I. Introduction

Medical research, product development and public health regulation have been on the minds of Canadians lately, due in large part to an array of controversies over the safety and efficacy of marketed drugs and the decision of the Supreme Court of Canada in Chaoulli regarding two-tiered medicine. In addition, Canadians have by now experienced a number of situations where products were approved by the Therapeutic Products Directorate (TPD) of Health Canada, only to experience reduced or even denied access owing to cost considerations. Moreover, the antennae of public interest scholars and commentators are being tweaked repeatedly over the increasing comfort level shown by the government with industry in relation to a wide array of issues relating to public health. These include, but are not limited to, the push by a number of agencies such as Industry Canada, Health Canada,

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the Canadian Institutes for Health Research (CIHR) and Genome Canada to engage in critical debate and policy development with industry over (1) the nature and degree of funding for medical research; (2) the importance of public-private partnerships in commercializing that research; (3) the extent of intellectual property and regulatory (IPR) rights attached to research products; and (4) the manner in which evidence of safety and efficacy is accrued and judged, given the present “front-loaded” approval regime and the potential “progressive licensing regime” for market authorization. Finally, it has become commonplace in media discussions of national productivity and prosperity to focus on stimulating innovation in technology-heavy sectors, particularly in the life and medical sciences.

There are a number of reasons why patent jurisprudence handed down by the Supreme Court of the United States (SCOTUS) is important for scholars of Canadian health law and policy – or indeed for those of any other nation seeking to leverage its domestic science and technology base to enhance productivity in the global marketplace. These can be grouped into three broad categories, each of which revolves around a central focus on IPR rights. The fourth, dealing with a domestic “innovation ecology,” and its relation to a global systems-based innovation ecology, is dealt with separately in a companion paper.

From an economic perspective, Canada is one of the largest trading partners of the United States. Even with a relatively small population of 32M and a GDP of U.S. $1T, total trade between nations was U.S. $500B in 2005. Added to this is the fact that the majority of successful Canadian small and medium sized enterprises (SMEs) in the biomedical industry typically have some form of venture capital funding from U.S. firms. Thus, foreign sources

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6 Hoover Institution, online: Hoover Institution <http://www.hoover.org/>.

of capital, particularly those from our largest and most valuable trading partner, continue to be important to the success of local firms. A related issue is that of economic efficiency for Canadian firms, particularly SMEs coming out of Canadian universities. This is because the costs of patenting and patent litigation escalate dramatically to the degree there are different standards of patentability in different jurisdictions. This concern extends to the growing desire by firms and government for regulatory harmony with the United States and European Union and for deregulation generally, which has become a topic of increasing debate over the last decade via the Smart Regulations policy— and in a manner more focused on medical product development owing to assertive harmonization efforts by Health Canada and Industry Canada in the context of drug approval, public-private partnerships in medical research, and IPR rights associated with food and drugs legislation and regulation.

A second set of issues revolves around the importance of IPR rights to a system of state-sponsored public health. IPR rights are responsible for the determination of whether and for how long products will be protected by patent and regulatory monopolies, and thus whether they are affordable and accessible to large swaths of the public, particularly those who are not shielded from monopoly costs via health care insurance. For example, the availability of cheaper generic alternatives is controlled in Canada, as in

(showing that, over the last seven years, foreign venture capitalists have been the fastest-growing source of venture capital in Canada); Nancy Hizaka-Vilardo, “Canadian Venture Capital Overview,” (Paper presented to the University of Toronto, 2006) [unpublished].


the United States, via so-called “linkage regulations” which tie regulatory approval and market entry of generics to IPR rights held by first entrants under the Patent Act, Food & Drugs Act and Food and Drugs Regulations. In addition to availability per se, IPR rights, and the degree to which they are harmonized with those of other jurisdictions, also dictate the safety and efficacy profile of marketed drugs, whether this is in the context of the historical front-loaded regulatory approval system (based in large part on the precautionary principle) or the new back-loaded progressive licensing regime (based on risk management principles) which would see certain drugs on market after Phase 2 testing rather than following testing on larger Phase 3 cohorts. Furthermore, it is becoming increasingly understood that the basket of IPR rights attaching to medical inventions dictates the distributive allocation of the benefits of publicly funded medical research amongst public and private actors responsible for generating, capitalizing and consuming them. Thus, IPR rights play a major role in determining the availability, price, safety and efficacy of medical products and testing procedures, as well as the degree and manner in which various strata of society benefit from the products of commercialization-intensive, publicly-funded research.

A third set of reasons focuses on the institutional structures that underpin IPR rights afforded to medical inventions. Primary among these is the fact that United States Patent and Trademark Office (U.S. PTO) practice dominates technology and patent-intensive industries such as those in chemical, pharmaceutical, biotechnology, internet-communications technology and natural resources sectors. Due to the larger and more dominant market, the U.S. PTO is often the first global application for Canadian firms.

13 Food and Drugs Act, R.S.C. 1985, c. F-27.
14 Food and Drugs Regulations, C.R.C., c. 870.
16 Bouchard, supra note 4; Bouchard and Lemmens, supra note 4.
More importantly, however, is the notion that SCOTUS is typically the court of first instance for novel patent issues from a global perspective, owing to the well developed nature of technology-intensive industries in the United States (though certainly this is changing over time as other nations become more adept at leveraging their science and technology (S&T) knowledge bases in various domestic, regional and global markets). Considerations such as these have a major impact on domestic health care firms wishing not only to fund and market their products in the United States, but also to gain leverage internationally from U.S.-vetted IPR rights. It is in this light that we look at the recent SCOTUS decision in *KSR v. Teleflex*.

II. *KSR v. TELEFLEX*

In late April 2007, SCOTUS released its decision in *KSR International Co. v. Teleflex Inc.*. In its reasons, SCOTUS explicitly rejected the Court of Appeals for the Federal Circuit’s (Federal Circuit) problematic teaching, suggestion, motivation (TSM) test for obviousness as overly “rigid,” and returned the focus of the test back to the “functional and flexible” factors laid out in the court’s seminal decision in *Graham v. John Deere*.

A. Case History

In November 2002, Teleflex filed suit against KSR, a Canadian corporation, in the United States District Court for the Eastern District of Michigan. Teleflex alleged that KSR infringed U.S. Patent No. 6,237,565 (the ‘565 patent),

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19 *Graham v. John Deere Co.*, 383 U.S. 1 (1966) at 17-18 [Graham] “Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.”
issued to Engelgau and licensed exclusively to Teleflex. The ‘565 patent related to a mechanism connecting an adjustable vehicular gas pedal to an electronic throttle control. KSR claimed Teleflex did nothing other than to combine known elements in a manner that would be obvious to a person having ordinary skill in the art (PHOSITA) and, therefore, that the invention was not patentable due to the fact that the obviousness requirement under §103 of the U.S. Patent Act was not satisfied. As discussed more fully below, both the U.S. Supreme Court and the Supreme Court of Canada have stated that the statutory obviousness requirement is one of the primary levers available to the modern state to weed out inventions that would not be disclosed or devised but for the inducement of a patent, in turn minimizing inefficient transfers of wealth under conditions where a patentee obtains a right to exclude others yet does not add to the store of public knowledge.

The District Court granted summary judgment in favour of KSR in December 2003. The court applied the test for obviousness set forth by SCOTUS in *Graham* informed by Federal Circuit’s TSM test and found there was “little change” in the teaching of the prior art and the claims at issue and thus that a hypothetical person with the appropriate training and expertise in the art would have found the invention obvious. With regard to the TSM test, the District Court held, based on evidence before it, that the state of the industry would lead inevitably to the combination claimed by the patentee and that the prior art contained both the basis for this conclusion and taught the solution faced by the inventors.

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20 §103 of the United States Patent Act (35 U.S.C.) states: “A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title [novelty], if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.”


22 Teleflex Inc. and Technology Holding Co. v. KSR International Co., 298 F. Supp. 2d 581 (2003) [District Court].

23 KSR, supra note 18 at 9 and 16.

24 Ibid.; see also District Court, supra note 22 at 590.

25 KSR, ibid. at 9.
Teleflex appealed, and the Federal Circuit reversed in January 2005.\textsuperscript{26} The Federal Circuit held that the District Court erred because it applied a version of the TSM test that was not “strict enough,”\textsuperscript{27} having failed to establish specific teaching, suggestion or motivation that would have led a person of ordinary skill in the art to combine the relevant prior art teachings in the manner claimed. A similar or parallel problem confronting a skilled technician is insufficient “because unless the prior art references address[ed] the precise problem that the patentee was trying to solve, the problem would not motivate an inventor to look at those references.”\textsuperscript{28} As a result, the lower court failed to address the relevant problem the patentee was trying to solve. The Federal Circuit further noted that genuine issues of material fact existed under the test applied by the District Court which rendered summary judgment of obviousness improper and that the “obvious to try” doctrine could not be used to support a finding of obviousness. The Federal Circuit vacated and remanded back to the District Court for rehearing.

KSR applied for certiorari in April 2005.\textsuperscript{29} In its supporting brief, it argued that the Federal Circuit’s motivation test was inconsistent with the Supreme Court’s Graham decision, claiming that in none of the decisions in which SCOTUS addressed the standard of patentability set forth in §103 did the court hold that “the statute was inapplicable to a claimed invention in the absence of some proven ‘teaching, suggestion, or motivation’ to combine or modify prior art references.” KSR also argued that if the TSM test is upheld, then “the ultimate question of patent validity under §103 effectively ceases to be a question of law, but is made to depend, instead, on the outcome of a hugely costly and unpredictable litigation over whether a hypothetical ‘person having ordinary skill in the art’ would have had hypothetical ‘motivation to combine’ pre-existing components for a particular application at a point in time.”

Conversely, Teleflex argued that the Federal Circuit’s ruling and TSM test generally were wholly consistent with the test for obviousness laid out by SCOTUS in Graham because under that test “the obviousness inquiry is highly fact specific.” In particular, Teleflex claimed\textsuperscript{30} that KSR’s allegations

\textsuperscript{26} (6 January 2006), 04-1152 (U.S.Fed. Cir.)[Federal Circuit].
\textsuperscript{27} KSR, supra note 18 at 9.
\textsuperscript{28} Ibid. at 10.
\textsuperscript{29} KSR International v. Teleflex Inc., 127 S. Ct. 1727 (2007) (Brief of the Petitioner).
rested on a “false caricature” of the Federal Circuit’s TSM inquiry as rigid, claiming that the Federal Circuit repeatedly held that the TSM test encompasses any available indication that a practitioner in the art would have had some reason to select certain elements of the invention, and thus includes evidence of “implicit” sources of motivation. As such, KSR and Teleflex took opposing views of the Federal Circuit’s TSM test: the former claiming it was narrow, rigid and exclusionary and the latter claiming that it was broad, flexible and contextual.

The United States Solicitor General (Solicitor General) was invited to submit a brief in October 2005. The Solicitor General took the position that the Federal Circuit’s TSM test conflicted with previous SCOTUS patent jurisprudence, placing undue restrictions on invalidating obvious patents under §103. This in turn resulted in unnecessary litigation costs and harm to competition. The doctrinal focus of the government’s brief was that Graham set forth a “flexible and functional” approach for determining obviousness which unlike the Federal Circuit’s rigid TSM test, represented an objective yet contextual framework for determining obviousness. A second and related concern expressed by the Solicitor General was that the Federal Circuit erred in treating one specific method of determining obviousness (TSM) as the exclusive means of showing obviousness, thus forgoing the flexible and functional approach mandated by Graham. The government also noted that prior high court jurisprudence stood for the proposition that the standard for obviousness is critical to ensure that free exploitation of ideas is the rule, to which the protection of a federal patent monopoly is the exception. A standard for obviousness that is too low inevitably entails substantial transaction costs to the public, as it sows the seeds for subsequent patent litigation, 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 prevents the public from enjoying the full benefit of the traditional patent monopoly. Shortly after the government filed its brief in May 2006 it was suggested that the

32 Hotchkiss v. Greenwood, 11 How. 248, 52 U.S. 248 (1851); Graham, supra note 19 at 3-4 and 11-12.
33 Citing an undocumented study by a “patent law professor,” Denis Crouch stated in his popular patent blog (Patently-O) that in cases where the U.S. Solicitor General issued an unqualified grant recommendation, grant rate by SCOTUS
unqualified recommendation by the Solicitor General presumably all but guaranteed grant of certiorari, which turned out to be correct.

The tone of the Solicitor General brief comports with the decision by SCOTUS in Graham,34 where the court held 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 practise the invention and that the obviousness requirement serves the important means of “weeding out” undesirable inventions. Indeed, as noted by Lunney,35 the greater the number of inventions that are in fact non-inventive (obvious) yet deemed patentable by the courts, the greater the transaction costs involved to the system, including determining the value of a patent for purposes of licensing, assignment and settlement, whether and how frequently parties will litigate patents, and how many patents a firm will obtain on the same or similar technology in order to avoid litigation. Such patents remain “in terrorem of the art,”36 enabling patentees to extract unwarranted license fees and monopoly rents under circumstances where they would otherwise receive nothing for such non-inventive disclosures.37 As discussed previously, the notion that the standard for obviousness is an important policy lever for government to control the socially efficient transfer of wealth in the context of “needed goods” such as innovative medical products and tools has particular relevance to multinational pharmaceutical and biotechnology firms.38

was 100% to date (15 of 15). In comparison, in cases where the Solicitor General makes “some sort” of a grant recommendation (qualified or unqualified), the grant rate was 90% to date (18 of 20) (the date at issue being June 7th, 2006). See Patently-O, online: <http://www.patentlyo.com/patent/2006/06/ksr_v_teleflex_.html>.

34 Supra note 19 at 10-11.
36 Royal Typewriter Co. v. Remington Rand, 168 F.2d 691 (2d Circ. 1948) [Royal Typewriter].
37 Lunney, supra note 35 at 384.
The Solicitor General was not the only amici in KSR. In excess of thirty-five amicus curie briefs were filed; of these approximately one third supported KSR, with the remaining two thirds supporting Teleflex. Other than that of the Solicitor General, the other brief seen to be influential was that by a group of twenty-four patent law professors (Law Professors), who claimed that the Federal Circuit’s current interpretation of the obviousness standard provided too many incentives for patentees to seek patent rights on obvious extensions of existing technologies. Unnecessary patents resulting from an improper test for obviousness thus lead to higher costs to consumers and higher transaction costs for the system due to the need to negotiate permission from numerous patent owners in order to bring obvious combination technologies to market and costs associated with licensing and enforcing unnecessary patents. Weak patents therefore create a drag on innovation.

SCOTUS granted certiorari June 2006, heard argument November 2006, and released its decision April 2007 after months of speculation regarding potential evisceration of the TSM test. However, while SCOTUS did overturn the TSM test as overly narrow, rigid and inconsistent with a determination of obviousness under §103 as illuminated by Graham, the court did not completely repeal it as feared. Rather, the test was demoted from a central focus to a helpful insight in the obviousness analysis, a point underscored by the U.S. PTO in its memorandum to the patent bar dated May 3, 2007, shortly after the decision was released.

Writing for a unanimous court, Justice Kennedy reaffirmed the functional and flexible approach to obviousness in Hotchkiss and Graham. The court held the Federal Circuit made four fundamental errors of law relative to the version of the TSM test applied in the case; in particular, it was incorrect for the Federal Circuit to determine obviousness exclusively by: looking

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41 KSR, supra note 18.
only at the narrow problem the patentee was trying to solve; determining that a person having ordinary skill in the art would be led only to that portion of the prior art designed to solve the same problem; determining that a patent claim could never be proved by showing the combination of elements was “obvious to try;” and by placing too much emphasis on hindsight bias in its determination of obviousness.\textsuperscript{42} The court rejected the Federal Circuit’s TSM test as narrow and rigid, shifting it instead to a “helpful insight.”\textsuperscript{43} Based on these errors, SCOTUS reversed and remanded the case for further proceedings consistent with the court’s opinion.\textsuperscript{44}

By encompassing both explicit (pre-\textit{KSR} TSM test) and implicit factors (PHOSITA going beyond the specific problem to be solved and related prior art using common sense and ordinary creativity), SCOTUS sidestepped the tautology inherent in the version of the TSM test applied by the Federal Circuit before \textit{Dystar}\textsuperscript{45} and \textit{Alza}.\textsuperscript{46} That is, an invention is obvious in the context of “Problem A” only where Problem A was expressly addressed in the prior art and was not solved. Previously, prior art used to identify or solve any other problem (e.g., Problem B, C, etc.); no matter how related it might be to Problem A was deemed to be insufficiently specific to guide the court to an opinion that the invention was obvious. The nuances of the decision relevant to Canadian law are presented in Section III.A., below.

The aftermath of the decision was marked by apparent controversy, if nothing else. In the days following release of the decision, there was anxiety on several high traffic patent blogs,\textsuperscript{47} leading to speculation that \textit{KSR} would open the floodgates to increased obviousness rejections, declarations of existing patents as invalid and increased litigation for actors in patent-intensive sectors – in short, “dark clouds of uncertainty” for paten-

\textsuperscript{42} \textit{Ibid.} at 6-17.
\textsuperscript{43} \textit{Ibid.} at 14-15.
\textsuperscript{44} \textit{Ibid.}, at 24.
\textsuperscript{46} \textit{Alza Corp. v. Mylan Labs Inc.}, 464 F.3d 1286 (2006) at 1291 [\textit{Alza}].
\textsuperscript{47} Patently-O, online: <http://patentlaw.typepad.com/>;
Patent Docs, online: <http://patentdocs.typepad.com/patent_docs/>;
The Fire of Genius, online: <http://www.thefireofgenius.com/>;
Patent Baristas, online: <http://www.patentbaristas.com/>;
Orange Book, online: <http://www.orangebookblog.com/>.
tees. In its comments on the case, the American Bar Association, which filed an *amicus* brief in support of Teleflex, went so far as to say SCOTUS had completely failed to set out a firm, clear test for obviousness. Reactions in the coming months were, not surprisingly, more nuanced and balanced and the decision was seen to have rocked the boat far less than anticipated. The position in print and electronic media by late 2007 was that *KSR* did not radically change the law of obviousness. This was supported by a memo from the U.S. PTO as early as May 3, 2007. Formal guidance by the U.S. PTO in October 2007 and case law since spring 2007 affirm that (a) *KSR* returned emphasis of the obviousness determination to the broad and flexible *Graham* factors informed by the objective yet contextual requirements of §103, and (b) that the TSM test remains relevant in determining obviousness. As discussed in detail below, the decision by SCOTUS in *KSR* is consistent with the view that inventions come into being in a highly complex and inherently creative fashion rather than in a simple linear and discrete manner.

### III. Implications for Canadian IPR Rights Landscape

#### A. Relevance to Canadian Patent Law Embedded Within a Global Patent Jurisdiction

(i) *Creativity and Inventiveness of the PHOSITA*

Central to *KSR* is how scientists working in the relevant art of invention were perceived by the U.S. Supreme Court and the reach of that perception into the construction and application of the legal test for obviousness. The decision underscored the inherent creativity of the PHOSITA and the ability of skilled technicians to employ that creativity both explicitly and implicitly.

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52 *KSR, supra* note 18 at 2.
in construing the prior art.\textsuperscript{53} For example, SCOTUS stipulated that the PHOSITA is endowed with sufficient creative abilities to enable him or her to look not just at explicit prior art relative to “Problem A,” but also to elements of the prior art designed implicitly to solve similar problems within the same industry or parallel problems in different industries.

The court stated expressly that the PHOSITA is not an automaton,\textsuperscript{54} adding context to the effect that “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.” From an evidentiary perspective, the level of skill and common sense is pitched neither at the level of the ordinary citizen nor at that of the inventor, but rather at the level of the ordinary person skilled in the art in that technical field.

The standard was clarified in two post-KSR pharmaceutical cases,\textsuperscript{55} where the Federal Circuit noted that there is no inventive step where a PHOSITA would have perceived a “reasonable likelihood of success” or “reasonable expectation of success” in pursuing a particular path towards invention, including in the context of “routine experimentation” using “well known” problem solving strategies. That routine experimentation is not the proper subject of a U.S. patent is supported by a line of pre-KSR appellate law\textsuperscript{56} and is wholly consistent with the notion that the normative PHOSITA is inherently creative and inventive.\textsuperscript{57}

\textsuperscript{53} Ibid. at 16-17, 24.
\textsuperscript{54} Ibid. at 17.
\textsuperscript{55} Alza, supra note 46; Pfizer Inc., v. Apotex Inc., 480 F. 3d 1348 (Fed. Cir. 2007) [Phizer]; see also Leapfrog Enterprises Inc. v. Fisher-Price and Mattel Inc., Case No 06-1402 (Fed. Cir..2007).
\textsuperscript{56} Pfizer, ibid.; see also In re Marck, 874 F.2d at 809 (citing In re Dow Chemicals Co., 837 F.2d 469 (Fed. Circ. 1988) at 473); In re Geisler, 116 F.3d 1465 (Fed. Circ. 1997) at 1470; In re Aller, 220 F.2d at 456; In re Kulling, 897 F.2d 1147 (Fed. Circ. 1990) at 1149; In re Luck, 476 F.2d 650 (CCPA 1973) at 652; In re Esterhoy, 440 F.2d 1368 (CCPA 1971) at 1389; In re Swentel, 219 F.2d 216 (CCPA 1955) at 219; In re Swain, 156 F.2d 256 (CCPA 1946) at 247.
(ii) Application to Obviousness in Canada

The level of creativity of the PHOSITA is central to numerous aspects of Canadian law on obviousness. Indeed, influential courts\(^5^8\) have taken the firm position in their leading patent jurisprudence that the PHOSITA cannot possess even a “mere scintilla” of inventiveness,\(^5^9\) particularly in biomedical litigation.\(^6^0\) Canadian courts, particularly the Federal Court of Appeal,\(^6^1\) continue to maintain this position notwithstanding increasing aspects of obviousness law relating to the medical sciences that render the assumption unworkable. This includes the fact that the PHOSITA is described as having read and understood all of the relevant prior art available; is endowed with all of the common knowledge pertinent to the field and all skills required to practice the invention\(^6^2\); is cognitively equipped to make all necessary logical and rational deductions required in order to understand and arrive at the invention\(^6^3\) (including conducting, analyzing and interpreting the results of...

\(^5^8\) Federal Court of Canada, Federal Court of Appeal and the Ontario Court of Appeal.

\(^5^9\) Beloit Canada Ltd. v. Valmet OY (1986), 64 N.R. 287, 8 C.P.R. (3d) 289 (F.C.A.) at 289 [Beloit]: “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.”

\(^6^0\) Bayer Aktiengesellschaft v. Apotex Inc., (2002), 16 C.P.R. (4\(^{th}\)) 417, [2002] O.J. No. 193 (C.A.) [Bayer]. Note while this case is an Ontario Court of Appeal decision, it has been cited with approval many times by the Federal Court of Canada and the Federal Court of Appeal, which hear substantially more patent cases, particularly those under the NOC Regulations. See Bouchard “Should,” “Living,” supra note 38 for review.


mechanical, routine or workshop-type testing); is a “paragon” of dexterity in undertaking those activities; is enabled by all relevant knowledge, best practices and prior art in the industry at the time of the claim date; and is employed in a state of the art research facility equipped with all relevant equipment and technology needed to derive or at least understand the invention. To make matters worse, the PHOSITA is deemed to spend his or her daily life in experimentation in pursuit of these goals, yet still has no spark of creativity.

Ironically, construction of the mythical PHOSITA was intended to render the test for obviousness objective rather than subjective, yet over time its application by Canadian courts has turned the test into one that is highly rigid in nature, not unlike the Federal Circuit’s pre-KSR TSM test. Given that the skilled technician has a mind willing to understand everything that is necessary in order to successfully solve the problem before him or her, and is not looking to fail in his or her research and development endeavors, it is perhaps understandable that a number of Canadian judges are beginning to take the position that it is appropriate for the court to cast the definition of the PHOSITA “well above the concept of an individual having no scintilla


64 Ibid., generally.
65 Beloit, supra note 59 at 294; Procter & Gamble Pharmaceuticals Canada Inc. v. Canada (Minister of Health), 2004 FCA 393 at para. 44, 248 D.L.R. (4th) 674 .
67 Bayer, supra note 60 at para. 61.
of inventiveness or imagination.”

Importantly, imparting creativity and inventiveness to the PHOSITA comports with the realities of contemporary drug development in multinational firms and is consistent with the fact that the PHOSITA provides the lens through which the court must gaze not only for obviousness, but also for most other aspects of the patentability analysis, such as anticipation, utility, enablement, sound prediction, ambiguity, lack of novelty, improper subject matter and whether the patent claims are broader than the disclosure section of the patent.

This lack of inherent creativity and inventiveness of the PHOSITA is the focal point for a number of undue “binary” (all or nothing) determinations relating to obviousness by Canadian courts, such as (1) whether the PHOSITA may properly consider routine, or indeed any, testing in the lead-up to invention in his or her determination of obviousness; (2) whether a PHOSITA exhibits more than a mere scintilla of inventiveness in his or her analysis; (3) whether the PHOSITA properly considered the impugned invention “obvious to try;” and (4) whether the PHOSITA “would have” v. “could have” arrived at the invention. The latter two issues relate directly to the creative capacity of the PHOSITA, as clearly a complete lack of inventiveness would preclude any such testing, even though it may have been completely obvious to undertake it based on the prior art.

The Canadian position on each of these points stands in stark contrast to appellate patent jurisprudence in other jurisdictions, particularly following KSR.

Generally, 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.


72 For example, in Pfizer Canada Inc. v. Novopharm Ltd., 2005 FC 1299, 42 C.P.R. (4th) 502, Justice Blanchard held (at para.119) that under current Canadian law it can be scientifically obvious to arrive at an invention in practice but that this need not be equivalent to a finding of legal obviousness. See also Bayer, supra note 60; Farbwerke Hoescht Aktiengesellschaft v. Halocarbon (Ontario) Ltd., [1979] 2 S.C.R. 929, 42 C.P.R. (2d) 145. For review of case law prohibiting per se “testing” and those arriving at the same conclusion in the obviousness determination through the “no scintilla” line of cases, see Bouchard “Should,” “Living,” supra note 38.
inventions. The lens through which the court must gaze is that of the skilled technician. An issue that frequently comes up in the obviousness analysis is whether or not experimental research or testing conducted in the lead-up to invention may be properly contemplated by the PHOSITA in order to conclude whether or not the invention constitutes a sufficient inventive step to be patentable. This is a critical component of the obviousness test, given that scientific inventions – particularly those in the life sciences – do not come about de novo. The issue of “testing” is thus shorthand for whatever scientific experimentation and research were conducted prior to crystallization of the invention. Testing that is non-inventive has been referred to by American, and some Canadian, courts as routine, ordinary, logical or workshop in nature.

Patentability of inventions based on routine workshop-type activity and the relationship thereof to innovation and competition law has a rich history in American, compared to Canadian appellate patent law. American courts have generally taken the position that routine workshop activity is not deserving of the patent monopoly and stifles competition. Under KSR, routine

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74 Section 28.3 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.

75 For review, see Bouchard “Living,” supra note 38. See also Hotchkiss, supra note 32; Graham, supra note 19; and KSR, supra note 18.

76 In Hotchkiss, SCOTUS held (at 267): “Unless more ingenuity and skill ... were required ... than were possessed by an ordinary mechanic acquainted with
testing in the lead-up period to invention that has a reasonable expectation of success can be properly contemplated by an ordinarily creative PHOSITA in the obviousness analysis. SCOTUS was clear on this issue, stating that “the results of ordinary innovation are not the subject of exclusive rights under patent law;” otherwise, “patents might stifle rather than promote the progress of useful arts,” contrary to the United States Constitution.

Unfortunately, this is not true of the Canadian PHOSITA, who by virtue of a complete lack of inventiveness cannot contemplate even the simplest testing leading to invention. Thus, scientific testing in the lead-up to invention vitiates obviousness in Canada, but not in the United States. As a result, the reference point for the obviousness analysis in Canada is the PHOSITA who has much less than the average level of normative creativity, or is indeed no PHOSITA at all due to a de minimus level of creativity. The result in either case is the removal of the PHOSITA from the determination of obviousness – contrary to section 28.3 of the Patent Act.

The level of creativity imparted to the PHOSITA by Canadian courts not only influences the determination of obviousness in the context of routine research but, as a PHOSITA with no inventiveness whatsoever clearly could not even contemplate testing in the lead-up to invention, it also forms the basis for rejection of obviousness in the “obvious to try” or “worth a try” cases (though one might argue these are different terms), as well as the requirement in Canadian law that a skilled technician “would” have arrived at an invention rather than “could” have arrived at it using ordinarily creative abilities. In other words, the skilled technician must have (rather than may have) come directly to the invention given the prior art and problem to be solved. The former is akin to the rigid requirement of the pre-KSR TSM test 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 Corp. v. Automatic Devices Corp., 314 US 84 (1941) and Graham, supra note 19.

77 KSR, supra note 18 at 13-16, 24.
78 Ibid. at 24.
79 U.S. Const., art. 1, § 8, cl. 8.
80 Beloit, supra note 59; Bayer, supra note 60; Q'Max, supra note 61; Sanofi-Synthelabo Canada Inc. v. Apotex Inc., 2006 FCA 421, 282 D.L.R. (4th) 179.
81 For application to U.S. and Canadian law, see Eisenberg, supra note 57 and Bouchard “Should,” “Living,” supra note 38.
in the context of “Problem A” described supra, while the latter is consistent with the ability of the PHOSITA to locate the invention implicitly in the prior art using an ordinary level of creativity under KSR. The lack of inventive ability of the Canadian PHOSITA is therefore responsible for the fact that four major areas of patent law in Canada are in complete disagreement with leading American patent jurisprudence. A similar discordance exists with respect to the creative abilities of the English PHOSITA.\textsuperscript{82}

B. Potential Impact on Canadian Inventors and Firms

On one hand, a low standard for patentability in Canada compared with jurisdictions with similar patent legislation will lead to a larger number of Canadian patents being issued. Similarly, multinational firms who have had weak patents invalidated in American, European or pan-Asian courts may see Canada in a comparatively attractive light (provided the market is sufficiently large to bear the costs of acquiring and enforcing IPR rights). In this sense Canada will be seen as a source of low hanging fruit for patents of a certain value.

On the other hand, it is equally if not more plausible that a comparative lowering of the standard for patentability in Canada may place undue and heavy burdens on Canadian inventors and firms that attempt to commercialize patented products and processes in the United States or more globally. In a global market where regulatory and jurisprudential harmony is becoming an increasingly valued commodity, domestic outliers will likely be seen as incongruent and costly outsiders from the perspective of both governments and firms. Clearly a scenario such as this, while hypothetical, has the potential to diminish the acquisition and licensing of disparate forms of intellectual property, but also to inhibit commercial partnership arrangements and render valuation of patents in the context of due diligence activities more expensive and burdensome.

\textsuperscript{82} For example, in Bayer, supra note 60, Justice Lederman commented (at 66) that there is: “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.” For a description and discussion of the creative abilities of the English PHOSITA in the context of invention in the medical sciences, see Genentech, supra note 63.
Given the escalating costs of patenting globally, a disparate set of patentability requirements in one jurisdiction would further suggest that acquiring global IPR rights may become prohibitively expensive for inventors and firms, especially for more vulnerable SMEs located in smaller markets. Not surprisingly, cost and administrative considerations of this nature have been frequently expressed by entrepreneurs and patent attorneys on both sides of the Canada-U.S. border since *KSR* was released. Indeed, Canadian firms and inventors, and their international partners, may decide not to patent in Canada at all to the extent that the requirements and costs of doing so are out of line with either their global IPR rights strategy or the size of the Canadian market. None of this bodes particularly well for the short-term global competitiveness and productivity of Canadians, and would be particularly ironic should the current test for obviousness breach any of the constitutional requirements to be unequivocal, predictable and fair, as argued previously.\(^83\)

### C. Importance of the Standard for Obviousness for Innovation and Competition

It is relatively straightforward that a disparate set of patentability requirements may be more costly in the short term to Canadian firms and inventors. Less obvious, however, is that a lower standard for patentability (in Canada or otherwise) may inhibit inventors and firms in their inventive and innovative endeavors over a longer time frame and where, as is true in the current public health context, the commercialization, availability and price of patented products are significantly influenced by domestic and international IPR rights.

Indeed, the importance of the push-pull between obviousness and inventiveness for a broad system of IPR rights-based innovation cannot be overestimated. Both the U.S. Solicitor General and SCOTUS have highlighted the importance of patent law in balancing innovation and competition. As noted by SCOTUS in *KSR*, “Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, for patents combining previously known elements, deprive prior inventions of their value or utility.”\(^84\) As a result, so-called weak patents

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83 Bouchard “Should,” *supra* note 38.
84 *KSR*, *supra* note 18 at 5.
“stifle, rather than promote, the progress of useful arts,” contrary to the U.S. Constitution.  

Landmark work by Teece has demonstrated that profits from innovation depend critically on the provisions of the existing appropriability regime available to support it. As discussed by Dosi et al., appropriability may indeed display a critical threshold effect in that a minimum level of IPR rights are necessary to motivate innovation, following which further strengthening of rights does not stimulate further innovation. Rather it encourages numerous types of social inefficiencies related to the acquisition and enforcement of IPR rights. This is an important consideration as it implies that linear rights stacking beyond a certain point will not yield further increases in innovative activity, as is often assumed. The non-linearity of the relation between IPR rights and innovation has particular resonance in the life sciences, owing to the fact that product development is far more costly than in other sectors and because the risks to human health assumed by ultimate end-users do not exist in other industries. Indeed, the Supreme Court of Canada stipulated in that patents involving pharmaceuticals are a special case with regard to the traditional patent bargain because of the considerable public interest at stake. As a result, pharmaceutical patents must be scrutinized carefully in order to determine if they merit grant of a monopoly privilege. This view explicitly rejects patents in the medical sciences as “sim-

85 Ibid. at 24.  
86 Supra note 79.  
88 Giovanni Dosi, Luigi Marengo & Corrado Pasquali, “How Much Should Society Fuel the Greed of Innovators? On the Relations Between Appropriability, Opportunities and Rates of Innovation” (2006) 35 Research Policy 1110 at 1111 (stating that “appropriability is likely to display a threshold effect, meaning that a minimum degree of appropriability is necessary to motivate innovative effort, but above such a threshold further strengthening of appropriability conditions will not determine further increases of R&D investments and rates of innovation. Rather, social inefficiencies such as ‘anti-commons’ effects ..., rent seeking behaviors, dissipation of quasi-rents into litigation etc. are much more likely to emerge”).  
89 Canada (Commissioner of Patents) v. Farbwerke Hoechst, [1964] S.C.R. 49 at 50, 41 C.P.R. 9 [Farbwerke].
ply property.” and is consistent with the court’s 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.

The position taken by SCOTUS in its leading patent jurisprudence, from *Hotchkiss*, through *Graham* to *KSR*, has been remarkably consistent over nearly a century and a half in tracking concerns expressed by the original framers of the U.S. Constitution regarding the need to balance the patent monopoly while stimulating healthy competition; that is, that patent law generally and the standard for obviousness specifically provides one of the more valuable mechanisms for government to weed out inventions that would not otherwise be disclosed or devised but for the inducement of a patent, and thereby to minimize inefficient transfers of wealth from a societal perspective. The obviousness requirement therefore fulfils the important economic function of preventing undeserved monopoly profits. As noted in the companion paper in the context of complex innovation networks, poor government oversight of patent policy, legislation and regulation can lead to significant social inefficiencies and costs to the public under conditions where monopoly pricing is maintained by overly broad, overly narrow or otherwise poorly thought out IPR rights. Reasoning of this nature permeates English, American, Australian, as well as Canadian, high courts. For example, in *Graham*, the U.S. Supreme Court cited Thomas Jefferson to the effect that the policy underpinning the patent system properly dictates that inventions that are sufficiently worthwhile to the public to warrant an exclusive patent must outweigh the restrictive effect of that monopoly.

90 Lunney, supra note 35 at 381-388.
91 Free World Trust, supra note 62 at para. 42; see also *RCA Photophone Ltd. v. Gaumont-British PictureCorp.* (1936), 53 R.P.C. 167 (C.A.) at 195 [*RCA Photophone*].
92 *Farbwerke*, supra note 89 at para. 18.
93 Varma & Abraham, supra note 21 at 55.
94 *RCA Photophone*, supra note 91 at 195; *Société Technique de Pulverisation Step v Emerson Europe Ltd.* (1993), R.P.C. 513 at 519 (C.A.).
95 *Hotchkiss*, supra note 32. See also *Graham*, supra note 19 at 3-4, 11-12.
97 Free World Trust, supra note 62 at 13; *Whirlpool*, supra note 62 at 37.
98 *Graham*, supra note 19 at 10-11.
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 expressed by the Supreme Court of Canada in its leading Whirlpool decision, where the court stated that improperly granted patents have the potential to significantly “chill” competition, to the detriment of the public.

The Solicitor General stated in its KSR brief that SCOTUS jurisprudence stood for the historical proposition that the obviousness requirement is critical to ensure free exploitation of ideas is the rule, to which the protection of a federal patent is the exception. A standard 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 and forecloses competitors from using the public storehouse of knowledge that should be freely available to all. It therefore prevents the public from benefit of the full patent monopoly. This comports with the court’s earlier decision in Graham, where SCOTUS held that the patent system was a carefully crafted bargain designed to encourage the creation and disclosure of new technologies in return for the right to practise the invention.

The text of KSR indicates a clear concern for the role of law in stimulating innovation, competition and progress in the useful arts, consistent with the Hotchkiss and Graham decisions and the language and narrative in the Solicitor General’s influential brief. It is this language and narrative that are sorely missed in leading Canadian jurisprudence on obviousness, particularly that of the Federal Court of Appeal. Undue incentives in the form of weak patents and their easy leveraging into market monopolies via certain forms of IPR rights – such as overly permissive patent jurisprudence and legislation – have become particularly problematic in the pharmaceutical industry, owing to its increasing dependence on the patentability of “me too” and formulation-intensive “line extension” products. For this reason,

99 Ibid. at 18.
101 Solicitor General Brief, supra note 31 at 9, 10, 16 and 18.
102 Hotchkiss, supra note 32; Graham, supra note 19 at 3-4, 11-12.
103 See also Law Professors, supra note 39 at 1, 10 and 13.
104 Supra note 19 at 10-11.
biotechnology firms (increasingly SMEs)\textsuperscript{105} are being looked to as the major source of invention and innovation in the life sciences.

Granting weak patents also provides a source of legitimate frustration for inventors and assignees of truly novel products and processes who are tarred with the same brush as patent trolls or other parties holding patents on non-inventive or weakly-inventive products and processes that are nevertheless protected by patent monopolies.\textsuperscript{106} These patents can in turn be used to chill competitors and thus prevent consumers from having access to novel or breakthrough products.\textsuperscript{107} For example, Lunney\textsuperscript{108} recently reported that the greater the number of inventions that are in fact non-inventive yet deemed patentable by the courts, the greater the transaction costs 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. Patents also hijack the IPR rights landscape,\textsuperscript{109} allowing patentees to extract unwarranted license fees and monopoly rents where they would otherwise receive nothing for non-inventive disclosures.\textsuperscript{110} A related finding was that the Federal Circuit’s pro-patent position on obviousness led to a substantial reduction in the percentage of patents deemed invalid based on obviousness,\textsuperscript{111} a circumstance no doubt related to legislation providing opportunity for ever-greening of products on which patents on the original chemical entity have long expired.\textsuperscript{112} Thus, in a complex system of innovation involving scientific, political, economic and legal considerations, weak patents and poorly considered case law can lead to numerous interrelated downstream

\textsuperscript{106} See for example data in Caffery & Rotter, supra note 11 and Hore, supra note 10 demonstrating that 75% of patents litigated on their merits under respective U.S. and Canadian “linkage regulations” regimes are either invalid or not infringed, yet keep corresponding generic products off market until all relevant patents are litigated.
\textsuperscript{107} Nova Scotia Pharmaceutical, supra note 100, as applied in Whirlpool, supra note 62.
\textsuperscript{108} Supra note 35 at 374.
\textsuperscript{109} Supra note 36.
\textsuperscript{110} Supra note 35 at 384.
\textsuperscript{111} Ibid., particularly Figs. 1 and 2 (noting that the percentage hovered around 70% between 1944 and 1982 and fell to 20% by 1995).
\textsuperscript{112} Caffrey & Rotter, supra note 11; Hore, supra note 10.
effects that combine to produce higher costs for consumers and an unnecessary drag on innovation.  

**IV. Summary & Conclusions**

In *KSR*, SCOTUS retooled the standard for obviousness to bring it back in line with the court’s previous decisions in *Hotchkiss* and *Graham*. A comparative review of the law of obviousness in the United States and Canada, and its relation to innovation and competition, was undertaken in Sections II and III. The focal point of observed differences is the inherent creativity and inventiveness of the PHOSITA, which in turn informs several binary and highly rigid aspects of Canadian patent law relevant to a statutory determination of obviousness. While American and English skilled technicians are viewed by courts in their parent jurisdictions as inherently creative and thus able to construe the prior art both implicitly and explicitly, the Canadian PHOSITA possesses not even a “mere scintilla” of inventiveness. As such, the reference point for the obviousness analysis in Canada, but not in the U.S. or U.K., is a PHOSITA who has much less than the average level of normative creativity, who is indeed no PHOSITA at all due to a *de minimus* level of creativity. The result in either case is removal of the PHOSITA from the obviousness determination, contrary to the provisions of Canadian patent legislation. As such, the current test for obviousness in Canada parallels in many important aspects the Federal Circuit’s much maligned pre-*KSR* “teaching, suggestion, motivation” test that was explicitly overturned in *KSR*. For reasons discussed in Section III, jurisdictional differences of this nature not only have the potential to harm Canadian inventors and firms seeking to market innovative products globally, but may also, paradoxically, inhibit strong innovation by granting weak patents in the context of permissive legislation and regulations governing the approval and marketing of medical products.

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