Telecommunications Workers Union* 2002 FCA 310, <htpp://decisions.fca-caf.gc.ca/en/2002/2002fca310/2002fca310.html>.
226. Bouchard, "Scientific Research," *supra* note 4; Valverde, "Authorizing the Production," *supra* note 164.
227. As discussed in Part 3.2 above.
228. *Eli Lilly & Co. et al. v Apotex Inc. et al.* (CAN Fed CA, 1997), 76 *Canadian Patent Reporter 3d ser.* 1 at p. 5.
229. *Merck Frosst v Minister of National Health & Welfare* (CAN Fed CA, 1994), 55 *Canadian Patent Reporter, 3d ser.* 302 at p. 319 [*Merck (FCA)*]; *Merck Frosst Canada v Canada* (CAN SC, 1998),*<http://scc.lexum.umontreal.ca/en/1998/1998rcs2-193/1998rcs2-193.html>, 2 Supreme Court Reports 3d ser.* 193 at para. 30.
230. *Pharmacia Inc. v Canada (Minister of National Health and Welfare* (CAN Fed CA, 1994), 58 *Canadian Patent Reporter, 3d ser.,* 209, p. 217; *Merck, supra* note 229 at p. 320; *Janssen, supra* note 70.
231. Varma and Abraham, "DNA is Different," *supra* note 95.
232. Robert P Merges, "Uncertainty and the Standard of Patentability," (1992) 7:1 *High Technology Law Journal* 1-70, <http://btlj.boalt.org/data/articles/7-1_spring-1992_merges.pdf> [Merges, "Uncertainty"].

Office ("PTO") and the courts. This conclusion however differs when one substitutes innovation for invention. The definition for innovation used here is that of Schumpeter[233] and Kitch[234]: innovation spans the time from the lead-up to invention, the moment of invention and all subsequent activities relating to product commercialization and launch.[235] Thus, invention is subsumed within innovation and constitutes only a small fraction of the risks and uncertainties encompassed by the latter. Kitch in particular was interested in encouraging efficient innovation and advocated broad patent rights (including exclusive ownership and broad licensing rights and patent scope) in order to recoup transaction costs and mitigate the risks and uncertainties involved in bringing risk-intensive products to market. This was seen to be necessary to motivate innovation and encourage efficient use of patents. Legal commentators and the courts have at times viewed strong patent rights as an appropriate economic solution[236] to the tragedy of the commons problem[237] and some data have been reported supporting the notion that strong intellectual property rights provide a needed level of encouragement to firms and inventors to commercialize rather than invent.[238] In this view, the main focus of patent law is not to encourage invention; rather it is to encourage commercialization and efficient use of ideas not yet reduced to practice in the same fashion as privatizing land is said to encourage landowners to use the resource efficiently.[239] Needless to say an economic theory of patent law that privileges strong patent and regulatory rights is by nature exclusionary and monopolistic.[240] Even so, it has has been widely claimed[241] that a strong role for single patentees in controlling commercialization is necessary in that firms in a highly competitive market, like the pharmaceutical sector, have insufficient incentive to innovate in the absence of strong patent

233. Joseph A Schumpeter, *Capitalism, Socialism and Democracy,* 1st ed. (Harper and Brothers, 1942) at p. 106.
234. Edmund Kitch, "The Nature and Function of the Patent System," (1977) 20:2 *Journal of Law & Economics* 265–290 at pp. 267–268; Robert P Merges, "Of Property Rules, Coase and Intellectual Property," (1994) 94:8 *Columbia Law Review* 2655-2675.
235. Richard R Nelson and Sidney G Winter, *An Evolutionary Theory of Economic Change* (Belknap Press, 1982) at p. 262: "The act of invention creates a new product or process, whereas the broader act of innovation includes the work necessary to revise, develop, and bring that new product or process to commercial fruition. This distinction has been attributed to Schumpeter."
236. Burk and Lemley, "Biotechnology," *supra* note 14 at p. 335; see also Rai, *supra* note 95 at pp. 99, 103, commenting that in *Re: Alappat*, Judge Newman of the Federal Circuit quoted with approval the following statement by the President of du Pont: "no matter how much money we spent on research and development the findings are not going to benefit the public unless there are suitable incentives [for] commercialization"; see also the Forward to Donald S Chisum, ed., *Principles of Patent Law: Cases and Materials* (West Pub/Law & Paralegal, 1998), where Federal Circuit Judge Rich stipulated that the function of the patent system is "to encourage the investment of risk capital in the commercialization of inventors."
237. Garrett Hardin, "The Tragedy of the Commons," (1968) 162 *Science* 1243–1248.
238. Robert P Merges and John Fitzgerald Duffy, *Patent Law and Policy: Cases and Materials*, 3d ed. (Michie Company, 2002) at pp. 727–728; Giorgio Sirilli, "Patents and Inventors: An Empirical Study," (1987) 16 *Research Policy* 157–174 at p. 164; Wesley M Cohen, Richard R Nelson, and John P Walsh, "*Links and Impacts: The Influence of Public Research on Industrial R&D,*" (2002) 48:1 *Management Science* 1–23, ; Ajay Agrawal and Rebecca Henderson, "Putting Patents in Context: Exploring Knowledge Transfer from MIT," 48:1 *Management Science* 44–60.
239. Kitch, *Nature*, *supra* note 234 at pp. 270-271.
240. Lara J Glasgow, "Stretching the limits of intellectual property rights: Has the pharmaceutical industry gone too far?", (2001) 41:2 *IDEA: The Journal of Law and Technology* 227–258, <http://www.idea.piercelaw.edu/articles/41/41_2/2.Glasgow.pdf> at pp. 229–230; see also, Robert P Merges and Richard R Nelson, "On the Complex Economics of Patent Scope," (1990) 90:4 *Columbia Law Review* 839–916, <http://cyber.law.harvard.edu/IPCoop/90merg2.html> at p. 873; Kenneth J Arrow, "Economic Welfare and The Allocation of Resources for Invention," RAND Paper (1962), <http://www.rand.org/pubs/papers/2006/P1856.pdf> at pp. 609, 617–618.
241. Burk and Lemley, "Biotechnology," *supra* note 14 at p. 337.

protection. Indeed Burk and Lemley have stated expressly that the Schumpeter-Kitch model holds as well for the pharmaceutical industry as it does in the biotechnology field due to similar "innovation profiles."[242] This conclusion is logical and stems from the notion that it is desirable as an economic matter to support the grant of strong patents in the pharmaceutical sector as a reward for grappling with the long and costly regulatory process and the high costs of strong innovation in an environment characterized by both scientific and economic uncertainty.

However, extension of the strong intellectual property argument from biotechnology to pharmaceuticals breaks down when what is rewarded with strong patents is not strong innovation but rather minor variations on existing inventions or worse "pseudo-inventions" where patents are granted for line extensions that are ultimately, and it must be said somewhat predictably,[243] held by courts to be invalid. As such, the Schumpeter-Kitch model ignores the significant differences in the scientific and commercial workings of the two industries generally as well as the manner in which they depend on basic research, particularly differences in the amount of in-house research and late stage in-licensing activities in both sectors. It also sidesteps the well-deserved criticism directed at the US $800M figure touted to be necessary for pharmaceutical drug development by DiMassi[244] Operation of the linkage regime governing pharmaceutical products in the United States has been estimated to extend effective patent protection for biomedical inventions up to fifty percent past the original patent term.[245] Indeed, Burk and Lemley themselves properly point out that efforts by pharmaceutical firms to obtain multiple patents on a single invention are "aberrations that represent a failure of [the patent] system rather its normal function."[246] Similar abuses have been described in Canada, and it is fair to say that given the scope of criticism leveled at the pharmaceutical industry for its heavy use of the linkage regulation regime in both jurisdictions that a low standard for inventiveness (equating to a stringent obviousness test from the perspective of competitors) can not, and indeed does not, support strong innovation in this sector, at least not that usually associated with "new" and "useful" inventions in the context of the traditional patent bargain. Regulations of this kind have been wielded by the pharmaceutical industry more as a sword in order to strategically carve out an ever-widening monopoly around old technologies rather than as a shield to protect truly novel inventions, as intended by the historical patent bargain.

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242. Burk and Lemley, "Biotechnology," *supra* note 14 at pp. 334, 351.
243. See for example Caffrey and Rotter, "Consumer protection, patents and procedure" (p. 40) and Ed Hore. *Patently Absurd: Evergreening of Pharmacuetical Patent Protection under the Patented Medicines (Notice of Compliance) Regulations of Canada's Patent Act* (2004), <http://www.canadiangenerics.ca/en/issues/patently_absurd_04.pdf> (at pp. 5 and 11) to the effect that about seventy-five percent of patents litigated on the merits under Hatch Waxman and the NOC Regulations in the United States and Canada are held either invalid or not infringed.
244. Joseph A DiMasi, "New Drug Innovation and Pharmaceutical Industry Structure: Trends in the Output of Pharmaceutical Firms," (2000) 34:4 *Drug Information Journal* 1169–1194; Joseph A DiMasi, "Risks in New Development: Approval Success Rates for Investigational Drugs," (2001) 69:5 *Clinical Pharmacology and Therapeutics* 297, <http://www.gmp.asso.fr/Documents/Biblio/Risks%20in%20new%20drug%20development.pdf>; Gardiner Harris, "Cost of Developing New Medicine Swelled to $802 Million, Research Study Reports," (3 December 2001) *Wall Street Journal* B14.
245. Glasgow, "Stretching the Limits," *supra* note 240 at pp. 255–257.
246. Burk and Lemley, "Biotechnology," *supra* note 14 at pp. 339, 352.

Over the last hundred and fifty years, American courts have grappled not infrequently with the effects of a narrow test for obviousness on innovation and how to appropriately balance public and private interests in the financial rewards of innovation in light of the traditional patent bargain. Most recently, *KSR v Teleflex* wound its way to the United States Supreme Court, eliciting *amicus curiae* briefs from the United States Solicitor General and a collation of law professors.[247] In its brief,[248] the U.S. Solicitor General stated that leading patent jurisprudence from the United States Supreme Court stood for the historical proposition that the standard for obviousness is critical to ensure that free exploitation of ideas will be the rule, to which the protection of a federal patent is the exception.[249] The government further noted that a standard for obviousness that is too low entails substantial transaction costs to the public, as it renders patent examination and litigation more costly, grants patentees unjustified rewards for disclosing non-innovative subject matter, forecloses competitors from using the public storehouse of knowledge that should be freely available to all, and thus prevents the public from benefit of the full patent monopoly. This comports with the U.S. Supreme Court's previous decision in *Graham*,[250] where the court held that the patent system was a carefully crafted bargain designed to encourage the creation and disclosure of new technologies in return for the exclusive right to practice the invention and that the obviousness requirement serves the important "means of weeding out" undesirable inventions. This position was maintained by the *KSR* court, which specifically underscored the importance of the inherent creativity of the PHOSITA and the ability thereof to employ that creativity both explicitly and implicitly in the *post hoc* obviouness analysis, including in the context of routine or workshop-type testing which the court viewed not as a product of innovation but rather of ordinary skill and common sense.

As noted by Lunney,[251] the greater the number of inventions that are in fact non-inventive in nature that are deemed patentable by the courts, the greater the transaction costs involved to the system, including a patent's value for purposes of licensing, assignment and settlement, whether parties will litigate patents and how frequently and how many patents a firm will obtain on the same or similar technology. As discussed above, such patents remain "*in terrorem* of the art,"[252] and enable patentees to obtain unwarranted license fees and monopoly rents under circumstances where they would otherwise receive nothing for such non-inventive disclosures.[253] Indeed, it has been demonstrated[254] that the United States Federal Circuit's pro-patent position, as it relates to

247. *KSR* United States Amicus Brief, *supra* note 42; *KSR* Brief of Twenty-Four Intellectual Property Law Professors, *supra* note 41. For a detailed review of the implications of KSR for Canadian patent law, see Ron A. Bouchard. "*KSR v. Teleflex* Part 1: Impact of U.S Supreme Court Patent Law on Canadian Intellectual Property and Regulatory Rights Landscape" (2008) 15 *Health Law Journal* (forthcoming)
248. *KSR* United States Amicus Brief, *supra* note 41, at pp. 9, 10, 16, 18.
249. *KSR* United States Amicus Brief, *supra* note 41; *Hotchkiss*, *supra* note 7; *Graham*, *supra* note 7.
250. *Graham*, *supra* note 7, at p. 690.
251. Lunney, "E-Obviousness," *supra* note 14 at p. 374.
252. *Royal Typewritter*, *supra* note 207.
253. Lunney, "E-Obviousness," *supra* note 14 at p. 384.
254. Lunney, "E-Obviousness," *supra* note 14, particularly Figs. 1 and 2. Lunney found that the percentage hovered around 70% between 1944 and 1982 and fell to 20% by 1995.

obviousness, has resulted in a substantial reduction in the percentage of patents held invalid on grounds of obviousness since establishment of the court in 1982. This finding is particularly relevant to pharmaceutical litigation because, unlike the biotechnology "revolution" which shifted the direct benefits of publicly funded research from the public to private firms on the understanding it would indirectly benefit the public at some later time, the emphasis of the pharmaceutical industry has always been to enhance shareholder value. A group of law professors in *KSR*[255] claimed that the Federal Circuit's interpretation of the obviousness standard up to that point provided incentives to patentees to seek patent rights on obvious extensions of existing technologies. This is relevant to the pharmaceutical industry, which depends heavily on line extension patents to prevent generic competition- particularly in jurisdictions where market entry is governed by linkage regulations. It was alleged by the law professors that a low standard for patentability leads inevitably to the grant of patent rights for which no patent incentive is needed. Unnecessary patents resulting from an improper test for obviousness lead to higher direct costs to consumers and higher transaction costs associated with the need to negotiate permission from additional patent owners in order to bring obvious combination technologies to market.[256] Weak patents create an unnecessary drag on innovation through higher prices to consumers and transaction costs associated with licensing and enforcing these unnecessary patents, in turn resulting in socially wasteful efforts to patent run-of-the-mill combinations of previously known technologies.

Merges' claim that the standard for obviousness should be sufficiently stringent (low) to compensate for the high cost of innovation[257] is particularly inapplicable to litigation under the NOC Regulations and *Hatch Waxman*. As noted above, this is because linkage regulations in both jurisdictions permit layering of multiple patents on a single marketed drug product. The fact that an essentially infinite number of patents can be listed against a marketed drug provides strong economic incentive for brand-name pharmaceutical companies to engage in low level innovative activity in order to have as many patents as possible to list for a marketed drug product,[258] predominantly under circumstances where patents on the original new chemical entity have expired.[259] The Supreme Court of Canada in *AstraZeneca* has echoed this argument,[260] rendering the reference to brand-name pharmaceutical firms, largely by themselves, as "innovator firms" somewhat ironic. Central to the problem is the fact that most patents listed on the patent register are not those for truly novel breakthrough

255. *KSR* Brief of Twenty-Four Intellectual Property Law Professors, *supra* note 41 at pp. 1, 10, 13.
256. *KSR* Brief of Twenty-Four Intellectual Property Law Professors, *supra* note 41 at p. 10.
257. Merges, "Uncertainty," *supra* note 234.
258. See generally notes 5, 7, 14 and 117 and references in note 112. For a review of patent layering and "evergreening" practices under the Regulations; see Romanow Report, *supra* note 117.
259. Song Hee Hong, Marvin D Shepherd, David Scoones, and Thomas TH Wan Hong, "Product-Line Extensions and Pricing Strategies of Brand-Name Drugs Facing Patent Expiration," (2005) 11:9 *Journal of Managed Care and Pharmacy* 746–754, <http://www.amcp.org/data/jmcp/formular_746-754.pdf> .
260. *AstraZeneca Canada*, *supra* note 5.

inventions,[261] but rather patents for incremental line extensions, which require substantially less investment by firms.[262] Indeed, given the low relevance requirement for listing a patent against a marketed reference product, it is not surprising that a large majority (75%) of patents litigated on the merits under both the NOC Regulations and *Hatch Waxman* have been declared by the courts to be invalid or not infringed.[263] In addition to keeping generic products off market, formulation-intensive line extensions also appear to be responsible for price rigidity[264] of brand-name drugs even after generic pharmaceutical companies get on market with lower priced alternatives. Hong[265] found that price rigidity could be attributed to line extension modifications or piggybacking on previously established market positions for the original patented drug rather than brand loyalty as previously thought: where no line extension existed for a given blockbuster drug, generic substitution of generic for brand versions was typically made by physicians and pharmacists. A similar claim against a low standard for nonobviousness has been made in the biotechnology sector[266] based primarily on the argument that the resulting patent thicket inhibits effecting licensing and subsequent innovation.

Competitive strategies by brand-name pharmaceutical companies under the linkage regulations regime such as those enumerated above have resulted in a substantial and growing imbalance between the needs of pharmaceutical patent holders and those of the market,[267] particularly for consumers who have

261. According to a recent report published in the French *La Revue Prescrire* (1981–2002) and a recent Canadian Patented Medicines Prices Review Board (PMPRB) report, only 1–5% of all new patented medical products in France and Canada are for truly novel products for which there are no existing competitors: See Joel Lexchin, "Intellectual Property Rights and the Canadian Pharmaceutical Marketplace: Where Do We Go from Here?: (2005) 35 *International Journal of Health Services* 237, at 243. In particular, the Canadian PMPRB found over a five year term that of 455 new drugs, 204 (45%) were line extensions, 226 (49.5%) drugs were new products or new dosage forms of existing medicines that provides moderate, little, or no improvement over existing medicines and only 25 (5.5% of total) comprised a substantial therapeutic improvement or breakthrough product. The French report assessed the innovative value of new drugs on the French market. It found that during a 21-year period 7 (0.25%) of 2,693 new drugs marketed constituted a major therapeutic innovation in an area where no treatment was previously available, 73 (10%) were important advances but with limitations and 1,780 (~91%) were either superfluous new products or new indications for older drugs that did not add to the clinical possibilities offered by previously available products. "Drugs in 2001: A number of Ruses Unveiled," (2002) 11*Prescrire* 58–60; Patented Medicine Prices Review Board, *Annual Report 2000*, <http://www.pmprb-cepmb.gc.ca/english/View.asp?x=113&mp=91>. In the United States, the FDA has indicated that only 15% of new medications marketed by brand-name pharmaceutical firms between 1989 and 2000 were true innovative drugs: Hong *et al.*, "Product-line Extensions," *supra* note 259 at p. 746.
262. The term "line extension" refers to a minor variation of an existing product, typically those on which there is substantial profit to be made. Line extensions in the pharmaceutical industry are analogous to those in the biotechnology industry discussed by Burk and Lemley, "Biotechnology," *supra* note 14, Varma and Abraham, "DNA is Different," *supra* note 95 and Rai, "Regulating Scientific Research," *supra* note 95. Line Extensions can be developed with very little effort and do not justify the grant of broad patent rights based either on theories of patent law put forward by Schumpeter, Kitch and Progeny.
263. See for example, Caffrey and Rotter, "Consumer Protection, Patents and Procedure," *supra* note 112; see also Edward Hore, "Patently Absurd: Evergreening of Pharmaceutical Patent Protection Under the Patented Medicines (Notice of Compliance) Regulations of Canada's Patent Act," Canadian Generic Pharmaceutical Association (6 December 2004). The relevance requirement has however been strengthened following amendments to the NOC Regulations in 2006. For an analysis of the reasoning behind this amendment and details of the statutory amendments, see the Regulatory Impact Analysis Statement, *supra* note 115.
264. See Hong *et al.*, "Product-Line Extensions," *supra* note 259: "price rigidity refers to the maintenance of monopoly prices following generic entry."
265. Hong *et al.*, "Product-Line Extensions," *supra* note 259 at p. 752.
266. Burk and Lemley, "Biotechnology," *supra* note 14 at p. 347.
267. See Varma and Abraham, "DNA is Different," *supra* note 95 at p. 55.

difficulty paying monopoly prices on essential medications.[268] As noted by Glasgow,[269] pharmaceutical patent rights result in significant transaction costs to the public and the monopoly granted to patentees can only be justified as a valid incentive to create and innovate to the extent that sufficient creation and innovation of new works occur to offset these costs. The evidence reviewed above however would suggest this is not the case. When compared with profits in the pharmaceutical industry, which are known to be well above that of the average Fortune 500 firm and have been for decades,[270] patent abuses of the type described above and the effects thereof on generic competitors and the public, appear to demonstrate that policies favouring a low threshold for pharmaceutical patentability cannot be justified on economic or public policy grounds. Practices of this nature represent not only an "aberration" of the traditional patent bargain as suggested by Burk and Lemley,[271] but are anticompetitive to the extent they result in unduly expanded "risk zone" for competitors and the public .[272]

Varma and Abraham[273] proposed that the obviousness test is the primary mechanism by which patent law minimizes inefficient transfers of wealth under circumstances patentees obtain the right to exclude others from making or using their invention yet do not add to the store of public knowledge, as would occur where patents are granted on obvious subject matter. Consistent with this argument is the notion that weak or over-extended patents lead to a significant dead-weight loss from the perspective of the public, particularly where monopoly pricing is maintained on products for which the original patent protection has long since expired. Under these conditions, society incurs a monopolistic welfare cost without obtaining truly new and useful products in return. This dilemma underscores the fact that the test for obviousness fulfils the important economic function of preventing undeserved monopoly profits. Concerns of this nature have been expressed by English,[274] American,[275] Australian[276] and Canadian[277] high courts. For example, in *Graham*,[278] the United States Supreme Court cited

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268. Ron A Bouchard, "Balancing Public and Private Interests in Commercialization of Publicly Funded Biomedical Technologies: Is there a Role for Compulsory Government Royalty Fees?" (2007) 13:2 *Boston University Journal of Science and Technology Law* (In Press), <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=981631>.
269. Glasgow, "Stretching," *supra* note 240 at pp. 230, 255–257.
270. A recent survey of Fortune 500 firms demonstrated that the return on capital in the pharmaceutical industry has far exceeded that for an index of all Fortune 500 firms since 1970. Median profits as a percentage of revenue for all firms were approximately 4, 5, 4, and 4% for FYs 1970, 1980, 1990 and 2000 respectively whereas those in the pharmaceutical sector were approximately 9, 10, 14 and 18% for the same years: "Pharmaceutical Industry Ranks As Most Profitable Industry – Again," (April 2002) Public Citizen, <http://www.citizen.org/pressroom/release.cfm?ID=1088>. This was true notwithstanding a potential reduction in research and development times required for drug development from 109 to 71 months (>3 yrs) from FY 1986 to FY 2000: "A Bitter Pill to Swallow: Myths and Realities of the Pharmaceutical Industry," European Generic Medicines Association Report, (2003).
271. Burk and Lemley, "Biotechnology," *supra* note 14, p. 339.
272. *Free World Trust*, *supra* note 7 at paras. 41, 43.
273. Varma and Abraham, "DNA is Different," *supra* note 95 at p. 55.
274. *RCA*, *supra* note 211, p. 195; *Société Technique de Pulverisation Step v Emson Europe Ltd* (1993) 513 *Reports of Patent Cases* at p. 519.
275. *Hotchkiss*, *supra* note 7; see also *Graham*, *supra* note 7.
276. *Aktiebolaget Hassle v. Alphapharm Ltd*, 2002 HCA 59, <http://www.austlii.edu.au/au/cases/cth/HCA/2002/59.html> at para. 164; see also Bureau of Industry Economics, "The Economics of Patents" (Australia, 1994) at p. 45.
277. *Free World Trust*, *supra* note 7 at para.13; *Whirlpool*, *supra* note 7 at para. 37.
278. *Graham*, *supra* note 7 at pp. 688–689.

Thomas Jefferson to the effect that the underlying policy of the patent system is such that inventions must be sufficiently worthwhile to the public to outweigh the restrictive effect of the patent monopoly. While the court noted that the inherent problem was to develop a means of weeding out inventions that would not otherwise be disclosed or devised but for the inducement of a patent, it also held[279] that to support a patent law which produces a minefield of non-inventive patents is "for all practical purposes to debilitate the patent system." Similar sentiments were recently expressed by the Supreme Court of Canada in its *Whirlpool* decision.[280]

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6. SUMMARY & CONCLUSIONS

THE PURPOSE OF THIS ARTICLE WAS TO ANALYSE THE ISSUE of whether scientific testing in the lead-up to invention should vitiate a finding of obviousness in pharmaceutical patent litigation. In particular, the role of the normative PHOSITA was examined. This is because s. 28.3 of the Act requires courts to evaluate obviousness through the eyes of the PHOSITA, in this case persons skilled in the art of industrial pharmaceutical research and development. A review of Canadian cases where the PHOSITA is assumed to possess not even a "mere scintilla" of inventiveness[281] and those adopting Harold Fox's express injunction against testing[282] reveals there is substantial confusion in Canadian courts as to whether testing can be properly contemplated in the obviousness analysis. A stringent standard for obviousness presents a particular problem in the pharmaceutical sector given that regulatory approval and marketing of pharmaceuticals is tied to patent protection for the resulting products via so-called linkage regulations. This is true of no other technology-specific sector in Canada or the United States. I argue that much of the confusion in the case law stems from the realities of the push-pull dynamic between obviousness and inventiveness and how this relates to the identity and inventive capacity of the normative PHOSITA.

In order to gain a better understanding of the issue, a social sciences construction of the normative practices of the pharmaceutical PHOSITA was undertaken. This involved evaluating the scientific norms of industrial pharmaceutical research and development, with particular focus on the identity and inventive capacity of the pharmaceutical PHOSITA. Two analytical methods were employed in the analysis: the tacit and focal knowledgebase framework of Polanyi and actor-network theory as described by Latour. Both methods yielded a nuanced and complex picture of the normative PHOSITA, who was seen to be highly creative and inventive. The normative PHOSITA was also viewed to be comfortable with, indeed strongly adapted to, working under conditions of profound uncertainty and ambiguity, with one eye focused firmly on the commercial, regulatory, legal and political implications of their day-to-day

279. *Graham*, *supra* note 7 at p. 694.
280. *Whirlpool*, *supra* note 7 at paras.41–42; see also *Nova Scotia Pharmaceutical*, *supra* note 193, p. 639; *RCA*, *supra* note 211, p. 195.
281. Part 2 above.
282. Bouchard, "Scientific Research," *supra* note 4.

activities. Moreover, from an ANT perspective, pharmaceutical inventions are not the result of individual scientists working alone in a laboratory but rather are the product of numerous actors working in concert with common (yet diverse) interests in the commercialization of pharmaceutical products. Based on these observations, the normative PHOSITA is more legitimately described using terminology that incorporates a combination of indeterminate and determinate language rather than the binary language currently used to describe both the PHOSITA and the role thereof in the obviousness analysis. As described, the social sciences analysis is consistent with a flexible approach to obviousness, which would allow contemplation of experimental testing in the *post-hoc* analysis without automatically vitiating a finding of obviousness. Finally, even assuming a modern deterministic approach to obviousness, it was demonstrated that certain elements of the "no testing" approach, in particular the "worth a try" formulation articulated by Justice Lederman in *Bayer*, is unworkable in light of current best-practices in pharmaceutical drug development.

The legal nexus between the normative PHOSITA and the test for obviousness was provided by a "purposive construction" of obviousness in accordance with the Supreme Court of Canada's leading patent jurisprudence. A purposive construction emphasizes the essence of an invention, including the steps taken to achieve it, rather than binary notions of testing/no testing, scintilla/no scintilla of inventiveness, whether the PHOSITA viewed the invention as not/worth a try, or whether the PHOSITA would have/could have arrived at the invention. This binary can also be extended to routine/not routine testing in so far as taking that approach is antithetical to recognizing the potential spectrum of inventive and non-inventive activity leading up to invention. Instead, a purposive approach to obviousness focuses on whether the testing leading up to the invention was, in the mind of the normative PHOSITA casting their mind back to the claim date in light of all the prior art, inventive or not, and whether in this light the PHOSITA would have come "directly and without difficulty to the invention." A purposive construction views the concepts of inventiveness and obviousness as tied together in a fluid and graded manner through the contextual and evidence-based skills of the PHOSITA and thus is at once objective and evidence-based, yet contextual.

Finally, it was argued that the purposive approach to obviousness is conducive to domestic and international patent policy which facilitates rather than impedes strong innovation. This is particularly relevant to the North American pharmaceutical industry due to peculiarities in the substance and procedure of the linkage regime governing drug approval and patenting and because the industry has become plagued by non-inventive line extension patents to the detriment of the public. This has resulted not only in less competition between brand and generic firms but also reduced access by the public to essential drugs. The importance of the obviousness test to innovation is underscored by Canadian and American appellate jurisprudence to the effect that the nonobvious requirement is the primary mechanism by which non-inventive patents are weeded out of the system and the public protected from undue patent monopolies.