

COMMON SENSE AND THE FACT FINDER WITHOUT SKILL IN THE ART: THE ROLE OF OBJECTIVE EVIDENCE IN ACHIEVING PROPER TECHNOLOGY SPECIFICITY

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I. INTRODUCTION

At the simplest level, the “misty”¹ requirement of nonobviousness is the line that separates innovations that are worthy of patent protection from those that are not.² To gain a government-sponsored monopoly via patent protection, an invention must be not only new and useful but also nonobvious.³ Unfortunately, despite the fundamental importance of plotting this nonobviousness line, it has a history of torturing the inquiries of fact finders. Increasingly, the broad spectrum of industries and “useful Arts”⁴ that utilize the patent system also clouds the inquiry, which is reflected in court decisions that unwittingly develop technology-specific jurisprudence by according precedential value to the factual circumstances of a particular case. This interpretive turmoil, and perhaps its resolution, arises in trying to understand the “level of ordinary skill in the art,” a legal determination that is critical to drawing the obviousness line but that necessarily rests on the factual circumstances of an industry or art.⁵ To penetrate the mist surrounding the level of ordinary skill, fact finders with little or no knowledge of a technological field require an analytical framework in which to ground their obviousness inquiry.

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¹ *Reiner v. I. Leon Co.*, 285 F.2d 501, 503–04 (2d Cir. 1960) (“The test laid down is indeed misty enough. . . . To judge on our own that this or that new assemblage of old factors was, or was not, ‘obvious’ is to substitute our ignorance for the acquaintance with the subject of those who were familiar with it.”).

² *See Graham v. John Deere Co.*, 383 U.S. 1, 11 (1966).

³ 35 U.S.C. §§ 101–103 (2006).

⁴ U.S. CONST. art. 1, § 8, cl. 8.

⁵ *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 427 (2007); *Graham*, 383 U.S. at 17; *infra* Part III.A.

Recently, the Supreme Court of the United States addressed the issue of obviousness in *KSR International Co. v. Teleflex Inc.*,⁶ a landmark case examining the obviousness of an automotive brake pedal technology. This decision arguably departed significantly from previous obviousness jurisprudence developed by the U.S. Court of Appeals for the Federal Circuit, which handles all patent appeals. Both the doctrinal upheaval and the mechanical nature of the invention in *KSR*⁷ raise an important question as to how the decision will affect future obviousness determinations in other industries. Most critically, the reliance on “common sense” in the Court’s analysis⁸ must be examined carefully for applicability to other cases, more closely aligned with the realities of the fact finder’s decision-making process, and ultimately reconciled with the fundamental goals of the patent system.

Although it upset the pre-*KSR* standard, the Court did not venture any jurisprudence to stand in its place, thus leaving lower courts and practitioners with the daunting task of developing new formulations of the obviousness inquiry. In theory, any lack of jurisprudential uniformity arising from the absence of a workable analytical framework will increase uncertainty in the patentability of inventions—a likely disincentive for industries to innovate. Then again, the Court has opened the way for the development of jurisprudence to address the needs and circumstances of particular industries in a clearer, more reasoned—and less ad hoc—manner. Furthermore, with the jurisprudential basis of previous industry-specific decisions undermined, courts will also have greater flexibility to depart from years of precedent that is no longer appropriate for particular technologies. Thus, *KSR* presents an opportunity to begin to approach the obviousness inquiry correctly.

This Comment contends that a fact- and evidence-based, rather than a primarily prior-art-based, approach embodies this flexibility while considering the needs and circumstances of each patentee industry with particularity. In examining obviousness in the mechanical, computer, and pharmaceutical arts, two general trends emerge with respect to so-called “secondary consideration” objective evidence. First, this Comment will argue that generalizing typical industrial circumstances at the time of invention yields a factual presumption about obviousness for each industry—a presumption of obviousness for mechanical and computer inventions and a presump-

⁶ *KSR*, 550 U.S. 398.

⁷ *See id.* at 405–09.

⁸ *Id.* at 420.

tion of nonobviousness for pharmaceutical inventions. Second, this Comment demonstrates that the importance of postinvention objective evidence varies according to the industry; evidence of commercial success, copying, and laudatory statements deserves the most weight for traditional mechanical inventions, the least weight for computer inventions, and a weight somewhere in the middle for pharmaceutical inventions. Focusing the inquiry in these two ways is critical to lend further predictability and stability to the obviousness jurisprudence across industries. Finally, this Comment concludes that a focus on secondary-considerations evidence is proper because this is the best evidence of an industry's patent needs.

Part II of this Comment analyzes the evolution of obviousness jurisprudence culminating in the Supreme Court's decision in *KSR* and then turns to a comparison of the theoretical neutrality of the patent system and the reality of industry-specific patentability results. Part III discusses how to properly understand the Person Having Ordinary Skill in the Art (PHOSITA) construct by elevating the importance of "secondary considerations" available at the time of invention and analyzes how the resultant obviousness findings can then be corroborated via related postinvention evidence. Part III then demonstrates how properly understanding the PHOSITA in the context of a particular industry improves the outcomes of industry-specific decisions, then compares these results to recent Federal Circuit decisions, and concludes by reconciling the results of this analytical framework to the goals of the patent system. Finally, Part IV offers closing thoughts on how objective evidence is the most direct indicator of an industry's patent needs and is thus the best guidepost for the obviousness fact finder.

II. THE DEVELOPMENT OF THE NONOBVIOUSNESS REQUIREMENT ENCOMPASSES ITS APPLICATION TO EMERGING TECHNOLOGIES

A. *The Meaning of "Obvious" Continues to Evolve*

The precise contours of the obviousness standard are critical for several reasons. It is one of three basic statutory requirements for patentability of an invention.⁹ Obviousness is also the most litigated aspect of patent validity.¹⁰ Apart from its status as a threshold require-

⁹ These three requirements are utility, 35 U.S.C. § 101 (2006); "novelty," *id.* § 102; and "nonobviousness," *id.* § 103. *See also, e.g.,* *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 149–50 (1989) (discussing the relationship among these three requirements).

¹⁰ LAURENCE H. PRETTY, *PATENT LITIGATION* 1-40 (2004).

ment for patentability, it is also a particularly difficult determination arising throughout the life cycle of a patent—during both the patent application process and any subsequent infringement and validity litigation. Although the obviousness issue must be addressed and decided at least once for every patent, the technical analysis nevertheless rests largely on the facts of a particular case as interpreted by a frequently untrained decision maker¹¹ via a minimal theoretical framework.¹² Likewise, although the specialized Federal Circuit was created in large part to remedy the “inherent ambiguity and complexity of the obviousness standard”¹³ by increasing uniformity,¹⁴ the Supreme Court’s reversal in *KSR* demonstrates that the flux in the obviousness doctrine continues. As Judge Learned Hand observed, nonobviousness is “as fugitive, impalpable, wayward, and vague a phantom as exists in the whole paraphernalia of legal concepts.”¹⁵

Hindsight bias is the most dangerous aspect of the obviousness determination because the fact finder always analyzes and decides with the benefit of knowledge that the putative inventor has already contributed to the public. Many jurisprudential developments in the history of the nonobviousness requirement occurred in part to reduce this temptation to succumb to hindsight bias.¹⁶ But it may be cognitively impossible for humans to disregard knowledge of an occurrence when calculating its possibility *ex post facto*.¹⁷ Therefore,

¹¹ The major exception, of course, is the patent examiner, who is required to have a formal education in science or engineering. U.S. Patent & Trademark Office, Patent Examiner Positions, <http://www.uspto.gov/web/offices/pac/exam.htm> (last visited Feb. 18, 2010).

¹² See *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); *infra* Part II.A.2.

¹³ Sean M. McEldowney, Note, *New Insights on the “Death” of Obviousness: An Empirical Study of District Court Obviousness Opinions*, 2006 STAN. TECH. L. REV. 4, ¶ 1, <http://stlr.stanford.edu/pdf/McEldowney-Obviousness.pdf>.

¹⁴ *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390 (1996); H.R. REP. NO. 97-312, at 20–23 (1981).

¹⁵ *Harries v. Air King Prods. Co.*, 183 F.2d 158, 162 (2d Cir. 1950).

¹⁶ For example, hindsight at least partially motivated both the Supreme Court’s “secondary considerations” and the Federal Circuit’s “teaching-suggestion-motivation” test. See, e.g., *Graham*, 383 U.S. at 36 (“[Secondary considerations] may also serve to ‘guard against slipping into use of hindsight’ and to resist the temptation to read into the prior art the teachings of the invention in issue.”) (citation omitted); *In re Rouffet*, 149 F.3d 1350, 1357–58 (Fed. Cir. 1998) (“To counter this potential weakness in the obviousness construct, the suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness.”).

¹⁷ Gregory Mandel, *Patently Non-Obvious II: Experimental Study on the Hindsight Issue Before the Supreme Court in KSR v. Teleflex*, 9 YALE J.L. & TECH. 1, 8 (2006). Based on his research, Professor Mandel argues that none of patent law’s doctrinal develop-

because of the essentiality and complexity of the obviousness determination and because of the fundamental human susceptibility to hindsight bias, providing the decision maker with a more robust analytical framework is critical.

1. The First One Hundred Years of the Nonobviousness Requirement

Perhaps not surprisingly, the nonobviousness requirement for patentability is the result of a long and indirect development process. Unlike the requirements of novelty and utility, obviousness was only incorporated as a statutory requirement after its articulation by the Supreme Court.¹⁸ In early patent jurisprudence, the word “invention” was sometimes read to encompass the idea of “nonobviousness,” which the Supreme Court first explicitly recognized as an additional requirement for patentability in *Hotchkiss v. Greenwood*.¹⁹ After one hundred years of relying on the *Hotchkiss* precedent as the basis of the nonobviousness requirement, the 1952 Patent Act codified the first statutory embodiment of the inventiveness or nonobviousness requirement in 35 U.S.C. § 103.²⁰ Section 103 replaced the less-definite “invention” language of *Hotchkiss* with the more operative idea of “nonobviousness” in the hope of increasing uniformity and definiteness.²¹ Cases following the enactment of § 103 have elaborated on the nonobviousness requirement in various ways, but the general concept has remained the same: “[T]he subject matter as a whole [cannot] 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 The various modes of interpreting this basic requirement throughout the history of its development provide helpful building blocks for a more robust post-*KSR* analytical framework.

ments are sufficient to overcome the inherent hindsight bias observed in the obviousness inquiry. *Id.* at 27.

¹⁸ See *supra* note 9 and accompanying text; *infra* note 20 and accompanying text.

¹⁹ 52 U.S. 248 (1851). The Court stated that “unless more ingenuity and skill . . . than were possessed by an ordinary mechanic” were required to arrive at the improved product, “there was an absence of that degree of skill and ingenuity which constitute essential elements of every invention”; the discovered improvement was thus “the work of the skilful [sic] mechanic, not that of the inventor.” *Id.* at 267. See generally 2 DONALD S. CHISUM, CHISUM ON PATENTS §§ 5.02–.02[1] (perm. ed., rev. 2007).

²⁰ Patent (Bryson) Act of 1952, ch. 950, 66 Stat. 792, 798 (codified as amended at 35 U.S.C. § 103 (2006)).

²¹ *Graham v. John Deere Co.*, 383 U.S. 1, 14–15 (1966).

²² 35 U.S.C. § 103(a) (2006).

Prior to the enactment of § 103 and to its case-law progeny, courts had long struggled with the *Hotchkiss* “invention” requirement, and various courts dealt with it in different ways. Of particular note are the objective factual circumstances that a number of courts employed to evaluate obviousness, especially the emphasis on evidence of long-felt yet unmet need and the failure of others.²³ During this period, Judge Learned Hand was one of the best-remembered, if not strongest, proponents of the use of “objective factors” in the obviousness determination.²⁴ Judge Hand adopted a comprehensive view of objective evidence and emphasized it as a vital part of the inquiry:

In dealing with the issue of invention, we have tried, so far as possible, to rely upon objective factors in preference to our a priori judgment [W]e look to the length of time during which the incentive existed to contrive the invention, to the number of unsuccessful efforts that were made in that period, to the density—so to speak—of those efforts at about the time when the invention was made, to whether success came independently to several inventors at about the same time, and to the extent to which after the invention appeared, it supplanted what had gone before.²⁵

This examination of objective evidence of nonobviousness was critical both to the jurisprudence of the pre-section 103 era and to the future development of so-called “secondary considerations.”

2. The Introduction of the *Graham* Framework

Shortly after the enactment of § 103, the Supreme Court developed a framework for applying the new statutory nonobviousness requirement to the facts of particular cases in *Graham v. John Deere Co.*²⁶ In *Graham*, the Court declared that, although patent validity is ultimately a question of law, the obviousness determination relies on several underlying factual inquiries.²⁷ The Court set out a four-prong framework for the obviousness analysis: (1) examine the scope and content of the prior art; (2) determine the differences between the

²³ See Joseph Scott Miller, *Level of Skill and Long-Felt Need: Notes on a Forgotten Future*, 12 LEWIS & CLARK L. REV. 579, 586 (2008) (compiling these cases).

²⁴ *Id.*; see also *Safety Car Heating & Lighting Co. v. Gen. Elec. Co.*, 155 F.2d 937, 939 (2d Cir. 1946) (emphasizing the importance of these factors); 2 CHISUM, *supra* note 19, § 5.05, at 5-639 (summarizing Judge Hand’s views).

²⁵ *Clark v. Wright Aeronautical Corp.*, 162 F.2d 960, 966 (2d Cir. 1947).

²⁶ 383 U.S. 1, 17–18 (1966); see also *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406–07 (2007) (discussing the role of the *Graham* decision in the obviousness inquiry).

²⁷ *Graham*, 383 U.S. at 17.

prior art and the claims under consideration; (3) evaluate the level of ordinary skill in the art; and (4) when appropriate, look to secondary considerations, such as commercial success, long-felt but unmet needs, and the failure of others.²⁸ Since that time, the *Graham* framework has been fundamental to the obviousness determination, and its importance was reaffirmed in *KSR*.²⁹ Notably, the decision on its face appears to “demote” objective evidence of nonobviousness, which was frequently considered critical in earlier decisions,³⁰ to a truly secondary position.

The *Graham* framework can be divided into two evidential categories. The first relates to the knowledge and ingenuity of the PHOSITA at the time of invention, and the second relates to the teachings of secondary considerations about the obviousness of the invention at that time. The relative importance of these two types of evidence has been debated, however, and it has received various treatments by the courts.³¹ Secondary considerations have been regarded alternately to be mere scale-tippers³² or to be the only safe basis for decision,³³ and this observation illustrates the greatest problem with the *Graham* framework—its failure to provide any tools for measurement within the framework. While *Graham* instructs courts how to approach the obviousness problem by outlining which questions to ask, it fails to specify how courts should interpret the answers to those questions—that is, the degree of “inventiveness” that is required for patentability.

3. The Appearance of the Teaching-Suggestion-Motivation Test

Responding to this “*Graham* gap,” the Federal Circuit began to emphasize a supplementary obviousness test, known as the “teaching-

²⁸ *Id.* at 17–18.

²⁹ *KSR*, 550 U.S. at 407 (“[T]he factors continue to define the inquiry that controls.”).

³⁰ See *supra* notes 23–24 and accompanying text.

³¹ Amanda Wieker, *Secondary Considerations Should Be Given Increased Weight in Obviousness Inquiries Under 35 U.S.C. § 103 in the Post-KSR v. Teleflex World*, 17 FED. CIR. B.J. 665, 674 (2008) (discussing the role of secondary considerations before and after *KSR*).

³² *Graham*, 383 U.S. at 36 (finding that evidence of long-felt but unmet need and of commercial success did “not, in the circumstances of this case, tip the scales of patentability”).

³³ See, e.g., *Diamond Rubber Co. v. Consol. Rubber Tire Co.*, 220 U.S. 428, 437, 441–45 (1911) (relying almost exclusively on what would now be called secondary considerations in finding patent validity).

suggestion-motivation” (TSM) test, to flesh out the framework.³⁴ The TSM test addressed the issue of the obviousness of combinations of elements previously known in the prior art,³⁵ which is an area of particular importance because “[m]ost if not all inventions arise from a combination of old elements.”³⁶ The basic premise of the TSM test—a combination invention is not obvious unless the prior art, the nature of the problem, or the skill of the PHOSITA suggested a combination of prior-art elements³⁷—developed in conjunction with other early obviousness doctrines in the Supreme Court, courts of appeals, and the Court of Customs and Patent Appeals, the Federal Circuit’s predecessor court.³⁸ Thus, although the Federal Circuit was later criticized for its reliance on the TSM test,³⁹ the test itself was a creature of extended historical development, like the nonobviousness requirement itself.

In the years following the *Graham* decision and the creation of the Federal Circuit, the Federal Circuit did indeed usher in an era of more well-defined and rigorous use of the TSM test.⁴⁰ But as the TSM test flourished, some began to complain that the test was too rigid and resulted in findings of nonobviousness for what were actually

³⁴ See, e.g., *Al-Site Corp. v. VSI Int’l, Inc.*, 174 F.3d 1308, 1323–24 (Fed. Cir. 1999) (“The party seeking patent invalidity based on obviousness must also show some motivation or suggestion to combine the prior art teachings. A suggestion or motivation to combine generally arises in the references themselves, but may also be inferred from the nature of the problem or occasionally from the knowledge of those of ordinary skill in the art.”) (citations omitted).

³⁵ See *id.*

³⁶ *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000).

³⁷ The TSM test first appears in *In re Bergel*, 292 F.2d 955, 956–57 (C.C.P.A. 1961) (“The mere fact that it is possible to find two isolated disclosures which might be combined in such a way to produce a new compound does not necessarily render such production obvious unless the art also contains something to suggest the desirability of the proposed combination.”).

³⁸ See, e.g., *Topliff v. Topliff*, 145 U.S. 156, 161 (1892) (discussing the relationship between the nature of the problem, the knowledge of the PHOSITA, and obviousness); *In re Adams*, 356 F.2d 998, 1002 (C.C.P.A. 1966) (“Of course all of the references may be used to show what the art knew, and in that sense ‘combined’ but the fact remains that neither reference contains the slightest suggestion to use what it discloses in combination with what is disclosed in the other.”); *In re Huntzicker*, 90 F.2d 366, 368–69 (C.C.P.A. 1937) (“We find nothing in the references to suggest that appellant’s new, useful, and commercially successful device might be constructed by combining some of their elements. We are of [the] opinion, therefore, that the appealed claims involve invention and are patentable.”).

³⁹ A famous, and very damaging, criticism of the TSM test as applied by the Federal Circuit is of course the Supreme Court’s *KSR* decision. See *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

⁴⁰ See, e.g., *In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002); *In re Dembiczak*, 175 F.3d 994 (Fed. Cir. 1999); *In re Rouffet*, 149 F.3d 1350 (Fed. Cir. 1998).

unpatentable improvements.⁴¹ For example, a rigid application of the TSM test frequently resulted in the requirement of an explicit teaching, suggestion, or motivation to combine elements in the prior-art publication itself, and without such an explicit hint, the combination was found to be nonobvious.⁴² Critics railed against “rigid preventative rules that deny fact-finders recourse to common sense”⁴³ and the death of obviousness.⁴⁴ While this revolt against the TSM test may be well deserved, courts must be careful not to “throw the baby out with the bathwater.”⁴⁵

4. The *KSR* Decision

In *KSR*, the Supreme Court called for a return to the foundations laid in *Graham* as the primary framework for understanding the nonobviousness requirement and finally dismissed the narrow application of the TSM test.⁴⁶ The Supreme Court chastised the Federal Circuit for its “rigid” approach and cited the Court’s own history of an “expansive and flexible” approach to the obviousness inquiry.⁴⁷ Rather than look to a teaching, suggestion, or motivation in “published articles and the explicit content of issued patents,”⁴⁸ the Court identified the three primary factors that urged the combination: the nature of the problem,⁴⁹ perceived market demand,⁵⁰ and common sense.⁵¹

⁴¹ See, e.g., *KSR*, 550 U.S. at 418–19.

⁴² See, e.g., Brief for Intellectual Property Law Professors as Amici Curiae in Support of Petitioner, *KSR*, 550 U.S. 398 (No. 04-1350) (arguing against this rigid application).

⁴³ *KSR*, 550 U.S. at 421.

⁴⁴ *McEldowney*, *supra* note 13, ¶ 2.

⁴⁵ This phrase comes from the German expression meaning “to reject the essential with the inessential, to discard what is valuable along with what is waste or useless.” 1 THE OXFORD ENGLISH DICTIONARY 851 (2d ed. 1989).

⁴⁶ *KSR*, 550 U.S. 398.

⁴⁷ *Id.* at 415.

⁴⁸ *Id.* at 419. Speaking directly to the TSM test, the Court stated that the obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* at 418.

⁴⁹ *Id.* at 419–20 (“One of the ways in which a patent’s subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent’s claims.”).

⁵⁰ *Id.* at 417 (“When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one.”).

⁵¹ The Court reasoned that the person of ordinary skill has sufficient motivation to pursue a finite number of predictable, feasible solutions to a known design need

Specifically, the *KSR* decision related to the obviousness of a patent in the mechanical arts—a combination of an electronic sensor and an adjustable automobile pedal such that the pedal’s position can be ascertained for computerized throttle control.⁵² Because both adjustable pedals and electronic sensors for computer-controlled throttles were known in the prior art,⁵³ the validity of the patent turned on the obviousness of the combination. Regarding this combination, the Court explained, “Common sense teaches . . . that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle.”⁵⁴ If the combination of known options is successful, the invention “is likely the product not of innovation but of ordinary skill and common sense.”⁵⁵

In relying on a common sense approach, however, the Court failed to make an important distinction between the application of an intuitive or “ordinary” understanding of the problem when attempting the combination and its application when determining the PHOSITA’s expectation of success.⁵⁶ Applying common sense to appreciate the likelihood of attempting the combination reveals whether the combination is “obvious to try,” whereas applying common sense to appreciate the a priori expectation of the combination’s success reveals whether the combination embodies the inventive step required for patentability.⁵⁷ The Court glosses over this distinction and, thus, suggests that where the invention is the product “of ordinary

or market pressure. *Id.* at 421. “If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.” *Id.*

⁵² *KSR*, 550 U.S. at 405–06.

⁵³ *Id.* at 408–09.

⁵⁴ *Id.* at 420.

⁵⁵ *Id.* at 421.

⁵⁶ A court requires a reasonable expectation of success of the combination invention to find the combination to be obvious. *See, e.g., In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988). Patent application examination rules also reflect this requirement. *See* PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2143.02 (6th ed. 2007).

⁵⁷ Courts have distinguished the obviousness of the attempted combination (referred to as “obvious to try”) from the obviousness of the invention itself. *See, e.g., Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1207–08 (Fed. Cir. 1991). The expectation of success is also legally distinct from the “inherency” or inevitability of success. *See, e.g., In re Rinehart*, 531 F.2d 1048, 1054 (C.C.P.A. 1976).

skill and common sense,” it is both obvious to try and lacking an inventive step.⁵⁸

Throughout this analysis, the Court directed little attention to the evaluation of secondary considerations, a matter that has traditionally demanded attention in the obviousness inquiry. In reference to this objective evidence, the Court only stated, “Like the District Court, finally, we conclude Teleflex has shown no secondary factors to dislodge the determination that [the claim] is obvious.”⁵⁹ Clearly, the Court considered the secondary-consideration evidence to be truly “secondary” in the analysis—useful only to the extent that it was necessary as a tiebreaker—or the issue would not have received such perfunctory treatment. In this way, the Court neglected to look to an indicator of nonobviousness, the development of which has been intertwined with the development of the nonobviousness requirement itself. Instead, the Court relied on “common sense,” without being specific as to exactly whose common sense served as the benchmark, and thus found the invention at issue in *KSR* to be an obvious combination of prior-art elements without any substantive analysis of the objective evidence.

The *KSR* decision must be evaluated both in the context of its particular facts and with a view as to how subsequent cases will apply its jurisprudential basis. At the factual level, the Court probably reached the correct result; had the Court more carefully and explicitly detailed its analytical steps, the outcome would probably not be altered. With respect to the analytical methodology in *KSR*, one favorable outcome is that the less rigid approach to the obviousness inquiry likely better reflects reality. The Court was clearly correct when stating that “[a] person of ordinary skill is also a person of ordinary creativity, not an automaton,”⁶⁰ and it is likewise true that a motivation to combine elements can exist in the prior art or the mind of the PHOSITA without need for the explicit teaching sometimes required under the TSM test. Furthermore, *KSR* has opened the way for alternative interpretations or standards for the obviousness determination; the undercutting of the TSM test wipes the slate clean for a new but flexible approach to develop to fill the “*Graham* gap.”

What *KSR* gives with one hand, however, it takes away with the other. The particular factual setting in the mechanical arts dominates the Court’s analysis. Reliance on nothing more than the

⁵⁸ *KSR*, 550 U.S. at 421.

⁵⁹ *Id.* at 426.

⁶⁰ *Id.* at 421.

“common sense” of the PHOSITA as a benchmark may not be appropriate in other contexts, particularly in highly complex industries where the application of concepts of “common sense” and “ordinary” by fact finders possessing different varieties of common sense is illogical. Therefore, while those not skilled in the mechanical arts⁶¹ can readily envision a brake pedal, an electronic sensor, and their combination, the same is not true for many other areas of technology. Comfort with a rationale that relies on “common sense” is thus extremely limited.⁶² Furthermore, the Court implied a questionable use of this common-sense approach by seeming to suggest that a simple motivation to combine, found anywhere, is sufficient to find an invention obvious regardless of the likely results of the combination. A more satisfying analysis would rely on an acknowledgment that the mechanical arts in many respects are now so well developed and understood—easily comprehensible even by lay people—that the certainty of the outcome elevates “obvious to try” to obviousness itself.

In addition to this doctrinal confusion, the analysis required under the *Graham* framework itself was weak. For example, the Court, relying on a résumé-type description, provided only perfunctory identification of the PHOSITA: “[T]he level of ordinary skill in pedal design was an undergraduate degree in mechanical engineering (or an equivalent amount of industry experience) [and] familiarity with pedal control systems for vehicles.”⁶³ This describes what the PHOSITA knows but not any degree of ingenuity. What does the PHOSITA do with this knowledge? The Court also gave short shrift to the objective evidence incorporated in *Graham*’s secondary considerations.⁶⁴ The Court passed up an opportunity to clarify the role these considerations play beyond the particular facts of the *KSR* case—as scale-tippers or as definitive evidence—by adopting the lower court’s determination without further discussion.⁶⁵ Consequently, by reverting to a pure *Graham* analysis, the Court failed to improve upon the obviousness doctrine and instead simply returned to the

⁶¹ These persons may include, presumably, members of the Supreme Court.

⁶² According to the Supreme Court, secondary considerations are useful for precisely this reason: “[t]hese legal inferences or subtests do focus attention on economic and motivational rather than technical issues and are, therefore, more susceptible of judicial treatment than are the highly technical facts often present in patent litigation.” *Graham v. John Deere Co.*, 383 U.S. 1, 35–36 (1966).

⁶³ *KSR*, 550 U.S. 412–13 (internal quotations omitted).

⁶⁴ See *supra* note 59 and accompanying text.

⁶⁵ *KSR*, 550 U.S. at 426.

pre-TSM state of uncertainty. The Court justifiably reduced one doctrine but did not provide anything in its place.

KSR has thus opened the way for greater flexibility in the obviousness determination. Yet as a result, the doctrine is still lacking in several respects. Courts now lack a judicially manageable standard for determining obviousness. While the *Graham* framework continues to teach courts how to approach the inquiry, it does not suggest how to analyze the factual results thus obtained to arrive at the requisite level of inventiveness, a legal determination. That is, the *Graham* analysis still does not explain how to tell if an invention is inventive enough. Likewise, although the use of common sense is generally admirable, especially when that use is by an acceptably knowledgeable source, “obvious to try” still should not be a substitute for a proper obviousness analysis in the absence of conditions suggesting that any obvious attempt will lead to an equally unquestionable success. The *KSR* decision also fails to address the issue of hindsight bias, which the TSM test was at least partially created to mitigate.⁶⁶ While the Court pays lip service to the reality of hindsight bias, the Court does not offer any alternative protection or even appear to consider the issue seriously.⁶⁷ The failure of the *KSR* analysis in these respects results in greater doctrinal uncertainty, particularly outside the mechanical context, which in turn creates a disincentive for the inventors who now have fewer tools to gauge the validity of any patents they have or seek. In particular, a greater risk of loss of patent protection may cause resource-intensive industries to forego some research and development activities to avoid any expectation of losses.

In sum, the Court in *KSR* properly returned significant flexibility to the obviousness analysis by rejecting the rigidity of the TSM test. The Court failed, however, to provide a new analytical framework for future determinations to supplement the “*Graham* gap” in the measurement of inventiveness. Because of the particular factual circumstances of the invention, the Court also failed to explicitly address other critical aspects of the obviousness doctrine. The failure to spell out analytical steps in addressing secondary considerations and the degree of ingenuity of the PHOSITA leaves the role of these factors

⁶⁶ *Supra* note 16 and accompanying text.

⁶⁷ *See KSR*, 550 U.S. at 421 (“A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning. . . . Rigid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it.”).

in question. These concepts merit new roles in tailoring the *Graham* inquiry.

B. The Evolution of Obviousness Includes the Advent of Technology Specificity within the “Neutral” Patent Framework

Before plunging into a revised theoretical framework for the obviousness determination, it is important to understand the goals enshrined in the patent bargain and the needs of patent-utilizing industries. That is, to comprehend the current importance of the obviousness doctrine, especially the importance of achieving success with respect to various industries, understanding its context generally within patent law is helpful. Only by keeping the fundamental goals and purposes of the patent system in mind can the propriety of its treatment of various industries—the most important benchmark for the success of the framework—be evaluated.

1. The Societal Bargain Embodied in the Patent System

Patents are a government-sponsored monopoly created to provide an incentive for innovation and technology development by rewarding meritorious inventions with a significant period of marketplace exclusivity.⁶⁸ Without proper profit incentives created by the possibility of monopoly, many inventors would forego expensive research and development investments because of the risk of irrecoverable losses.⁶⁹ For example, without any restriction on competition, inventions that are costly to develop but cheap to copy would be rapidly mimicked in the marketplace and would result in one party bearing research costs while reaping only a portion of the profits.⁷⁰

⁶⁸ *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 730–31 (2002); *see also* *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 167 (1989) (describing the federal patent law as a “careful balance between public right and private monopoly to promote certain creative activity”).

⁶⁹ *See, e.g., Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 599 (Fed. Cir. 1985) (“The encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude.”); FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY Executive Summary, at 2 (2003), *available at* www.ftc.gov/os/2003/10/innovationrpt.pdf (“This property right can enable firms to increase their expected profits from investments in research and development, thus fostering innovation that would not occur but for the prospect of a patent.”).

⁷⁰ Profitability will depend on what is known as the “first-mover advantage”: “Investment in innovation is driven by expectations of transitory monopoly returns that innovations are supposed to yield. There have always been two strategies to protecting these monopoly returns. The first relies on patents, the second on developing innovations in secrecy and getting to the market first.” Rajshree Agarwal & Michael Gort, *First-Mover Advantage and the Speed of Competitive Entry, 1887–1986*, 44 J.L. &

This phenomenon is particularly evident in some industries, such as those where research and development cycles are more lengthy or resource intensive.⁷¹

In exchange for this limited patent monopoly, the public benefits from the required disclosure of the details of the patentee's invention, which increases the store of public knowledge and promotes further advances.⁷² Additionally, at the end of the monopoly period, the invention is entirely dedicated to the public.⁷³ In that respect, the patent system represents a "bargain" between the inventor and society.⁷⁴

Over-extending patent protection to inventions that do not truly represent scientific or technological advances risks the public paying a premium for knowledge already in the public store or for inventions that only represent a trivial improvement over what is already available.⁷⁵ In theory, the patentability of an invention should reflect a reality that it would not have been financially practical to develop the invention but for the incentive of a patent.⁷⁶ The nonobviousness

ECON. 161, 161 (2001); *see also* FED. TRADE COMM'N, *supra* note 69, ch. 2, at 4 (discussing the problem of so-called "free riders" as a disincentive to innovate).

⁷¹ FED. TRADE COMM'N, *supra* note 69, ch. 2, at 4; *see id.* ch. 3, at 9 (discussing the importance of patent rights to prevent free riding in the pharmaceutical industry, where patents are "essential" to recouping "significant investments in research and development").

⁷² *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150–51 (1989) ("The federal patent system thus embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years.").

⁷³ *Id.* at 151 ("[U]pon expiration of that period, the knowledge of the invention inures to the people . . .").

⁷⁴ *Id.*

⁷⁵ "As we refrain from granting patents on inventions that are not new, we must also refrain from granting patents on those inventions which would arise *spontaneously*, given the need or desire for them, as the yelp of the dog surely follows from stepping on his tail . . ." Giles S. Rich, Assoc. Judge, U.S. Court of Customs & Patent Appeals, Acceptance Speech for the 1963 Kettering Award at the George Washington University: The Vague Concept of "Invention" as Replaced by Sec. 103 of the 1952 Patent Act (June 18, 1964), in 46 J. PAT. OFF. SOC'Y 855, 859 (1964).

⁷⁶ *See id.*; *Graham v. John Deere Co.*, 383 U.S. 1, 11 (1966) (describing the "inherent problem" of creating patentability standards as that of "develop[ing] some means of weeding out those inventions which would not be disclosed or devised but for the inducement of a patent"); *supra* note 69 and accompanying text. In an interesting piece of scholarship arguing for the resurrection of the TSM test after *KSR*, Randall Hirsch asserts that the obviousness determination turns on the subjective measure of a discovery's "inventiveness" only because a more objective measure of sufficient societal benefit is not practicable. Randall J. Hirsch, Comment, *Well Duh: Obviousness, Gas Pedals, and the Teaching-Suggestion-Motivation Test*, 6 NW. J. TECH. &

requirement plays a role in policing the granting of patents by ensuring that the system is not overinclusive in its protection and by providing the theoretical flexibility that the novelty and utility requirements for patentability cannot.

2. The Effect of Emergent Technologies on Both the Patent Bargain and Industrial Neutrality

These fundamental goals and the public-private exchange embodied in the U.S. patent system have remained relatively unchanged since its inception. But with the advent of the “digital revolution,” patent protection is particularly important to promote and protect the efforts of inventors in emerging industries.⁷⁷ U.S. patent law has thus evolved to face the challenges that a myriad of new and advancing technologies has presented. In particular, although Congress has responded with some statutory changes, most notably the § 103 non-obviousness requirement, a general reluctance to address these new technology developments statutorily has remained.⁷⁸ The changes that most clearly respond to industrial and technological developments—many of which were inconceivable at the creation of the patent system⁷⁹—occurred in the federal courts, which have tackled these challenges by developing new judicial doctrines and analytical frameworks in a nearly constant state of flux.⁸⁰ This tension between legislative and judicial action—between the need to adjust quickly to evolving technology and the need to have an equitable impact across

INTELL. PROP. 89, 91–92 (2007), <http://www.law.northwestern.edu/journals/njtip/v6/n1/5/Hirsch.pdf>.

⁷⁷ For an interesting study of the impact of recent technology changes on patent applicant prosecution practice, see John R. Allison & Mark A. Lemley, *The Growing Complexity of the United States Patent System*, 82 B.U. L. REV. 77 (2002).

⁷⁸ Brian Kahin, *Patents and Diversity in Innovation*, 13 MICH. TELECOMM. & TECH. L. REV. 389, 391 (2007) (questioning this reluctance throughout the patent system and the resulting “one size fits all” approach). Congress is also limited in its ability to engage in direct statutory tailoring by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) requirement that patent rights be enjoyable “without discrimination as to . . . the field of technology.” Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1197 (1994), available at http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm.

⁷⁹ See Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1159 (2002) (comparing the “homogenous” mechanical inventions at the time of the Framers with the current diversity of patent law).

⁸⁰ See generally *id.* (arguing that patent law is becoming increasingly technology specific because of the federal courts’ reliance on “an ad hoc combination of judicial anthropology and *stare decisis*”).

various industries—presents a unique challenge in promoting the patent system’s underlying goals across various industries.

On the one hand, patent statutes and regulations are facially neutral with respect to arts and industries. The patent system does not differentiate between types of inventions and is considered “technology-neutral.”⁸¹ Patent statutes and regulations related to patentability do not reflect any of the differences that might exist between the circumstances and needs of various industries, and they generally are inappropriate vehicles for addressing the ever-changing issues of fast-paced technological development.⁸²

On the other hand, as courts have interpreted the statutory patentability requirements on the particular facts of various industry-specific cases, this “neutral” system has been flexed in response to the realities of the inventive process and marketplace competition of various industries.⁸³ The true problem with this facially neutral but practically biased system is the failure of the courts to recognize their role in the development of industry-specific doctrine and the impact their decisions have beyond the cases and facts at hand.

3. Recognizing Diverse Innovation Environments Across Industries

Different industries clearly have different needs:

A wealth of empirical evidence demonstrates deep structural differences in how industries innovate. Industries vary in the speed and cost of research and development (“R&D”), in the ease with which inventions can be imitated by others, in the need for cumulative or interoperative innovation rather than stand-alone development, and in the extent to which patents cover entire products or merely components of products.⁸⁴

For example, the pharmaceutical and biotech industries require extensive and costly research to put a product on the market; a risky hit-or-miss discovery process is coupled with extensive regulatory con-

⁸¹ *Id.* at 1158.

⁸² Kahin, *supra* note 78, at 393 (“It now appears that the extraordinary difficulty of trying to reform a monolithic system means that legislative reform will be unable to keep pace with problems as they develop.”); *see also* Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827, 841–42 (1999).

⁸³ Burk & Lemley, *supra* note 79, at 1156 (“Of late, however, we have noticed an increasing divergence between the rules themselves and the application of the rules to different industries.”).

⁸⁴ Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1577 (2003).

trol of marketing.⁸⁵ The life sciences industry generally needs a significant monopoly period to recoup investment and maintain profitability.⁸⁶ In contrast, software and electronics industries have relatively short product life cycles; product development and generational replacement are comparatively rapid.⁸⁷ In the case of software, development is generally not as highly human-resource or capital intensive.⁸⁸ With these two industries constituting the most active areas of patenting activity,⁸⁹ the adaptation of patent law to secure its goals with respect to both industries seems a legitimate objective.

At present, the most unsettling aspect of this adaptation process is that industry-specific patentability standards have already emerged without a clear intention to create new doctrine.⁹⁰ In a series of scholarship, Professors Dan Burke and Mark Lemley have explored the

⁸⁵ For example, “the average cost of developing a new medicine [is] \$1.3 billion . . . including the cost of failures and capital,” and “the R&D process takes an average of 10 to 15 years.” PHARM. RESEARCH & MFRS. OF AM., PHARMACEUTICAL INDUSTRY PROFILE 2008, at 2, 3 (2008), available at <http://www.phrma.org/files/2008%20Profile.pdf>.

⁸⁶ Burk & Lemley, *supra* note 84, at 1581–83.

⁸⁷ FED. TRADE COMM’N, *supra* note 69, ch. 3, at 45 (“[T]he rate of technological change in the software and Internet industries is rapid. Imitation may occur quickly, and entire product life cycles sometimes pass before patents can be issued.”). This may be due in part to Moore’s Law, which states that the number of transistors on a chip will double every two years, correlating to a doubling of computer performance every eighteen months. *E.g.*, Michael Kanellos, *Moore’s Law to Roll on for Another Decade*, CNET NEWS, Feb. 10, 2003, <http://news.cnet.com/2100-1001-984051.html> (quoting Intel cofounder Gordon Moore as projecting that his Moore’s Law would apply for at least another decade).

⁸⁸ FED. TRADE COMM’N, *supra* note 69, ch. 3, at 45 (“[I]nnovation in the software and Internet industries generally requires considerably less capital than innovation in other high-tech industries.”); Burk & Lemley, *supra* note 84, at 1582 (“In the computer industry, for example, it has long been possible for two programmers working in a garage to develop a commercial software program.”).

⁸⁹ The following were the ten most frequently patented technology divisions in the U.S. Patent and Trademark Office (USPTO) in 2006: (1) Active Solid-State Devices; (2) Semiconductor Device Manufacturing: Process; (3) Multiplex Communications; (4) Telecommunications; (5) Chemistry: Molecular Biology and Microbiology; (6) Electrical Computers and Digital Processing Systems: Multicomputer Data Transferring; (7) Drug, Bio-Affecting and Body Treating Compositions; (8) Computer Graphics Processing and Selective Visual Display Systems; (9) Pulse or Digital Communications; and (10) Communications: Electrical. Patent Tech. Monitoring Team (PTMT), U.S. Patent and Trademark Office, Patent Counts by Class by Year: 01/01/1977–12/31/2008, <http://www.uspto.gov/web/offices/ac/ido/oeip/taf/cbcb.pdf> (last visited Feb. 18, 2010).

⁹⁰ Burk & Lemley, *supra* note 79, at 1205 (“Patent law is becoming technology-specific. The legal rules applied to biotechnology cases bear less and less resemblance to those applied in software cases. While there may be good policy reasons to treat the two industries differently, the current legal rules are . . . an ad hoc combination of judicial anthropology and *stare decisis*.”).

emerging issue of technology specificity and found that “in the industries of biotechnology and software . . . the Federal Circuit has gotten the policy precisely backwards, perhaps because it is not making industry-specific patent policy intentionally.”⁹¹ The resulting disparity in treatment among industries does not accurately reflect needs and upsets the balance between promoting innovation and promoting public disclosure, the twin aims of the patent system.⁹² On one hand, if patentability standards are overinclusive (i.e., if patents that do not represent true invention steps are granted), incentives to the patentee are increased, but the public pays in the form of monopoly prices for inventions that were either already available in the public domain or represent trivial improvements. On the other hand, if patentability standards are underinclusive (i.e., if patents are denied to true inventive steps), the public benefits in the short term by receiving the fruits of the invention at a reduced price, but the long-term incentive available to the inventor is diminished. Thus, maintaining the proper balance is crucial. Although building flexibility into the system to account for the disparities in the inventive environment across industries is desirable, the development of industry-specific jurisprudence in an ad hoc or unintentional manner (as appears to be the case) may frustrate the patent system’s fundamental purpose.

In light of both the danger of this ad hoc, one-off approach and the opportunity for rethinking the obviousness inquiry that *KSR* represents, federal courts should now attempt to harmonize the obviousness doctrine to better address different industries’ needs and the realities of their invention environments.

C. The Case for Technology-Specific Obviousness Considerations Is Strong

The increased flexibility in the obviousness doctrine since *KSR* opens the door for the Federal Circuit to develop an industry-specific approach to properly and thoughtfully address the various needs and circumstances of patent-dependent industries. The reinvention of several key obviousness concepts can create manageable standards and address industry-specificity without requiring statutory de-

⁹¹ Burk & Lemley, *supra* note 84, at 1578.

⁹² See Burk & Lemley, *supra* note 79, at 1205–06; see also BD. ON SCI., TECH., & ECON. POLICY, POLICY & GLOBAL AFFAIRS DIV., NAT’L RESEARCH COUNCIL OF THE NAT’L ACADS., A PATENT SYSTEM FOR THE 21ST CENTURY: COMM. ON INTELLECTUAL PROPERTY RIGHTS IN THE KNOWLEDGE-BASED ECONOMY 35–41 (Steven A. Merrill et al. eds., 2004), available at <http://books.nap.edu/html/patentsystem/0309089107.pdf> (describing the industry-specific costs and disparate benefits of the current patent system as one of several reasons the system requires re-examination).

neutralization. First, by reconsidering the *Graham* analysis, courts can utilize the “secondary considerations” (objective evidence) of each industry to inform the characterization of the PHOSITA. Rather than consider this evidence to be “secondary” in time or importance, objective evidence can answer the question of how the PHOSITA uses prior-art knowledge. Second, by properly identifying and understanding the proper objective factors, the courts can establish an analytical framework to lend consistency and predictability to obviousness determinations. This stability in turn strengthens the incentive to innovate. Furthermore, by agreeing on which factors are important, fact finders can use evidence that does not depend entirely on retrospective analysis to fill the hole left by the apparent demise of the TSM test. Such determinations in turn may rely exclusively on the prior art to bridge the gap between the fact finder’s “common sense” and the PHOSITA’s inherent inventiveness. Third and finally, by viewing the inventions of each industry through this obviousness analytical framework—trusting objective evidence particular to each industry or art rather than previous ad hoc judicial determinations—the proper result is achieved for each industry.

III. OBJECTIVE EVIDENCE IS THE BEST INDICATOR OF OBVIOUSNESS AND THE NEEDS OF INDUSTRY

A. *Who is the PHOSITA?*

Under the *Graham* framework, the PHOSITA is the yardstick against which fact finders measure all inventions.⁹³ But who is this critical “person”? *Graham* teaches that the court will look to the scope and content of the prior art, differences between the prior art and the claims, and the level of ordinary skill in the pertinent art.⁹⁴ Related to each of these three steps, the PHOSITA embodies the level of ordinary skill and knows the entire contents of the prior art at the time of the invention.⁹⁵ Thus, the PHOSITA is a legal construct who is *not* equivalent to the inventor.⁹⁶ Keeping this in mind is critical

⁹³ See *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

⁹⁴ *Id.*

⁹⁵ “The legal construct also presumes that all prior art references in the field of the invention are available to this hypothetical skilled artisan.” *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998); see also *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1453 (Fed. Cir. 1984) (“[T]he real meaning of ‘prior art’ in legal theory . . . is knowledge that is available, including what would be obvious from it, at a given time, to a person of ordinary skill in an art.”).

⁹⁶ “This legal construct is akin to the ‘reasonable person’ used as a reference in negligence determinations.” *In re Rouffet*, 149 F.3d at 1357.

because obviousness is determined from the baseline of the PHOSITA (an objective perspective), not from the baseline of the inventor (a subjective perspective). If the inventiveness of the putative inventor extends beyond the capability of the PHOSITA for the invention at issue, it is considered nonobvious.⁹⁷ At this point the analytical framework falters. Because of the “*Graham* gap,” no clear yardstick exists with which to compare this level of ordinary skill to the skill presented by the inventor.⁹⁸ While *Graham* requires the comparison, it does not teach what level of inventive step is nontrivial and nonobvious.⁹⁹

1. The Traditional Understanding of the PHOSITA

Unfortunately, the traditional definition of the PHOSITA and the related extent of factual inquiry elaborated in court decisions do not help fill this gap. Currently, the factual inquiry yields only (1) the field of the PHOSITA’s knowledge (her position in the field of related academic work), (2) the PHOSITA’s educational background and curriculum vitae experience, and (3) the tools with which the PHOSITA works (the relevant prior art).¹⁰⁰ This type of inquiry does not illuminate what *use* the PHOSITA makes of this background or what degree of inventiveness or innovation the PHOSITA possesses. Although previous decisions do an excellent job of describing in detail the art “known” by the theoretical PHOSITA, these same decisions rely on conclusory statements about the PHOSITA’s motivations or acts in using this knowledge. For example, in the *Graham* decision itself, after extensive discussion of the background of the patent and prior art, the Court simply states, “Certainly a person having ordinary skill in the prior art, given the [mechanism of the improvement], would immediately see that the thing to do was what *Graham*

⁹⁷ See 35 U.S.C. § 103(a) (2006).

⁹⁸ See *supra* Part II.A.

⁹⁹ For an argument that the TSM test *was* an appropriate approach to filling this gap, see Hirsch, *supra* note 76.

¹⁰⁰ See *AllVoice Computing PLC v. Nuance Commc’ns, Inc.*, 504 F.3d 1236, 1240 (Fed. Cir. 2007) (“AllVoice’s counsel defined ‘a person of ordinary skill in the art’ in the context of this case as ‘someone who has a degree in computer science or something equivalent and 2–3 years experience programming in Windows.’”); *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1356 (Fed. Cir. 2007) (“[A] person of ordinary skill in the art would have a bachelor’s degree in pharmaceutical science or analytical chemistry, and some experience in drugs and drug preparation.”); *supra* note 63 and accompanying text.

did.”¹⁰¹ Future obviousness pupils can only speculate how the Court achieved this insight into the PHOSITA so effortlessly.

Yet courts are not without the ability to improve this PHOSITA analysis in both structure and transparency. Particularly, many objective ex ante factors actually teach about the context in which the PHOSITA lives, what the PHOSITA knows, and how creative the PHOSITA is. These factors can also help calculate the probability of discovery at a particular time in the art. The actual artisan can thus be compared to this ex ante theoretical construct. Similarly, to corroborate the preceding primary analysis, objective ex post factors also address the degree to which the inventor rose above the theoretical PHOSITA’s circumstances to become truly inventive. Together, this collection of factual considerations can be used to shed light both on the inherent degree of inventiveness of the PHOSITA in a particular field and on the degree of inventiveness actually displayed by the inventor. The results of a factual inquiry, not of additional hypothetical wanderings, become the yardstick against which inventiveness is measured.

Accordingly, in addition to the prior-art analysis required in *Graham*, a number of fact-based indicia—particularly an updated analysis of secondary considerations—help to understand the PHOSITA. Collectively these indicia demonstrate, via tangible evidence that is intellectually accessible to fact finders regardless of technical sophistication, how the PHOSITA responds to the encountered prior art.

2. The Primacy of Secondary Considerations Reinterpreted

Secondary considerations, or Judge Hand’s “objective factors,” should not really be treated as secondary; while “secondary” can refer to being either second in time or second in importance, neither of these labels is appropriate. Rather, consideration of such objective factual evidence should form a primary part of the determination of the level of ordinary skill in the art. The Federal Circuit and its predecessor have repeatedly reaffirmed the primacy of secondary-consideration evidence by stating that it is “always to be considered, and accorded whatever weight it may have.”¹⁰² As evidence that is na-

¹⁰¹ *Graham v. John Deere Co.*, 383 U.S. 1, 25 (1966).

¹⁰² *In re Mageli*, 470 F.2d 1380, 1383 (C.C.P.A. 1973); *see also Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538–39 (Fed. Cir. 1983). The *Stratoflex* court stated, It is jurisprudentially inappropriate to disregard any relevant evidence on any issue in any case, patent cases included. Thus evidence rising

turally relevant to the nonobviousness of the invention, it should not be ignored when it is available.¹⁰³ Likewise, as evidence that is intuitively appealing and more susceptible to a “common sense” evaluation than the frequently highly technical prior-art evidence, it serves to orient the fact finder in his *Graham* analysis of the PHOSITA.¹⁰⁴ In addition to this benefit of intellectual accessibility, secondary considerations deserve whatever weight they merit, like any relevant evidence. This evidence should not be “secondary” at all.

A wealth of sources exists for mining potential secondary considerations; to name but a few, such sources include the Supreme Court and the *Graham* decision itself (commercial success, long-felt but unsolved needs, failure of others),¹⁰⁵ Federal Circuit decisions (copying, unexpected results and properties, licensing activity, and skepticism within the field),¹⁰⁶ the insightful obviousness analyses of Judge Learned Hand (density of inventive efforts and simultaneous invention),¹⁰⁷ and legal scholarship.¹⁰⁸ Traditionally, these and similar sources have defined secondary considerations in such a way that they either do or do not exist in a particular case and thus require no more than a binary “yes or no” response that does little to enable a sophisticated analysis of degree.

Recent scholarship has reshaped the form of the inquiry to respond to the continuum of circumstances that can realistically appear

out of the so-called ‘secondary considerations’ must always when present be considered en route to a determination of obviousness. Indeed, evidence of secondary considerations may often be the most probative and cogent evidence in the record. . . . It is to be considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art.

Id. (citations omitted).

¹⁰³ *In re Palmer*, 451 F.2d 1100, 1104 (C.C.P.A. 1971); *see also In re Mageli*, 470 F.2d at 1383 (“[E]vidence bearing on the facts is never of ‘no moment,’ is always to be considered, and accorded whatever weight it may have.”).

¹⁰⁴ *Supra* note 62 and accompanying text.

¹⁰⁵ *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966) (listing “[s]uch secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc.”).

¹⁰⁶ *See, e.g., In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998) (listing “copying, . . . unexpected results created by the claimed invention, unexpected properties of the claimed invention, . . . licenses showing industry respect for the invention, . . . and skepticism of skilled artisans before the invention”) (citations omitted).

¹⁰⁷ *Supra* note 25 and accompanying text.

¹⁰⁸ *See, e.g., Burk & Lemley*, *supra* note 84, at 1651 (listing “standard secondary considerations of nonobviousness” and describing their varying roles as “micro policy levers” in different industries).

within a particular fact pattern.¹⁰⁹ With this approach, whether a particular “square” fact will fit into the “round” category defined in the traditional secondary-consideration analysis no longer is in question. For example, the location of the observed evidence along a spectrum of potential circumstances can be identified, and when viewed in light of the activities of others in the actual field, the totality of this evidence will suggest some particular degree of inventiveness. Does this comparison suggest an innovative leap? If so, the invention is likely nonobvious. How does the analysis change if the circumstances surrounding the evidence were different, such as if fewer artisans were active in the field or if an enabling component appeared more recently? A holistic approach allows consideration of evidence in all situations where it is available and is adaptable to a wide variety of circumstances regardless of its ability to fit neatly within traditional secondary considerations categories.

In this vein, Professor John Duffy has recently suggested analyzing the length of time between the appearance of the technology enabling the invention and the invention itself rather than merely looking for evidence of a long-felt but unmet need.¹¹⁰ This time period could then be evaluated in the context of the particular field’s rate of innovation—the time required for research developments in a field to be followed by utility developments—to lend further industry specificity to the inquiry.¹¹¹ Similarly, the cost and uncertainty overcome in the particular inventive process could be situated on a spectrum of cost and uncertainty and compared to the aggregate measurements in a particular field rather than looking for evidence of the narrowly construed considerations of simultaneous invention by others, failure of others, or copying.¹¹² In theory, a patentability analysis

¹⁰⁹ See, e.g., sources cited *infra* notes 110–12.

¹¹⁰ Generally, an obvious discovery may not be made until some prior art change yields a “new component necessary for the innovation (a supply-side change) or a new market demand (a demand-side change).” John F. Duffy, *Nonobviousness—The Shape of Things to Come: A Timing Approach to Patentability*, 12 LEWIS & CLARK L. REV. 343, 346 (2008). If no such change can explain the discovery—i.e., if supply and demand considerations are unchanged for a substantial period of time—“then the innovation was almost certainly nonobvious.” *Id.*

¹¹¹ See, e.g., Jacob Schmookler, *Changes in Industry and in the State of Knowledge as Determinants of Industrial Invention*, in THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS 195, 195–96 (Nat’l Bureau of Econ. Research ed., 1962).

¹¹² Professors Dan Burk and Mark Lemley advocate addressing technology specificity by contextualizing a particular innovation within the collective industry:

A more efficient approach would be to inquire more generally into the cost and uncertainty of innovation in an industry as a whole, and to set rules that apply to a given industry. Uncertainty is difficult to measure

should not be relegated to a particular group of predefined categories of “secondary considerations”; *any* appropriate evidence that speaks to the obviousness of the invention should be considered according to where it appears along the relevant spectrum of possibilities.

Such objective evidence should also be divided in another way for analytical purposes: it should be separated into those indicia that are recognizable at the time of the invention (i.e., the “prior art”) and those that only appear after the invention (usually in the marketplace where the invention is offered). Of the two categories, objective evidence that exists or occurs prior to the invention is probably a more reliable indicator of obviousness because it is less easily manipulated by the other (non-innovation) activities of the inventor, such as marketing efforts. In addition, these preexisting factors will play a significantly more substantial role in the patent application and prosecution process, during which substantially less data may be available with which to analyze ex-post obviousness factors. In general, objective evidence appearing at the time of invention will speak to the level of skill and inventiveness in the art and the “probability” of invention, whereas postinvention evidence serves to corroborate these conclusions with the opinion of the marketplace.¹¹³ Stated another way, the former is a fundamental evaluation of how the invention measures up to the work of the theoretical PHOSITA, and the latter is a derivative indicator.

a. Objective Evidence Prior to the Time of Invention

At the time of invention, the objective evidence can be further divided into two categories: facts demonstrating the actual level of skill and inventiveness of the field of actual artisans (as compared to the theoretical PHOSITA) and facts indicating the probability of representativeness of this field (the likelihood that these actual artisans approximate the PHOSITA). The actual level of skill in the aggregated field can be understood by looking at the amount of time be-

with respect to a specific invention. It is uncertainty across many inventions—the number of inventions that do not pan out and consequently do not result in patent applications—that the test is designed to measure. That measurement can only be done in the aggregate, rather than in individual terms. On this more general approach, uncertainty of innovation as a nonobviousness factor would be a macro policy lever.

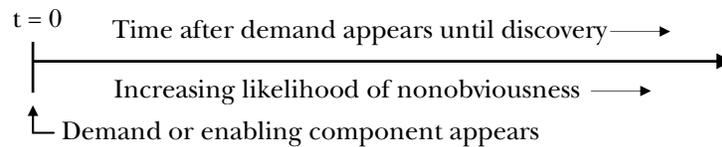
Burk & Lemley, *supra* note 84, at 1662.

¹¹³ See, e.g., *Dickey-John Corp. v. Int'l Tapetronics Corp.*, 710 F.2d 329, 346 (7th Cir. 1983).

tween supply- or demand-side changes and the resulting discoveries or failures by those in the field.¹¹⁴ This “appearance-timing” analysis essentially requires viewing the claimed invention in the context of changes in the prior art or in circumstances of invention that make the invention possible. For instance, a new market demand that is quickly and easily met with a combination of preexisting elements suggests obviousness whereas the first appearance of the same invention ten years later seems much less likely to be obvious. By comparing the timing of the appearance of enabling components or tangible market demand to the timing of the invention, questions of degree can be considered.

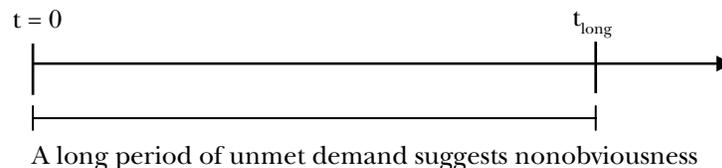
The classic secondary considerations of long-felt but unmet need, the failure of others, and simultaneous invention represent extremes on this appearance-timing spectrum:

Appearance-Timing Spectrum



On one side of the spectrum, a long-known but unmet market demand for a product requiring the invention, which was not satisfied until the discovery of the invention, suggests nonobviousness¹¹⁵:

A. One Extreme



¹¹⁴ See discussion *supra* note 110. Of course, identifying and isolating the relevant changes poses a distinct challenge within the factual inquiry.

¹¹⁵ *E.g.*, *In re Mahurkar Double Lumen Hemodialysis Catheter Patent Litig.*, 831 F. Supp. 1354, 1378 (N.D. Ill. 1993) (“The existence of an enduring, unmet need is strong evidence that the invention is novel, not obvious, and not anticipated. If people are clamoring for a solution, and the best minds do not find it for years, that is practical evidence—the kind that can’t be bought from a hired expert, the kind that does not depend on fallible memories or doubtful inferences—of the state of knowledge.”), *aff’d*, 71 F.3d 1573 (Fed. Cir. 1995).

If the invention were obvious, the desire for profit would have been sufficient to satisfy the need quickly¹¹⁶ :

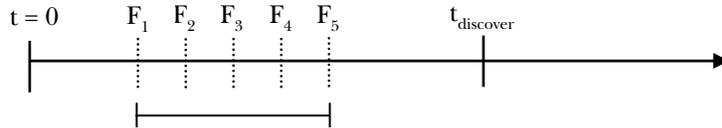
B. The Other Extreme



Nearly simultaneous demand appearance and supply discovery suggests obviousness

Likewise, the failure of others also suggests that a demand for the invention exists and has been identified but that designing and implementing a solution is not obvious.¹¹⁷ This implies a level of difficulty and complexity that cannot be overcome by an obvious combination of prior-known elements. Thus, a large number of failures in a short period following a supply or demand change suggest that a solution is not obvious¹¹⁸ :

C. Variation 1



Multiple prior failures by others suggests nonobviousness

On the other side of the spectrum is near-simultaneous invention by two or more parties. Multiple coincident successes suggest

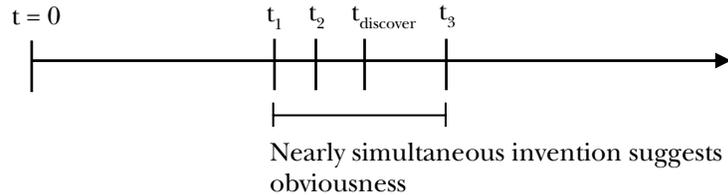
¹¹⁶ E.g., *In re Fielder*, 471 F.2d 640, 644 (C.C.P.A. 1973) (“A defect in a product or process spurs the businessman to deploy resources for discovering a solution. . . . Existence of the defect creates a demand for its correction, and it is reasonable to infer that the defect would not persist were the solution ‘obvious.’” (quoting Richard L. Robbins, Note, *Subtests of “Nonobviousness,”* 112 U. PA. L. REV. 1169, 1172 (1964))).

¹¹⁷ E.g., *Advanced Display Sys. v. Kent State Univ.*, 212 F.3d 1272, 1285 (Fed. Cir. 2000) (“[S]uch evidence of failed attempts by others could be determinative on the issue of obviousness.”).

¹¹⁸ Failure of others is also related to the probability calculus in that, in addition to suggesting the density of marketplace and invention competition facing the inventor, for every failure registered by another party, the probability of the inventor’s success increases from any knowledge of failure that enriches the prior art. See *infra* note 124.

that the invention is obvious, especially where these discoveries occur shortly after the supply or demand change¹¹⁹:

D. Variation 2



Under the appearance-timing analysis, each of these three particular objective considerations (long-felt but unmet need, the failure of others, and simultaneous invention) is viewed preferably not as simply present or absent. Rather, all of the evidence is viewed in its totality, giving the discovery's location on the appearance-timing continuum whatever probative value it has. Thus, the inventor's actual level of inventiveness becomes evident by comparison to the efforts and inventive abilities of other actual artisans in the field during the period following a change in supply or demand¹²⁰ regardless of the presence or absence of a particular consideration as traditionally understood.

In addition to evaluating the level of inventiveness of the PHOSITA's field by looking at the degree of inventiveness of an actual group of skilled artisans in the marketplace, understanding how well these actual artisans replicate the inventiveness of the theoretical PHOSITA is necessary. Accordingly, the probability that the actual accurately represents the theoretical must be taken into account. One factor in evaluating this "probability of representativeness" is the density of competition. If the aggregated field of potential inventors working to address the same problem or make the same improvement serves as a rough approximation of the theoretical PHOSITA, the field more likely represents the level of ordinary skill and inven-

¹¹⁹ See, e.g., *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 883–84 (Fed. Cir. 1998) (examining the interplay between "evidence of contemporaneous development" and "long-felt but unsolved need," not long-felt need in isolation").

¹²⁰ Although the issue of supply- and demand-side changes has been more typically related to the strength of a commercial success argument, see, e.g., *Am. Infra-Red Radiant Co. v. Lambert Indus., Inc.*, 360 F.2d 977, 989–91 (8th Cir. 1966), the implications of such changes logically extend to secondary considerations of nonobviousness more generally.

tiveness when competition is denser.¹²¹ Thus, in a “thick” marketplace, an inventor who succeeds where others have failed has more likely made a true inventive step.¹²² Additionally, more resources being expended on an area where competition is denser means that even a nonobvious invention will likely be discovered more quickly¹²³ because the rate of the search will be faster.¹²⁴ Finally, the cost and uncertainty of innovation in the industry itself also factor into the probability determination. Understanding the degree of uncertainty is useful in that the greater the uncertainty in the field, the less likely actual prior-art activities and information are predictive of future results.¹²⁵ In such cases, the experience of the field of actual potential inventors may not accurately represent the knowledge and experience of the PHOSITA. Thus, the crowdedness of the field, the pace of research, and the field’s degree of certainty all figure into the representativeness determination. When the appearance-timing information is viewed in light of the degree of artisan-PHOSITA resemblance, such preinvention evidence speaks strongly to inventiveness.

¹²¹ A statistical analogy is provided by the Central Limit Theorem, which says that for any population having a finite mean and standard deviation, the sampling distribution of the sample mean increasingly resembles a normal distribution as the sample size increases. According to this theory, the larger the sample size, the more likely the mean of the sample approximates the mean of the population. DAVID K. HILDEBRAND, R. LYMAN OTT & J. BRIAN GRAY, BASIC STATISTICAL IDEAS FOR MANAGERS 228–30 (2d ed. 2005).

¹²² Another statistical analogy is provided by the concept of the confidence interval. Confidence that a particular sample is or is not an outlier of the sample population is inversely proportional to the square root of the sample size. As the sample size increases, the confidence level increases, and whether a particular data point is an outlier is more certain. *Id.* at 269–72.

¹²³ Considering the “time” axis of the appearance-timing spectrum not in terms of particular units of time measurement (days, weeks, years, etc.) but rather in terms of inventive attempts by those addressing the supply or demand change is helpful. Theoretically, for the purposes of evaluating appearance timing, many inventors active across a short unit of time may be equivalent to a few inventors over a longer period.

¹²⁴ Basic probability teaches that the probability of an event equals the ratio of the number of available favorable outcomes to the total number of possible outcomes. As negative possible outcomes are eliminated, the probability of favorable outcomes increases. HILDEBRAND, OTT & GRAY, *supra* note 121, at 84–85.

¹²⁵ A final statistical analogy is the concept of standard deviation, which measures the amount of variability in a sample. If the standard deviation of a sample is high, the particular value of the next single measurement is less certain, but the properties of the distribution itself may be known. *Id.* at 35–37. In investment terms, “it is reasonable to assume that portfolios with histories of high variability also have the least predictable future performance” although, “[o]f course, there is no risk in hindsight.” RICHARD A. BREALEY, STEWART C. MYERS & FRANKLIN ALLEN, PRINCIPLES OF CORPORATE FINANCE 184 (9th ed. 2008).

b. Objective Evidence After the Time of Invention

After the time of invention, additional factors emerge that may corroborate the obviousness or nonobviousness of the invention. These factors speak to how the marketplace perceives the invention and can indicate an extension beyond the ordinary level of skill and inventiveness in the art. Generally, these provide later-in-time objective evidence to bolster the obviousness evidence that was available at the time of the invention. For example, to the extent that commercial success is due to the merit of the invention, it may be a sign of nonobviousness.¹²⁶ Great commercial success implicitly suggests that the market harbored a long-felt need that others failed to satisfy¹²⁷ and thus can be used postinvention to corroborate evidence of long-felt need and failure of others at the time of invention.¹²⁸

Likewise, use of the invention by competitors—whether by licensing, copying, or infringing—is a corollary and corroborative of the failure of others in the field.¹²⁹ Both legal and illegal forms of copying suggest that while a competitor was interested in satisfying a market demand in other ways, it was unable or unwilling to do so.¹³⁰

¹²⁶ Both the Supreme Court and Federal Circuit have accepted commercial success as evidence of nonobviousness in many cases. *See, e.g.*, *Goodyear Tire & Rubber Co. v. Ray-O-Vac Co.*, 321 U.S. 275, 279 (1944) (upholding lower-court determination based on finding of commercial success); *Akzo N.V. v. U.S. Int'l Trade Comm'n.*, 808 F.2d 1471, 1481 (Fed. Cir. 1986). But a nexus must exist between the patent's claim and the commercial success. *See, e.g.*, *Cable Elec. Prods., Inc. v. Genmark, Inc.*, 770 F.2d 1015, 1027 (Fed. Cir. 1985).

¹²⁷ *E.g.*, *Dickey-John Corp. v. Int'l Tapetronics Corp.*, 710 F.2d 329, 346 (7th Cir. 1983) (“If the patent in issue filled a need that was not only genuine, but long felt—that is, long *consciously* recognized—the inference is that for a long period of time actual artisans were attempting to solve the problem. The greater the need, and the longer it was felt, the stronger the inference.”).

¹²⁸ In fact, Judge Hand felt that commercial success was only relevant as an indicator of nonobviousness when preceded by a long-felt but unmet need. *See* *Ruben Condenser Co. v. Aerovox Corp.*, 77 F.2d 266, 268 (2d Cir. 1935).

¹²⁹ *See, e.g.*, *Advanced Display Sys. v. Kent State Univ.*, 212 F.3d 1272, 1285 (Fed. Cir. 2000) (finding defendant's “wholesale copying of the claimed invention”—after “entirely unsuccessful” independent efforts—to be “compelling evidence of nonobviousness”); *Dow Chem. Co. v. Am. Cyanamid Co.*, 816 F.2d 617, 622 (Fed. Cir. 1987) (noting that the defendant “tried but failed to develop the claimed invention and copied it instead”); *Vandenberg v. Dairy Equip. Co.*, 740 F.2d 1560, 1567 (Fed. Cir. 1984) (finding that evidence of copying is particularly useful “where the copyist had itself attempted for a substantial length of time to design a similar device, and had failed”).

¹³⁰ *See, e.g.*, *Panduit Corp. v. Dennison Mfg. Co.*, 774 F.2d 1082, 1099 (Fed. Cir. 1985) (“That [defendant], a large corporation with many engineers on its staff, did not copy any prior art device, but found it necessary to copy the [invention] of the claims in suit, is equally strong evidence of nonobviousness.”), *vacated*, 475 U.S. 809 (1986) (questioning the standard of review applied by the Federal Circuit).

This may mean that the innovator discovered a solution that was not obvious to others of ordinary skill and thus suggests the nonobviousness of the invention.

Finally, artisans' statements of professional approval or disapproval are the equivalent of a retrospective analysis of the prior-art situation by those skillful in the art.¹³¹ While it may not be a perfect hindsight evaluation because artisans are not necessarily equivalent to theoretical PHOSITAs, this evidence has the advantage both of being from a backward-looking point of view (similar to a court's determination) and of deriving from intimate background knowledge in the field of the invention (greater than that of a typical court).¹³² Given these corroborative functions, postinvention evidence of commercial success, copying, and artisans' statements should be given weight as additional objective evidence.

3. Emphasizing Objective Evidence as the Best Way to Understand *Graham's* PHOSITA

After *KSR*, any obviousness determination should be increasingly fact- and evidence-based. Rather than considering objective evidence as "secondary," such evidence should form a critical part of the *Graham* analysis. This evidence helps to understand the inventive position of the PHOSITA beyond the assistance provided by the bare construct of the *Graham* comparison; it is used to see what the gap between the prior art and the claimed invention means—whether it represents a true inventive step. The objective evidence available at the time of invention informs the inquiry into the level of skill and inventiveness of the artisans in the field (e.g., appearance timing, including long-felt need and the success or failure of others) and tells how closely this approximates the PHOSITA and future results by informing the probability of representativeness (e.g., density of compe-

¹³¹ See, e.g., *Libbey-Owens-Ford Co. v. BOC Group, Inc.*, 655 F. Supp. 897, 914–16 (D.N.J. 1987) (citing an alleged infringer's statements of praise made prior to litigation as "a strong indication of the non-obviousness" of the invention); cf. *Minn. Mining & Mfg. v. Smith & Nephew, PLC*, No. 3-91 CIV 274, 1992 U.S. Dist. LEXIS 22785 (D. Minn. July 27, 1992) (ordering discovery of marketing and sales data relating to defendant's allegedly infringing products as probative of both the patent's nonobviousness and defendant's subjective beliefs about the "relative uniqueness, superiority and marketability of a disputed patent").

¹³² For a discussion of this issue, see Rebecca S. Eisenberg, *Obvious to Whom? Evaluating Inventions from the Perspective of PHOSITA*, 19 BERKELEY TECH. L.J. 885, 888 (2004). In particular, artisans' statements can somewhat mitigate the fundamental dangers of hindsight bias in patent law that were evidenced in the *KSR* decision—after-the-fact determinations based on common sense made by those with little relevant technical knowledge. See *supra* notes 16–17, 61–62, 67 and accompanying text.

tition, pace, and uncertainty of innovation). Additional objective evidence available at the time of litigation and potentially prosecution (e.g., commercial success, copying by others, and artisans' statements) corroborates the pre-existing objective evidence but probably commands less importance because of the significant influence of other activities by the inventor.

As noted in *KSR*,¹³³ a frequent complaint¹³⁴ about the use of "secondary considerations" is the lack of available evidence,¹³⁵ but finding the evidence is easier if the inquiry is considered in broader terms than usual. For instance, long-felt need and the failure of others require specific evidence satisfying predefined notions. If these are reconstrued as considerations of "appearance timing," any evidence can be used to understand where the PHOSITA lies relative to the continuum of possible skill and inventiveness. In a complementary fashion, the probability of representativeness reveals how well this objective evidence, to whatever extent it is available, represents the PHOSITA and the PHOSITA's theoretical inventive activity.

B. Objective Evidence Directly Demonstrates the Innovation Needs of Different Industries

The true test of an obviousness analytical framework that is grounded in objective evidence is its suitability to the ever-changing needs of patent-dependent industries. Not only is objective evidence more attuned to the needs of the fact finder without skill in the art, but also, because it flows directly from the inventive circumstances within the art, it provides the best evidence of industry needs and how the patent system can appropriately respond to those needs.

¹³³ *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 425–26 (2007); *supra* text accompanying note 59.

¹³⁴ In conjunction with his empirical study of hindsight bias, Professor Gregory Mandel's review of Federal Circuit and district court obviousness decisions reveals that traditional "[s]econdary consideration evidence appears to affect only a small percentage of non-obvious decisions." Gregory N. Mandel, *Patently Non-Obvious: Empirical Demonstration that the Hindsight Bias Renders Patent Decisions Irrational*, 67 OHIO ST. L.J. 1391, 1425 (2006). Professor Mandel argues that this is insufficient to mitigate the hindsight bias that he observed in his study. *Id.*

¹³⁵ Furthermore, a lack of evidence of traditional secondary considerations (commercial success, long-felt but unmet need, copying, etc.) was previously considered to have no bearing whatsoever on the obviousness determination. *See, e.g.*, *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 960 (Fed. Cir. 1986); *Medtronic, Inc. v. Intermedics, Inc.*, 799 F.2d 734, 739 n.13 (Fed. Cir. 1986); Steven P. Smith & Kurt R. Van Thomme, *Bridge Over Troubled Water: The Supreme Court's New Patent Obviousness Standard in KSR Should Be Readily Apparent and Benefit the Public*, 17 ALB. L.J. SCI. & TECH. 127, 189 (2007). Thus, the conceptualization of objective evidence as a continuum departs from this convention.

1. Industrial Contexts

To understand the implications of a one-size-fits-all patent system across the range of applicable technologies, conditions in three disparate industries are analyzed: the mechanical, pharmaceutical, and computer industries. As the tentative foundation for new obviousness jurisprudence, the *KSR* decision can be considered the mechanical-arts benchmark from which decisions based on other technologies will depart. The patent system was originally created primarily to protect mechanical technologies,¹³⁶ and so the development of the field extends back to at least the inception of the patent system.¹³⁷ Therefore, the mechanical arts are unsurprisingly generally well developed and well understood in comparison to most other patent-utilizing technology fields,¹³⁸ and developments in the mechanical arts are now patented with less and less frequency.¹³⁹ Thus, in many cases, “common sense” may be enough for most people to understand developments in this field because inventions (such as the brake pedal in *KSR*) have components that are readily identifiable and whose functions frequently can be understood intuitively by non-artisans.¹⁴⁰ The well-developed character of the field and the layperson’s ease of grasping general concepts make the mechanical arts an appropriate baseline in the obviousness determination. They serve a similar function as a representative of the middle ground between the disparate needs of the computer and pharmaceutical industries; while the mechanical arts cover a broad range of development uncer-

¹³⁶ Historical circumstances suggest that patent law doctrines were created with primarily mechanical inventions in mind:

The “useful arts” envisioned by the Framers were mechanical inventions useful in a primarily agrarian economy. . . . As late as 1950, though, most inventions were still mechanical in nature. It is only in the last half-century . . . that patent law has lost its primarily mechanical character, branching out into biotechnology, semiconductors, computer hardware and software, electronics, and telecommunications.

Burk & Lemley, *supra* note 79, at 1159; *see also* Allison & Lemley, *supra* note 77, at 79.

¹³⁷ *See* Burk & Lemley, *supra* note 79, at 1159 (contrasting this history with the relatively recent advent of other technology areas).

¹³⁸ *E.g.*, *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970) (characterizing “mechanical or electrical elements” as “involving predictable factors” with “performance characteristics predicted by resort to known scientific laws” and characterizing “most chemical reactions and physiological activity” as “involving unpredictable factors”).

¹³⁹ Allison & Lemley, *supra* note 77, at 93.

¹⁴⁰ For example, the *KSR* decision “originated from litigation revolving around a relatively simple automobile mechanical patent involving technology with which most are familiar.” Smith & Van Thomme, *supra* note 135, at 134.

tainty, cost, and speed, as well as varying degrees of patent coverage,¹⁴¹ the computer and pharmaceutical industries occupy the extremes of these spans.

In contrast to the mechanical arts, the computer industry is characterized by a relatively short product development cycle, low capital intensity, and a short product life cycle.¹⁴² Generally, products are rapidly superseded by new generations in the marketplace (frequently within a year or two)¹⁴³ and may be readily copied and sold.¹⁴⁴ Programs and equipment can be developed from scratch or, more frequently, based on improvements or modifications of previous applications.¹⁴⁵ In addition, the software marketplace is not extensively government regulated but instead relies on voluntary standards developed by industry members.¹⁴⁶ With respect to the industry's pa-

¹⁴¹ This is due in part to the broad range of industrial applicability of mechanical inventions in contrast to the narrower industrial settings of pharmaceutical and computer arts. Many mechanical inventions encompass automotive, medical device, or electronic technologies, for example, with corresponding and distinct innovation and patenting patterns. See Allison & Lemley, *supra* note 77, at 89, 91–94.

¹⁴² See FED. TRADE COMM'N, *supra* note 69, ch. 3, at 2 (“[C]omputer hardware and software industry representatives . . . described an innovation process that is generally significantly less costly than in the pharmaceutical and biotech industries, and they spoke of a product life cycle that is generally much shorter.”).

¹⁴³ See *supra* note 87 and accompanying text. For example, Apple has released a new generation of its “Classic” iPod every year since its introduction of the first model. Apple.com, Identifying iPod Models, <http://support.apple.com/kb/HT1353> (last visited Feb. 18, 2010). This is consistent with an incremental or cumulative nature of product development. See *infra* note 145 and accompanying text.

¹⁴⁴ This is obviously not unique to this industrial context given the general function of patents to prevent copying by competitors, and industry members express conflicting opinions on the value of patents in preventing such “free riding.” See FED. TRADE COMM'N, *supra* note 69, ch. 3, at 48–49. It is nonetheless pervasive and problematic for many reasons. See, e.g., Brian Grow et al., *Dangerous Fakes: How Counterfeit, Defective Computer Components from China Are Getting into U.S. Warplanes and Ships*, BUSINESSWEEK, Oct. 2, 2008, at 34, available at http://www.businessweek.com/magazine/content/08_41/b4103034193886.htm (underscoring the dangerous and pervasive problem of counterfeit computer components purchased by the U.S. military).

¹⁴⁵ FED. TRADE COMM'N, *supra* note 69, ch. 3, at 44–45; Richard C. Levin, President, Yale Univ., Speech at the FTC/DOJ Joint Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy (Feb. 6, 2002), available at <http://www.ftc.gov/opp/intellect/020206ftc.pdf> (“[I]n contrast to this discrete nature of chemical and pharmaceutical products, in other key technologies, such as microelectronics, telecommunications and computers, [progress] was cumulative.”); see also Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 CAL. L. REV. 1, 41 (2001) (discussing the impact of cumulative innovation on the scope of patent protection).

¹⁴⁶ See, e.g., BRIAN KAHIN, COMPUTER & COMM'NS INDUS. ASSOC., PATENT REFORM FOR A DIGITAL ECONOMY 24 (2006), available at http://www.ccianet.org/CCIA/files/ccLibraryFiles/Filename/000000000081/CCIA_WP_PatReformDigEcon.pdf

tenting needs, the complexity of electronics products poses special patenting problems. Because a wide array of features, components, functions, etc., are encompassed within each product—each of which may be patentable individually¹⁴⁷—generally no one-to-one correspondence exists between a patent and a product in the computer industry.¹⁴⁸ For these reasons, the computer industry is particularly vulnerable to patent thickets, innocent infringement, and patent trolling,¹⁴⁹ and the computer industry has thus led the call for patent reform.¹⁵⁰

Strongly opposing any patent reform, and in stark contrast to the computer industry, is the pharmaceutical industry, where a handful of patents generally protect a long-lived product.¹⁵¹ A pharmaceutical company generally relies on a short list of patented, marketed products to support its entire operation,¹⁵² which is characterized by a long product development cycle, high capital intensity, and a generally long but variable product life cycle.¹⁵³ With

(“Cognizant of the need to spur innovation and create new markets, IT firms invest heavily in developing standards. Freely usable nonproprietary standards . . . were responsible for the rapid uptake and spectacular success of the Internet, the Web, and the many services and products built on top of these platforms.”).

¹⁴⁷ *E.g.*, Kahin, *supra* note 78, at 390 (observing that in “the extreme complex-product environment associated with information technology[,] . . . an inexpensive product may contain thousands, perhaps tens or hundreds of thousands of potentially patentable functions and components”).

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*; FED. TRADE COMM’N, *supra* note 69, ch. 3, at 34–41 (discussing the problems of “patent thickets” and “non-practicing entities” such as “‘professional’ patent assertion companies”).

¹⁵⁰ *E.g.*, KAHIN, *supra* note 146, at 5 (“Today, talk of reform is widespread and loudly voiced, especially in the high-tech community. Is the patent system broken? Many in information technology say that it is . . .”).

¹⁵¹ *Id.* at 6 (“Yet efforts to reform the system through legislative action are easily paralyzed by highly motivated contending interests. Pharmaceutical companies with a handful of patents protecting billions of dollars in drug investment do not want to see the value or power of these patents diminished in any way.”).

¹⁵² FED. TRADE COMM’N, *supra* note 69, ch. 3, at 5 (“The brand-name companies’ trade association reports that most newly marketed drugs do not cover their average development costs. Brand-name companies typically rely on a small number of ‘blockbuster’ drugs to recoup their overall investment in innovation, including R&D costs for failed products.”); *see also* PHARM. RESEARCH & MFRS. OF AM., *supra* note 85, at 3.

¹⁵³ Pharmaceutical and biotech corporate representatives described the industries’ innovation as “costly and unpredictable, requiring significant amounts of pioneering research to discover and test new drug products.” FED. TRADE COMM’N, *supra* note 69, ch. 3, at 1. These firms desire patents to prevent free-riding by rivals so as to ensure that the firms “recoup the substantial capital investments made to discover, test, and obtain regulatory approval of new drug products,” and they emphasized the

respect to the industry's patenting needs, the length of a product development cycle is typically long but extremely unpredictable because of considerable uncertainty in innovation.¹⁵⁴ With respect to patent-holder revenue, the effective patent life is comparatively short¹⁵⁵ because the research, development, and regulatory-approval processes are so lengthy.¹⁵⁶ Finally, the pharmaceutical marketplace requires regulatory approval for entry,¹⁵⁷ a burden not as common outside this industry. Thus, to support the cost and uncertainty of product development, pharmaceutical innovation requires generally strong patent protection.¹⁵⁸

2. Developing Industry-Specific Factual Presumptions

When undertaking a factual, evidence-based inquiry in conjunction with a post-*KSR* obviousness determination, the characteristics of each industry at the time of invention will necessarily play an important role. To the extent that such characteristics are generalizable across each industry, the objective evidence examined and weighed in the obviousness determination may be generalizable as well. Of course, some evidence may require a true case-by-case analysis even within an industry, such as where generalities do not apply to the circumstances of a particular case. Yet a properly applied factual presumption on elements of the obviousness determination lends a desirable consistency to the analysis and ensures that the needs of the industry are properly addressed.

In contrast to how some have characterized previous obviousness determinations,¹⁵⁹ these presumptions are factual, not legal. Previous

importance of patent protection in attracting necessary high-risk capital investments. *Id.*

¹⁵⁴ *Id.* ch. 3, at 16 (“[T]he pharmaceutical industry is several times more R&D intensive than any other industry.” R&D is particularly lengthy for biotechnology firms, because biotechnology innovation is more uncertain than innovation in other industries.”).

¹⁵⁵ According to the pharmaceutical industry group The Pharmaceutical Research and Manufacturers of America (PhRMA), the effective patent life of drug patents is shortening and will likely continue to do so. PHARM. RESEARCH & MFRS. OF AM., *supra* note 85, at 16 (“While total patent life in the U.S. is 20 years, for medicines, much of that span is spent in research and development. For example, drugs with more than \$100 million in annual sales had an effective patent life of 11 years in 2003 through 2005. There is evidence that effective patent life is shortening and will continue to decline.”).

¹⁵⁶ *Id.* at 3 (“[T]he R&D process takes an average of 10 to 15 years.”).

¹⁵⁷ *See id.* at 4–5.

¹⁵⁸ *See supra* note 153 and accompanying text.

¹⁵⁹ *See generally* Burk & Lemley, *supra* note 79. Professors Burk and Lemley argue that Federal Circuit decisions have developed separate standards for particular in-

decisions have been criticized for too closely following judicial, rather than technology and innovation, trends:

We just keep replicating the old results based on the old precedents, whether they have kept pace with changes in business, changes in technology, or changes of a different sort [W]e just get the Federal Circuit talking to itself, with the brief writer just being the echo of what we wrote in all those prior cases. And then we write some more cases, and the cycle just goes on and on and on. And it certainly lacks the benefit of being tightly wired to the evolving reality.¹⁶⁰

Courts risk turning factual presumptions into de facto legal presumptions when they refer to previous decisions rather than to the true factual underpinnings of the inventive process, and the criticism of the technology-specificity of obviousness determinations suggests that this often leads to incorrect results. Yet a properly understood factual presumption may be rebutted easily by an accurate factual inquiry¹⁶¹ and acts as a safeguard against overreliance.

Although the concept of generalizing to factual presumptions may be useful, this is only true when attempting to understand the theoretical mindset of the PHOSITA at the time of the invention. Postinvention presumptions are not proper because postinvention objective evidence merely corroborates obviousness inferences based on circumstances at the time of invention and does not teach anything new about the PHOSITA. These later considerations may be deemed truly “secondary.” The particular circumstances of each industry speak to the utility and appropriate weight of this postinvention corroborative evidence for the fact finder, but they do not suggest a place for ex post facto evidence within a presumed starting point of obviousness or nonobviousness.

Thus, for each industry, understanding exactly where preinvention presumptions are appropriate and how best to apply them is useful. Industrial characteristics must be considered with respect to the appearance-timing analysis, the probability of representativeness, and the secondary corroborative evidence, but only the former two inform the primary factual presumption.

dustries by “substitut[ing] caricature for a nuanced understanding of the technology” and warn that these standards are then applied deferentially in subsequent decisions. *Id.* at 1191.

¹⁶⁰ Kahin, *supra* note 78, at 396 (quoting Judge Michel of the Federal Circuit).

¹⁶¹ Experience has shown that a misunderstood “legal” presumption is not as easily ignored. Burk & Lemley, *supra* note 79, at 1185.

3. Applying Industrial Characteristics to Achieve the Proper Factual Presumptions

First, an analysis of the characteristics of the mechanical arts suggests a preinvention factual presumption of obviousness. Although appearance timing necessarily depends on when the invention appears in relation to the appearance of a supply or demand change, the advanced development of the mechanical arts means that these inventions generally appear quickly,¹⁶² though significant variability exists.¹⁶³ The present comparatively extensive understanding of the underlying principles, clear from the prior art, means that developments are frequently rapid,¹⁶⁴ which creates a significantly larger hurdle to demonstrating nonobviousness than was present historically. Because of this significant suggestion of obviousness, evidence of long-felt but unmet need or the failure of others is particularly relevant and persuasive. These considerations strongly suggest nonobviousness when viewed against the backdrop of the high level of ordinary skill in the art. Likewise, the adeptness of the actual mechanical engineer probably is considerably representative of the theoretical PHOSITA in the mechanical arts. Although the density of competition is likely to be case-specific and particular to the object of the invention, the cost and uncertainty of innovation in the mechanical arts is sufficiently low that even the successes or failures of a few artisans can demonstrate whether the problem can be solved using only the level of ordinary skill. Thus, these industrial characteristics suggest a strong factual presumption of obviousness, although evidence of nonobviousness likewise has significant weight given the broader spectrum of particular industrial settings that the mechanical arts encompass.¹⁶⁵

If a mechanical invention faces a high burden to show nonobviousness, postinvention objective evidence of commercial success, copying, or artisan praise is particularly important to rebut this factual presumption. Similar to the preinvention analysis, the presence of these factors may have considerable weight where a high level of ordinary skill is apparent. Commercial success and copying because of the technical merit of the invention can demonstrate nonobviousness because a range of alternative solutions is likely in a well-developed field. Likewise, given the lower complexity and uncertain-

¹⁶² See *supra* notes 138–40 and accompanying text.

¹⁶³ See *supra* note 141 and accompanying text.

¹⁶⁴ See *supra* notes 138–40 and accompanying text.

¹⁶⁵ See *supra* note 141 and accompanying text.

ty of the field, laudatory statements by peers are likely to be rare unless a solution is nonobvious.¹⁶⁶ Such evidence is especially critical where the degree of variability in the sophistication of the mechanical arts results in a poor fit between the factual presumption and the actual inventive circumstances.

Recent decisions support this rebuttable factual presumption of obviousness. The *KSR* decision has shown that remarkably little is required to demonstrate obviousness in the mechanical arts; namely, prior-art references containing the elements and common sense will suffice. Although not expressly addressed in the decision, the court implied that objective evidence probably has to be quite strong to be considered a significant factor and overcome the presumption of obviousness. In the later Federal Circuit decision, *In re ICON Health & Fitness, Inc.*,¹⁶⁷ which concerned a treadmill containing a folding base that stayed upright by use of a spring mechanism, the court reaffirmed the high level of ordinary skill and the general presumption of the obviousness of combinations that was apparent in *KSR*.¹⁶⁸

Similarly, an analysis of the characteristics of the computer arts suggests a preinvention factual presumption of obviousness. Although computers and related technology are newer than mechanical endeavors, the art is nevertheless sophisticated and rapidly advancing.¹⁶⁹ Swift product-development timelines in response to changing market demands suggest that the appearance-timing analysis favors a factual presumption of obviousness. The high level of skill of the ordinary computer engineer, also evidenced by the ability to address technological challenges confidently, cheaply, and rapidly,¹⁷⁰ closely resembles that of the theoretical PHOSITA. Specific objective evidence suggesting nonobviousness thus has considerable impact when it contradicts these assumptions about the predictability and high level of skill in the art. In all these ways, the computer-arts analysis closely resembles the mechanical-arts baseline and its factual presumption of obviousness.

¹⁶⁶ But examining the extent to which this evidence relates to the technical merit of the patented invention, as distinguished from the effects of other marketplace forces or of incorporation of the invention as a component of a larger product that is successful, copied, or praised, is always necessary. This is frequently referred to as the “nexus requirement.” See, e.g., *Cable Elec. Prods., Inc. v. Genmark, Inc.*, 770 F.2d 1015, 1027 (Fed. Cir. 1985).

¹⁶⁷ 496 F.3d 1374 (Fed. Cir. 2007).

¹⁶⁸ *Id.* at 1380–82 (providing an analysis of the obviousness of a combination of prior art references that echoes the analysis in *KSR*).

¹⁶⁹ See *supra* notes 142–45 and accompanying text.

¹⁷⁰ See *supra* notes 87–88 and accompanying text.

In other ways, the analysis necessarily departs from the mechanical arts. Most importantly, the analysis by the fact finder is considerably complicated by the fact that the technical concepts are less accessible to the layperson. Reliance on common sense or intuitive understanding is insufficient, and a factual presumption of obviousness may lead alternatively to a desirable simplification of the evidence examined by the fact finder or to an undesirable overreliance on the presumption. In either case, although a factual presumption of obviousness may be appropriate and common sense may still be relevant, evaluating objective evidence in the computer arts may necessarily require a more careful assessment than the cursory *KSR* opinion may suggest.

Other distinctions between the mechanical arts and the computer arts significantly complicate the analysis of postinvention evidence. The historical types of objective evidence discussed earlier¹⁷¹ were identified to address the mechanical arts, and the evolving applications of the patent system means that their use in more modern industrial contexts is not always without criticism.¹⁷² The most significant issue for the computer arts is the general lack of correspondence between the invention and the product.¹⁷³ The industry's marketed products are highly complex and involve a multitude of patentable components.¹⁷⁴ Therefore, tying the commercial success of a product to the nonobviousness of a component is generally difficult except in rare cases. Where the market success of a product *can* be attributed to a discrete, unique feature or function related to the patented improvement, however, the suggestion of nonobviousness is particularly strong. Another aspect of this ill adaptation is the ability to patent software functions, somewhat akin to patenting *concepts*, in a way that was not possible in the mechanical arts, in which patents were generally limited to a tangible apparatus or process.¹⁷⁵ Finally, computer

¹⁷¹ See *supra* notes 105–08 and accompanying text.

¹⁷² See, e.g., Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CAL. L. REV. 805, 837–43 (1988) (“Nonetheless, commercial success may be an inappropriate factor in patent decisions, because it relies upon indirect evidence, and because it assumes a simplistic conceptual model of innovation.”).

¹⁷³ E.g., Kahin, *supra* note 78, at 390.

¹⁷⁴ *Id.*

¹⁷⁵ For a discussion of this historical evolution, see Cohen & Lemley, *supra* note 145, at 7–14; see also Kahin, *supra* note 78, at 389 (“The United States patent system has embraced new areas by expanding in several distinct directions: basic science (biotechnology), mathematics and logic (software), and the social sciences and liberal arts professions (business methods). This new subject matter is far removed from the 19th Century industrial technologies that the system was designed for.”).

and software development occurs in consortiums of patent holders who pool and cross-license patents in an effort to enable the development of industry standards and avoid the paralysis of patent thickets, which is an environment not historically contemplated.¹⁷⁶ Thus, while copying by others and artisans' laudatory statements still form part of any factual inquiry into obviousness, they cannot be viewed merely as present or absent; the fact finder must weigh the totality of the evidence and give due regard to the nature of the patented invention and the patentee's relationship to others in the industry. Postinvention objective evidence likely will frequently be of little use in rebutting a factual presumption of obviousness because of these complexity issues, and its use may even be ill advised where the fact finder is not sufficiently apprised of these divergences.

Another recent Federal Circuit decision, *Leapfrog Enterprises v. Fisher-Price, Inc.*,¹⁷⁷ reinforces the similarities between the obviousness analyses in the computer and mechanical arts that are fundamental to their shared resultant presumption.¹⁷⁸ *Leapfrog* involved an "interactive learning device" that the court characterized as the combination of a similar analogue prior-art device and modern electronics.¹⁷⁹ The court then found this combination obvious, as in *KSR*, in light of the common sense of those skilled in the art¹⁸⁰ and thus made it clear that the notion of "common sense" indirectly supporting a factual presumption of obviousness also applies in the electronics setting. *Leapfrog* also lends support to the idea that postinvention secondary considerations will rarely overcome the presumption of obviousness created by the preinvention factual environment:

The district court explicitly stated in its opinion that Leapfrog had provided substantial evidence of commercial success, praise, and long-felt need, but that, given the strength of the prima facie obviousness showing, the evidence on secondary considerations was inadequate to overcome a final conclusion that [the invention] would have been obvious.¹⁸¹

While this statement is not surprising—in fact, it is probably expected—greater analysis as to why the "substantial evidence" failed to overcome the presumption of obviousness would have been instructive.

¹⁷⁶ See *supra* notes 146–49 and accompanying text.

¹⁷⁷ 485 F.3d 1157 (Fed. Cir. 2007).

¹⁷⁸ See *id.*

¹⁷⁹ *Id.* at 1158.

¹⁸⁰ *Id.* at 1161.

¹⁸¹ *Id.* at 1162.

Finally, an analysis of the characteristics of the pharmaceutical arts suggests a preinvention factual presumption of *nonobviousness* that derives from significantly different factual analyses and generalizations from the previous two cases. With respect to appearance timing, the length of time between the appearance of the invention and the appearance of a supply or demand change is still relevant, but in this case distinguishing between the time of the invention and the time of the invention's appearance in the marketplace, which may be ten to fifteen years later, is especially critical.¹⁸² So while it is useful to compare the relative time to invention to that of similarly situated pharmaceutical developments for signs of nonobviousness, the use of evidence of a long-felt but unmet need must be prudent. For example, with notable exceptions,¹⁸³ many diseases and conditions tackled by pharmaceutical inventions have been known for as long as humans have been around to suffer them, but the critical date for the timing analysis is actually the formulation of the basic biological understandings that make the development of treatments possible. In addition, significant regulatory lag time¹⁸⁴ means that the unmet need will continue to be unmet for a significant period after a treatment's discovery. Finally, success is the exception rather than the rule,¹⁸⁵ and the failure of others (likely including considerable prior efforts by the patentee) can generally be assumed unless negated by evidence of the simultaneous invention by another. Thus, given the generally sluggish pace of invention, the appearance-timing analysis suggests a low level of ordinary skill in the pharmaceutical arts. Likewise, with so little predictability in the art that the utility of the invention for its in-

¹⁸² See *supra* note 85.

¹⁸³ Among these exceptions is severe acute respiratory syndrome (SARS), which was only first reported in February 2003. CTRS. FOR DISEASE CONTROL & PREVENTION, DEP'T OF HEALTH & HUMAN SERVS., FACT SHEET: BASIC INFORMATION ABOUT SARS (2004), <http://www.cdc.gov/ncidod/sars/pdf/factsheet.pdf>. In contrast, diseases such as obesity and diabetes are known historically but have dramatically increased in prevalence in recent years. CTRS. FOR DISEASE CONTROL & PREVENTION, DEP'T OF HEALTH & HUMAN SERVS., OBESITY AND OVERWEIGHT: U.S. OBESITY TRENDS 1985–2007 (2008), <http://www.cdc.gov/obesity/data/trends.html>; CTRS. FOR DISEASE CONTROL & PREVENTION, DEP'T OF HEALTH & HUMAN SERVS., NUMBER (IN MILLIONS) OF CIVILIAN/NONINSTITUTIONALIZED PERSONS WITH DIAGNOSED DIABETES, UNITED STATES, 1980–2006 (2008), <http://www.cdc.gov/diabetes/statistics/prev/national/figpersons.htm>.

¹⁸⁴ According to PhRMA, Phase I, II, and III clinical studies together require six to seven years to complete and are followed by FDA review of an applicant's New Drug Application (NDA) for six months to two years. PHARM. RESEARCH & MFRS. OF AM., *supra* note 85, at 4.

¹⁸⁵ *Id.* at 3 (“[F]or every 5,000 to 10,000 compounds tested, just 5 will make it to clinical trials and, of those, only 1 will eventually receive FDA approval.”).

tended purpose is not known for ten years or more,¹⁸⁶ saying that an invention is obvious to one of ordinary skill is quite difficult. A factual presumption of nonobviousness applies unless evidence such as simultaneous invention by others or the appearance of the invention immediately following a demand-side change overcomes this presumption.

As with computer inventions, the analysis of postinvention objective evidence is complicated by the presence of other factors that have not figured into the traditional, mechanical-arts-based analysis. In particular, both the generally one-to-one patent-to-product correspondence and the regulatory scheme overlaying the development and marketing of a drug or biologic product affect this assessment. Because the product is almost unquestionably an appropriate surrogate for the patent, evidence of commercial success may be useful if compared to other drugs or treatments addressing the same condition. Artisans' statements, frequently in the form of clinical-study data, may be particularly useful because of the general unity of invention and product. In particular, the regulatory structure of the pharmaceutical industry, which frequently results in abundant objective data, provides the opportunity to examine the postinvention perspective of other artisans in the field. Yet this regulatory structure also suggests that evidence related to commercial success or copying may be less relevant because, for example, the requirement of regulatory approval results in limited approved patient-treatment options and creates additional hurdles for market entry. Despite these regulatory constraints, significant postinvention evidence of the superiority or inferiority of the invention remains available and useful to corroborate or rebut the presumption of nonobviousness.

The Federal Circuit has addressed obviousness in the pharmaceutical arts numerous times since the *KSR* decision. For example, in *Takeda Chemical Industries v. Alphapharm Pty. Ltd.*,¹⁸⁷ the court easily found a patented pharmaceutical compound to be nonobvious.¹⁸⁸ *Takeda* involved a patent covering a single diabetes compound that was structurally similar to a compound disclosed in a prior patent covering a broad group of potentially anti-diabetic compounds.¹⁸⁹ In support of the general nonobviousness of novel pharmaceutical compounds, even where structurally similar, the court stated, "[I]n cases involving new chemical compounds, it remains necessary to

¹⁸⁶ See *supra* note 85.

¹⁸⁷ 492 F.3d 1350 (Fed. Cir. 2007).

¹⁸⁸ See *id.* at 1364.

¹⁸⁹ *Id.* at 1353.

identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound.”¹⁹⁰ The court’s significant reliance on the lack of a reasonable expectation of success as a basis for finding nonobviousness further acknowledged the unpredictability in the art.¹⁹¹ Finally, the court also alluded to the one-to-one patent-to-product correspondence and considerable evidence of commercial success, which undoubtedly did not contradict the presumption of nonobviousness.¹⁹² Thus, the factual presumption of nonobviousness was maintained.

Another case, *Pfizer, Inc. v. Apotex, Inc.*,¹⁹³ provides a cautionary tale about how far this presumption will go. In *Pfizer*, the Federal Circuit found a pharmaceutical salt form obvious and unpatentable in light of the prior disclosure of the chemical structure in its neutral form.¹⁹⁴ Despite the traditional treatment of the pharmaceutical arts as unpredictable for patent purposes,¹⁹⁵ the court found that the availability of only fifty-three pharmaceutically acceptable salt-forming ions motivated this particular combination and that “obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success.”¹⁹⁶ Likewise, Pfizer’s significant objective evidence of nonobviousness was “in any event insufficiently probative of non-obviousness to overcome the evidence of the prior art teachings.”¹⁹⁷ Interestingly, the Federal Circuit has already suggested limiting this seeming reversal of principles to its “particularized facts.”¹⁹⁸

Generally, by focusing on the objective evidence peculiar to an industry and technical problem, the appropriate obviousness “base-

¹⁹⁰ *Id.* at 1357.

¹⁹¹ *Id.* at 1361.

¹⁹² *Id.* at 1352–53 (mentioning that the compound claimed in the disputed patent was the active ingredient in a drug that grossed \$1.7 billion in sales in a single year).

¹⁹³ 480 F.3d 1348 (Fed. Cir. 2007).

¹⁹⁴ *Id.* at 1372.

¹⁹⁵ *See, e.g., In re Lalu*, 747 F.2d 703, 706–07 (Fed. Cir. 1984) (stating that the obviousness determination ultimately requires inquiring into whether anything in the prior art would suggest any expected properties of new chemical compounds); *see also supra* note 138 and accompanying text.

¹⁹⁶ *Pfizer*, 480 F.3d at 1364.

¹⁹⁷ *Id.* at 1369.

¹⁹⁸ “[O]ur conclusion was based on the ‘particularized facts of this case.’” *Takeda Chem. Indus. v. Alphapharm Pty. Ltd.*, 492 F.3d 1350, 1359 (Fed. Cir. 2007) (quoting *Pfizer*, 480 F.3d at 1367). Thus it seems that this is an instance in which other inventive circumstances would rebut a factual presumption of nonobviousness.

line” can be established. This emphasis on objective evidence may counteract any tendency to generalize the *KSR* decision beyond its particular facts. Thus, despite the apparent demise of the TSM test, a fact finder’s intuition about “common sense” is limited to appropriate circumstances. Courts are also freed from reliance on previous cases in a particular technology if they have a means of “fleshing out” the *Graham* analysis to better understand what level of inventiveness is required for patentability.

4. Objective Evidence as the Best Direct Evidence of an Industry’s Patent Needs and Resulting in the Proper Patent Bargain for Diverse Industries

While it is not possible or wise to completely generalize the obviousness analysis with respect to the mechanical, computer, and pharmaceutical arts, two useful trends do emerge. First, generalizing typical factual circumstances at the time of invention yields a factual presumption about obviousness for each industry—a presumption of obviousness for mechanical and computer inventions and a presumption of nonobviousness for pharmaceutical inventions. Second, the importance of postinvention evidence varies according to the industry—evidence of commercial success, copying, and laudatory statements deserves the most weight for traditional mechanical inventions and the least weight for computer inventions. Focusing the inquiry in this way is critical to lend further predictability and stability to the obviousness jurisprudence across industries.

Of greater significance, the result of these factual presumptions comports with the goals of the patent system and corrects previously noted judicial errors. Although the patent system was initially developed to protect mechanical inventions,¹⁹⁹ it is more importantly designed to spur the innovation and advancement of the useful arts.²⁰⁰ With the clear focus of innovation now moved beyond mechanical arts,²⁰¹ the objective of patent law should not be the broad and strong protection of mechanical inventions at the expense of other industries. As the *KSR* decision suggests, the acknowledgment of a generally high level of ordinary skill in the mechanical arts means that many discoveries in the broad spectrum of mechanical developments will not and should not be patentable for obviousness reasons. These mechanical discoveries still clearly benefit society, but the strong fun-

¹⁹⁹ *Supra* note 136.

²⁰⁰ *See supra* Part II.B.1.

²⁰¹ For a statistical study of these trends, see Allison & Lemley, *supra* note 77; *see also supra* note 89.

damental knowledge and predictability of the art frequently will make innovation cheap enough that a first-mover advantage may be sufficient to cover the costs of innovation.²⁰² Thus, the particular industrial context directly demonstrates the scope of the mechanical arts' patent needs, and *KSR* confirms that a factual presumption of obviousness and a corresponding high threshold to patentability are proper.

Similar treatment of computer inventions is also appropriate and in the best interest of the public and potential patentees. A presumption of obviousness and a high level of ordinary skill will help ensure that only true technological breakthroughs are patentable. This is the reform that the computer industry seeks in its criticism of the current output of the patent system. By making it considerably more difficult to obtain a patent in the computer field, the need for extensive patent cross-licensing and pooling is avoided, and patent trolls who do not practice under the patents they seek to assert cannot profit from the unwitting infringement of others.²⁰³ Considering the benefits associated with a contraction of computer patent protection, the industry will lose little in exchange. The product development cycle and product life cycle are both so short and the products at issue generally are so complex that the majority of innovations can be protected by the first-mover advantage.²⁰⁴ Thus, the true innovators in the computer industry—and not the patent trolls—stand to benefit from reducing the availability of patent protection. Again, the analysis of objective evidence leads not only to the proper obviousness presumption but also to a direct expression of the computer industry's needs.

Finally, for a multitude of reasons, the presumption of nonobviousness for pharmaceutical inventions comports with the goals of the patent system. Evidencing its own needs, the pharmaceutical lobby is the strongest opponent of patent reform because it relies so heavily on the enforcement of relatively few key patents to recoup its extensive investment during its monopoly period.²⁰⁵ Without patent protection for a particular compound, that compound is unlikely to be developed regardless of its public health benefit. Furthermore, without the presumption of broad patent protection for all of its products, the pharmaceutical industry in its current form would face a significant challenge to its viability because the rewards of a strictly

²⁰² See *supra* notes 70, 138–40 and accompanying text.

²⁰³ See *supra* notes 149–50 and accompanying text.

²⁰⁴ See *supra* notes 70, 142–47.

²⁰⁵ See *supra* note 152 and accompanying text.

first-mover advantage system would not be worth the risk associated with the high percentage of failures. This incentive to innovate, such that the invention would likely not occur at all but for the monopoly prize, is exactly the intended function of the patent system.²⁰⁶ Finally, where a product is truly obvious, the adversarial system and strong incentives for generic competition will likely lead to the proper finding of nonobviousness. Therefore, encouraging the sort of broad protection that is engendered by a presumption of nonobviousness in the pharmaceutical industry is proper, and the industry's typical inventive circumstances reveal its need for this presumption.

IV. CONCLUSION

The paradox of the nonobviousness standard is that it is both incapable of formulation and prone to oversimplification; it is flexible in the circumstances of disparate industries and devastating in its uncertainty. This is especially clear when considering the long evolution of the nonobviousness requirement—beginning with a vague requirement of “invention,” followed by *Graham's* imprecise four-part analysis and the Federal Circuit's more definite TSM test, and finally arriving at the new opportunity for redefinition presented by the *KSR* decision. Perhaps regrettably, while the Supreme Court's *KSR* decision now mandates a more flexible obviousness determination, it does not teach how to achieve this laudable goal without repeating the errors of the past—a series of decisions tailoring the obviousness determination to particular industries in exactly the wrong way. For innovation to benefit from society's patent bargain, taking advantage of the flexibility of the facially neutral system and more coherently recognizing the diverse innovation environments and marketplace needs across industries is necessary. Utilizing technology-specific considerations within the obviousness inquiry is the best way to achieve the goals of the patent system.

The ideal approach for federal courts to achieve this harmonization is by using a fact-based approach that emphasizes the value of objective evidence in informing the *Graham* analysis—to understand and compare the actual and the theoretical levels of ordinary skill in the art. This entails using the objective evidence available in every determination, especially an expanded understanding of the traditional “secondary considerations.” For example, such customary preinvention evidence as long-felt but unmet need, the failure of others, and simultaneous invention by multiple parties informs the

²⁰⁶ See *supra* note 76 and accompanying text.

obviousness determination, and these serve as clear guideposts on the more generally applicable appearance-timing spectrum. Similarly, degrees of commercial success, copying by others, independent professional statements of approval, and comparable postinvention considerations corroborate the results of the analysis of preinvention objective evidence. Together, an inclusive inspection of the full breadth of pre- and postinvention objective evidence will fill the “*Graham* gap”—that lack of clear teaching on what is “inventive enough.” By interpreting the availability of this evidence broadly, a wealth of concrete information becomes available to inform the analysis of the theoretical PHOSITA, and the temptation to succumb to hindsight bias is reduced.

When the *Graham* knowledge gap is filled in this way, patterns emerge within particular patenting industries. Clearly, the mechanical and computer arts generally must surpass a high theoretical degree of ordinary skill because of the advanced technical state of much of those arts, the high degree of skill of the average actual artisan, and the relatively low degree of uncertainty when inventing, all of which together create a presumption of obviousness. On the other hand, the pharmaceutical arts must surpass a considerably lower ordinary-skill level because of the high degree of unpredictability in the art and the lack of understanding of much of the underlying science, both of which create a presumption of nonobviousness. Although these presumptions may be rebutted by the presence of a variety of additional objective evidence, those cases will likely be the exception.

Finally, as a correct response to the divergent needs of these industries, a fact- and evidence-based approach comports with the public policy goals of the patent system. In particular, the computer industry will benefit from a higher patentability standard via a corresponding decrease in the frequency of patent thickets and patent trolls, and the pharmaceutical industry will view a presumption of patentability as an adequate safeguard of the high-risk investments required to support lengthy and uncertain drug development. Thus, objective evidence serves not only to improve and clarify the obviousness determination itself, it is also the best direct evidence of these industries’ innovation needs. By performing both functions, it easily harmonizes and protects the interests of both society and innovator—the two parties to the patent bargain.