

SECONDARY CONSIDERATIONS IN NONOBVIOUSNESS ANALYSIS: THE USE OF OBJECTIVE INDICIA FOLLOWING *KSR V. TELEFLEX*

NATALIE A. THOMAS*

One of the basic requirements for patenting an invention is that the invention be nonobvious. Following the Supreme Court's decision in Graham v. John Deere, secondary considerations—also known as objective indicia of nonobviousness—have been considered when determining whether an invention is nonobvious. Secondary considerations provide tangible evidence of the economic and motivational issues relevant to the nonobviousness of an invention. Types of secondary-considerations evidence include commercial success, long-felt but unmet need, and copying by competitors. For many years, the Federal Circuit's teaching, suggestion, or motivation test often eliminated the need for the court to rely on secondary considerations in the obviousness inquiry. Due to the Federal Circuit's stringent application of this test, the obviousness inquiry was generally resolved by examining the prior art.

In 2007, the Supreme Court decided KSR v. Teleflex, which endorsed a flexible obviousness analysis and rejected the Federal Circuit's strict application of the teaching, suggestion, or motivation test. Following KSR, scholars predicted that secondary-considerations evidence would provide a critical tool for patentees seeking to demonstrate the nonobviousness of an invention. Inspired by that prediction, this Note evaluates how secondary-considerations evidence has been utilized in the first few years post-KSR. It finds that the Federal Circuit has continued to impose stringent relevancy requirements on the use of secondary-considerations evidence, and that it remains difficult for patentees to employ secondary considerations in favor of a nonobviousness conclusion. Specifically, secondary-considerations evidence has not been used with much success outside of pharmaceutical patent cases. More often than not, the Federal Circuit has summarily dismissed secondary-considerations evidence as insufficient in cases involving mechanical arts patents. This Note concludes by suggesting that the Federal Circuit's current practice for using secondary considerations should inform proposals by scholars for industry-specific tailoring of the patent system and patent law's use of secondary considerations, and that the Federal Circuit should continue to engage with secondary-considerations evidence in order to provide more guidance to lower courts during the post-KSR transition period.

* Copyright © 2011 by Natalie A. Thomas. J.D., 2011, New York University School of Law; Ph.D., 2008, New York University; B.S., 2003, Duke University. For comments on earlier drafts, I thank Professors Herbert Schwartz, Katherine Strandburg, Oren Bar-Gill, and the fellows of the Lederman/Milbank Fellowship in Law and Economics. I would also like to thank the members of the *New York University Law Review*, especially Brian Lee, David Lin, Chris Kochevar, and Daniel Derby, for their efforts in preparing this Note for publication. Any errors are my own.

INTRODUCTION

To qualify for a patent, an inventor must contribute a novel, useful, and significant technical advance. In other words, the advance must not be obvious or trivial. This requirement seems only fair. The national patent system established under the Constitution contemplates such a quid pro quo: In exchange for disclosing his or her invention to the public, an inventor is rewarded with a temporary, exclusive right.¹ The public does not benefit from the award of a patent right for an obvious discovery, since such an award would remove a clear and evident improvement from the public domain for the patent term.²

The nonobviousness requirement was first codified in the 1952 Patent Act.³ Although the nonobviousness requirement was a natural addition to the Patent Act, given the patent system's goal of promoting innovation, courts and the Patent and Trademark Office (PTO)⁴ have struggled to create a coherent procedure for determining when a claimed "invention" is in fact nonobvious. Indeed, it is challenging to articulate how *anyone* might go about determining if a claimed invention is nonobvious.

This obviousness inquiry is significant because millions of dollars may ride on a patent examiner's judgment as to whether a patent should issue and on a judge or jury's determination of whether an issued patent is invalid for obviousness.⁵ The inquiry is further compli-

¹ 35 U.S.C. § 154 (2006) (outlining a patent term of twenty years).

² See *Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp.*, 340 U.S. 147, 152 (1950) ("The function of a patent is to add to the sum of useful knowledge. Patents cannot be sustained when, on the contrary, their effect is to subtract from former resources freely available to skilled artisans.").

³ Patent Act of 1952, Pub. L. No. 593, § 103, 66 Stat. 792, 798.

⁴ The Patent and Trademark Office (PTO) is the agency within the Department of Commerce responsible for examining patent applications and granting patents (as well as registering trademarks). *The USPTO: Who We Are*, U.S. PATENT & TRADEMARK OFFICE, <http://www.uspto.gov/about/index.jsp> (last visited Oct. 23, 2011). During the patent examination process, the PTO staff rejects patent applications that fail to meet the statutory requirements for patentability. A patent examiner with skill in the relevant technology area conducts the first official assessment of the obvious or nonobvious nature of a claimed invention. See PATENT & TRADEMARK OFFICE, *MANUAL OF PATENT EXAMINING PROCEDURE* § 2141, at 2100-115 to -118 (6th ed. 2007), available at http://www.uspto.gov/web/offices/pac/mpep/mppep_e8r6_2100.pdf (setting forth guidelines for an examiner's analysis of the nonobviousness requirement). If the examiner finds the invention obvious, she will reject the application. *Id.* at 2100-116 to -117. Appeals from PTO denials of patent applications are heard by panels of at least three members of the PTO's Board of Patent Appeals and Interferences. 35 U.S.C. § 6(b). The panels are staffed by administrative patent judges, the Board's directors, and the Commissioner for Patents. *Id.* § 6(a). These decisions can subsequently be appealed to the United States Court of Appeals for the Federal Circuit. *Id.* § 141.

⁵ See John R. Allison et al., *Valuable Patents*, 92 GEO. L.J. 435, 440-41 (2004) (noting median direct litigation costs of \$2 million per party in 2003 in patent suits with \$1 million

cated by the fact that it occurs *ex post* and is often made by a factfinder⁶ lacking skill in the art.⁷ Technically inexperienced factfinders may allow hindsight to affect the obviousness inquiry.⁸ What seems obvious now may not have been obvious at the time of invention.

In order to guide the obviousness inquiry, the Federal Circuit—the court with appellate jurisdiction over patent cases⁹—adopted a teaching, suggestion, or motivation (TSM) test. A proposed invention was obvious if a teaching, suggestion, or motivation in the prior art pointed to the invention. The TSM test was intended to structure the obviousness inquiry, but instead led to instances of patents of questionable validity being upheld.¹⁰ In the 2007 case *KSR International v. Teleflex Inc.*, the Supreme Court rejected the Federal Circuit’s rigid application of the TSM test and emphasized that the touchstones of the obviousness inquiry are flexibility and common sense.¹¹ In the wake of *KSR*, many predict that it will be easier to prove patents obvious.¹² Decision makers must strike a delicate balance between

to \$25 million at stake); *see also* JAMES BESSEN & MICHAEL J. MEURER, *PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK* 105 tbl.5.2, 108 tbl.5.3 (2008) (estimating a \$275,000 average value for patents worldwide and a \$332,800 average value for chemical composition patents, based on market regression calculations in 1992 dollars).

⁶ Multiple parties may assess the obviousness or nonobviousness of an invention, including PTO examiners, judges, and juries, depending on the stage of the proceeding. For the purposes of this Note, a reference to “factfinder” or “decision maker” implicates the relevant party.

⁷ Patent examiners are grouped by specialization. Thus, an examiner often has a technical background that renders her generally competent to examine the patent application assigned to her specialization group. *See supra* note 4 (explaining the PTO procedure). In contrast, judges are often assumed to be laypersons without specialized technical knowledge. *See Safety Car Heating & Lighting Co. v. Gen. Electric Co.*, 155 F.2d 937, 939 (2d Cir. 1946) (“Courts, made up of laymen as they must be, are likely either to underrate, or to overrate, the difficulties in making new and profitable discoveries in fields with which they cannot be familiar . . .”).

⁸ *See infra* note 29 (discussing the challenges of hindsight bias).

⁹ 28 U.S.C. § 1295 (2006) (delimiting the Federal Circuit’s jurisdiction).

¹⁰ *See, e.g.*, 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, 665 (2008) (describing the teaching, suggestion, or motivation (TSM) test’s impact on patent quality).

¹¹ *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 419–22 (2007).

¹² *See, e.g.*, Ali Mojibi, *An Empirical Study of the Effect of KSR v. Teleflex on the Federal Circuit’s Patent Validity Jurisprudence*, 20 ALB. L.J. SCI. & TECH. 559, 581–84 (2010) (conducting an empirical study to test the hypothesis that *KSR* heightened the standard for finding inventions nonobvious); Janice M. Mueller, *Chemicals, Combinations, and “Common Sense”: How the Supreme Court’s KSR Decision Is Changing Federal Circuit Obviousness Determinations in Pharmaceutical and Biotechnology Cases*, 35 N. KY. L. REV. 281, 285–86 (2008) (observing that *KSR* appears to make obviousness easier to establish); Jennifer Nock & Sreekar Gadde, *Raising the Bar for Nonobviousness: An Empirical*

ensuring that obvious inventions are not given patent protection and ensuring that an invention that was nonobvious at the time of invention is found nonobvious when later assessed by a court or the patent office.

Patent case law provides for the use of secondary-considerations evidence—also referred to as objective indicia of nonobviousness—to aid the obviousness inquiry.¹³ This evidence is considered more judicially cognizable than the highly technical facts frequently involved with patent litigation, as it is generally rooted in nontechnical facts about the invention, such as industry response or commercial success.¹⁴ Following *KSR*, some scholars have predicted that secondary considerations will be critical to patentees' future efforts in demonstrating that their inventions are nonobvious.¹⁵

This Note examines the state of secondary-considerations evidence in the first few years after *KSR*. Part I provides an overview of the nonobviousness requirement of patentability, secondary considerations, and the *KSR* decision. Part II empirically examines the Federal Circuit's treatment of secondary-considerations evidence in the years after *KSR* and concludes that such evidence has not been used with much success outside of pharmaceutical patent cases. More often than not, courts have summarily dismissed secondary-considerations evidence as insufficient. Part III considers how current use of such evidence should inform proposals for altering the use of secondary considerations. In addition, this Part contends that the use

Study of Federal Circuit Case Law Following KSR, 20 FED. CIR. B.J. 369, 378–81 (2011) (noting that *KSR*'s holding suggests that it will be easier to find an invention obvious and that early predictions and analyses regarding the impact of the decision suggest the same); Diane Christine Renbarger, Note, *Putting the Brakes on Drugs: The Impact of KSR v. Teleflex on Pharmaceutical Patenting Strategies*, 42 GA. L. REV. 905, 908–09 (2008) (noting that *KSR* may have heightened the standard for finding pharmaceutical inventions nonobvious).

¹³ See, e.g., *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966) (endorsing the use of secondary-considerations evidence to shed light on the obviousness inquiry).

¹⁴ *Id.* at 36 (“[Secondary-considerations evidence] focus[es] attention on economic and motivational rather than technical issues and [is], therefore, more susceptible of judicial treatment than are the highly technical facts often present in patent litigation.”); see Michael Abramowicz & John F. Duffy, *The Inducement Standard of Patentability*, 120 YALE L.J. 1590, 1655–57 (2011) (arguing that the inducement standard requiring courts to consider secondary-considerations evidence is “more administrable than the current system”); Richard L. Robbins, Note, *Subtests of “Nonobviousness”: A Nontechnical Approach to Patent Validity*, 112 U. PA. L. REV. 1169, 1172 (1964) (noting that inquiries into “economic and motivational . . . issues . . . are more amenable to judicial treatment than are the technical facts with which the courts generally struggle”).

¹⁵ See Daralyn J. Durie & Mark A. Lemley, *A Realistic Approach to the Obviousness of Inventions*, 50 WM. & MARY L. REV. 989, 1004–07 (2008) (“As the legal rules that fight hindsight bias, such as the TSM test, are trimmed back . . . patentees will want to rely more on so-called secondary considerations of nonobviousness . . .”).

of secondary-considerations evidence should be increased to guide the obviousness inquiry with a judicially accessible source of information about the inventive process.

I

THE NONOBVIOUSNESS REQUIREMENT, SECONDARY CONSIDERATIONS, AND *KSR v. TELEFLEX*

A. *The Nonobviousness Requirement*

Although not initially included in the patent statute passed by the First Congress in 1790,¹⁶ the nonobviousness requirement is now considered the ultimate threshold for patentability.¹⁷ This requirement is codified in § 103 of the Patent Act:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.¹⁸

The nonobviousness requirement reserves patent protection for innovative contributions. However, if the threshold for patentability is too high, then researchers will be less likely to pursue socially beneficial research paths.¹⁹ Promoting the optimal level of innovation requires striking the right balance in defining obviousness. Congress attempted to define obviousness in the context of the patent system as that which would have been obvious at the time of the invention to a person having ordinary skill in the art (PHOSITA), replacing the prior focus on “invention.”²⁰

Unfortunately, the statutory codification of the nonobviousness requirement for patentability does not provide a framework for deter-

¹⁶ Patent Act of 1790, ch. 7, 1 Stat. 109 (repealed 1793).

¹⁷ 2 DONALD S. CHISUM, CHISUM ON PATENTS § 5.06, at 5-735 (2010) (“The nonobviousness requirement of Section 103 is the most important and most litigated of the conditions of patentability.”).

¹⁸ 35 U.S.C. § 103(a) (2006).

¹⁹ See, e.g., Michael J. Meurer & Katherine J. Strandburg, *Patent Carrots and Sticks: A Model of Nonobviousness*, 12 LEWIS & CLARK L. REV. 547, 563 (2008) (“If the nonobviousness threshold is . . . set too high, . . . non-optimal and inefficiently difficult projects will have to be undertaken to obtain a patent.”).

²⁰ ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 629–30 (4th ed. 2007). See generally John F. Duffy, *Inventing Invention: A Case Study of Legal Innovation*, 86 TEX. L. REV. 1, 33–43 (2007) (describing the evolution of the standard of invention).

mining what would have been obvious to a PHOSITA at the time of invention. In *Graham v. John Deere Co.*, the Supreme Court explained how the obviousness analysis under § 103 should be performed.²¹ Under *Graham*, courts apply a fact-based inquiry to determine whether or not the claimed subject matter of a patent is obvious as a matter of law.²² First, courts must determine the scope and content of the prior art. Second, courts must identify the differences between the prior art and the claims at issue. Third, courts must ascertain the level of ordinary skill in the art.²³ Based on this three-step inquiry, courts may determine the obviousness of the invention at issue.²⁴ However, *Graham* also provided a fourth step: the utilization of secondary considerations. The Court explained as follows: “Such secondary considerations as commercial success, long-felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.”²⁵

B. Secondary Considerations

Rather than focusing on the specifics of the technological advance, a secondary-considerations analysis approaches nonobviousness through an examination of “economic and motivational . . . issues.”²⁶ Although their weight in the obviousness inquiry is an open question, secondary considerations are most likely termed “secondary” because they “are relevant through a process of inference to the ultimate technical issue of nonobviousness,” not because they are of lesser importance.²⁷ Because secondary considerations do not require a detailed understanding of technology, they can significantly aid judicial assessments of patent validity. In addition, by providing objective

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

²² *Id.* at 17.

²³ *Id.*

²⁴ For example, if the decision maker finds that the prior art contains references that largely overlap with the claimed invention with only minute differences distinguishing the claimed invention, and the level of skill in the art is high (assume that the typical person having ordinary skill in the art is found to have ten years of engineering experience and an advanced degree), then the conclusion that the invention is obvious (and not patentable) seems reasonable.

²⁵ *Graham*, 383 U.S. at 17–18.

²⁶ *Id.* at 36.

²⁷ Andrew Blair-Stanek, *Increased Market Power as a New Secondary Consideration in Patent Law*, 58 AM. U. L. REV. 707, 712 (2009) (quoting Donald S. Chisum, Professor, Univ. of Wash. Law Sch., Recent Developments in Patent Law, Address Before the AIPLA Annual Meeting (Oct. 26, 1984), in 1984 AIPLA BULL. 618, 620–21) (internal quotation marks omitted).

information about the context for the inventive process, secondary considerations may prevent hindsight bias from affecting decision makers' assessments of the obviousness of an invention;²⁸ decision makers may be prone to such bias once the invention is sitting before them.²⁹ Following *Graham's* endorsement of secondary considerations, courts adopted secondary-considerations analysis as a critical part of the nonobviousness inquiry.³⁰

Many secondary considerations have been proposed by scholars and cited by courts.³¹ The most common include commercial success,

²⁸ *Graham*, 383 U.S. at 36 (“[Secondary considerations] may also serve to ‘guard against slipping into use of hindsight.’” (quoting *Monroe Auto Equip. Co. v. Heckethorn Mfg. & Supply Co.*, 332 F.2d 406, 412 (6th Cir. 1964))).

²⁹ See HERBERT F. SCHWARTZ & ROBERT J. GOLDMAN, *PATENT LAW AND PRACTICE* 90–91 (6th ed. 2008) (noting that secondary considerations “focus the decision maker’s attention on the circumstances surrounding the origin of the claimed invention” and “may help the decision maker avoid the use of hindsight”). Hindsight bias is a cognitive phenomenon that causes people to overstate or overestimate the predictability or likelihood of past events. See Jeffrey J. Rachlinski, *A Positive Psychological Theory of Judging in Hindsight*, 65 U. CHI. L. REV. 571, 576–81 (1998) (defining hindsight bias and summarizing the psychological literature on hindsight bias). The specter of hindsight bias is a constant concern in determinations of obviousness. Under § 103, the factfinder must determine whether an invention would have been obvious to a person having ordinary skill in the art (PHOSITA) at the time of invention. 35 U.S.C. § 103 (2006). Once the factfinder knows that the invention exists today, it can be difficult to prevent hindsight bias from affecting the factfinder’s analysis. See Gregory N. Mandel, *Patently Non-obvious: Empirical Demonstration That Hindsight Bias Renders Patent Decisions Irrational*, 67 OHIO ST. L.J. 1391, 1404 (2006) (“Overestimating the likelihood of a known invention occurring will tend to make the invention appear obvious. Perhaps even more powerfully, the tendency to overestimate the foreseeability of the invention will make the invention appear to have been more obvious than it actually was.”); *id.* at 1419 (concluding from empirical studies of hindsight bias, including one of first-year law students participating as mock jurors, that hindsight bias significantly impacts nonobviousness decisions in patent law).

³⁰ See, e.g., *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538–39 (Fed. Cir. 1983) (“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.”); *In re Fielder*, 471 F.2d 640, 644 (C.C.P.A. 1973) (“[S]uch evidence must *always* be considered in connection with the determination of obviousness.”); George M. Sirilla, *35 U.S.C. § 103: From Hotchkiss to Hand to Rich, the Obvious Patent Law Hall-of-Famers*, 32 J. MARSHALL L. REV. 437, 535–48 (1999) (describing the evolution of the use of secondary considerations in the PTO’s *Manual of Patent Examining Procedure* and in Federal Circuit doctrine); Dorothy Whelan, Note, *A Critique of the Use of Secondary Considerations in Applying the Section 103 Nonobviousness Test for Patentability*, 28 B.C. L. REV. 357, 364–65 (1987) (noting that the Federal Circuit adopted secondary considerations as the fourth part of the obviousness inquiry).

³¹ See *Graham*, 383 U.S. at 17–18 (highlighting the use of the secondary considerations of commercial success, long-felt but unsolved needs, and the failure of others); Blair-Stanek, *supra* note 27, at 712–13 (“Courts to date have developed nine secondary considerations: (1) long-felt need; (2) failure of others; (3) commercial success; (4) commercial acquiescence via licensing; (5) professional approval; (6) copying by and praise from infringers; (7) progress through the PTO; (8) near-simultaneous invention; and (9) unexpected results.”); Robbins, *supra* note 14, at 1172–83 (proposing the use of long-felt

long-felt but unmet need, failure of others, and professional approval or skepticism.³² Generally, secondary-considerations evidence supports a finding of nonobviousness.³³ For example, failure of others may indicate that others attempted to find a solution but failed, suggesting that the successful inventor's discovery truly was nonobvious.³⁴ Whether all secondary considerations are equally informative, or accurately illuminate the nonobviousness of an invention, is debated.³⁵ Some scholars criticize the use of any secondary considerations, arguing that they are not objective enough or that they fail to combat hindsight bias.³⁶ Despite these critiques, the Supreme Court continues to endorse secondary considerations.³⁷ As post-*KSR* decision makers have more license than ever to consult secondary-considerations evidence, it is important to understand both how it is used in practice and how its use could be improved. To ground the discussion, the remainder of this Section details some commonly accepted secondary considerations.

Commercial success is the first secondary consideration listed in *Graham* and also the most commonly invoked.³⁸ In theory, if a product that is expected to be commercially successful was obvious to invent, then other competitors likely would have already developed

demand, commercial success, commercial acquiescence, simultaneous solution, professional approval, and progress through the PTO); Whelan, *supra* note 30, at 370–74 (discussing the use of licensing, copying by an infringer, progress through the PTO, near-simultaneous invention, and professional approval).

³² See generally SCHWARTZ & GOLDMAN, *supra* note 29, at 91–93 (listing commonly invoked secondary considerations); Whelan, *supra* note 30, at 366 (same).

³³ One exception is secondary-considerations evidence of simultaneous invention. See DAN L. BURK & MARK A. LEMLEY, *THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT* 117 (2009) (noting that simultaneous invention is not supportive of nonobviousness). A competitor's showing that several inventors converged on the invention in question at the same time would suggest that the inventive step was obvious. In such a situation, a likely explanation would be that the state of the art developed to the point where the inventive step became possible and therefore obvious.

³⁴ Robbins, *supra* note 14, at 1173.

³⁵ See Whelan, *supra* note 30, at 377–80 (arguing that commercial success, licensing, copying, and progress through the PTO should not be independently relevant in the obviousness analysis under § 103); see also Blair-Stanek, *supra* note 27, at 724–28 (proposing the use of increased market power as a stand-alone secondary consideration and critiquing the use of licensing and commercial success as currently implemented).

³⁶ See Mandel, *supra* note 29, at 1421–25 (concluding that secondary considerations do not ameliorate hindsight bias because such evidence is infrequently available and often unreliable). See generally Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CAL. L. REV. 803 (1988) (critiquing the use of secondary considerations).

³⁷ See *infra* Part I.C (discussing *KSR* and the continued recognition of secondary considerations).

³⁸ *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966); Wieker, *supra* note 10, at 675 (“Commercial success is the most frequently encountered secondary consideration.”).

it.³⁹ In that case, the market for subsequent entrants to achieve commercial success would be depleted. The potential for achieving commercial success is thought to drive inventors to formulate solutions to existing problems to satisfy marketplace demands. If an inventor develops a product that is commercially successful, presumably others recognized the product's potential for commercial success, attempted to develop a solution to the same problem, and failed.⁴⁰

Long-felt but unmet need is a closely related and frequently invoked secondary consideration. The underlying rationale for accepting long-felt demand as evidence of nonobviousness partially overlaps with that for accepting evidence of commercial success.⁴¹ An industry's desire for an improvement in technology provides a motivation for invention.⁴² Because it can be assumed that a market exists for a product that satisfies a long-felt need, an inventor or businessperson working in the field has an incentive to develop a solution. If the demand for a solution persists over time, despite this potential reward, the solution may be assumed to be nonobvious. Thus, if a patentee can prove that his invention satisfies a long-felt need, the invention is likely nonobvious.

A third secondary consideration is failure of others.⁴³ If others facing the same state of the art attempted to develop a solution to satisfy a need but failed—while the inventor succeeded—by inference, the solution employed by the inventor must be nonobvious. If the solution were obvious, it is assumed that others working to solve the same problem also would have succeeded.

Professional approval is an additional secondary consideration that can illuminate the viewpoint of a PHOSITA at the time of invention. Contemporaneous statements about an invention may assist a factfinder in determining whether those with ordinary skill in the art would have found the invention obvious. If experts in the field contemporaneously hailed the invention as revolutionary or as answering a long-felt need, a hypothetical PHOSITA would probably have found

³⁹ SCHWARTZ & GOLDMAN, *supra* note 29, at 92.

⁴⁰ See Robbins, *supra* note 14, at 1175 (outlining inferences that can be drawn from commercial success).

⁴¹ Wieker, *supra* note 10, at 677 (“The premise behind the secondary consideration of long felt need is closely aligned with that of commercial success. Both concepts assume that a defect in the market creates economic incentives that lead inventors to find a solution and, therefore, to reap economic rewards.”).

⁴² Robbins, *supra* note 14, at 1172.

⁴³ *Graham*, 383 U.S. at 17; Robbins, *supra* note 14, at 1174 (proposing the failure of others as an indication of nonobviousness).

the invention nonobvious.⁴⁴ Similarly, if competitors or experts in the field had expressed surprise or doubt as to whether the invention was possible, that skepticism may be construed as evidence that the invention was nonobvious.⁴⁵

Finally, unexpected results is a frequently invoked secondary consideration.⁴⁶ Evidence of unexpected results may provide a reliable indicator of whether an invention is nonobvious because the probable or anticipated result of an experiment is likely to be embodied in an obvious invention.⁴⁷ The courts and the PTO are more inclined to accept secondary-considerations evidence of unexpected results in “the less predictable fields, such as chemistry, where minor changes in a product or process may yield substantially different results.”⁴⁸ Finally, relying on a demonstration of unexpected results is consistent with the innovation policy viewpoint that “low probability experimentation should generally be rewarded.”⁴⁹

While secondary considerations may offer insights for determining the obviousness of an invention, the evidence must be relevant to the analysis. For example, commercial success might be attributable to appealing packaging or advertising and not to the invention itself. Alternatively, a patentee might have developed the solution to a long-felt but unmet need due to innovations in complementary technology that changed the state of the art. In such a scenario, the change in technology might make what was previously nonobvious to unsuccessful would-be inventors obvious to inventors working in the context of a different state of the art.⁵⁰ Similarly, praise by competitors might have been made in order to gain investors’ interest in the competitors’ work in the same field. Such statements might be self-serving and thus would need to be scrutinized for context and relevancy. To

⁴⁴ See generally Robbins, *supra* note 14, at 1181–82 (outlining the justification for relying on evidence of professional approval as an indicator of nonobviousness).

⁴⁵ See, e.g., Whelan, *supra* note 30, at 373 (describing the potential informational value of competitor or industry skepticism).

⁴⁶ Harris A. Pitlick, *Some Thoughts About Unexpected Results Jurisprudence*, 86 J. PAT. & TRADEMARK OFF. SOC’Y 169, 169 (2004) (“Evidence of unexpected results is no doubt the most prevalent form of evidence of nonobviousness relied on by patent applicants during patent examination. Indeed, there are hundreds of published cases wherein the sufficiency of such evidence to rebut a case of *prima facie* obviousness was in issue.”).

⁴⁷ See *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995) (“One way for a patent applicant to rebut a *prima facie* case of obviousness is to make a showing of ‘unexpected results’ The basic principle behind this rule is straightforward—that which would have been surprising to a person of ordinary skill in a particular art would not have been obvious.”).

⁴⁸ *Id.*

⁴⁹ Abramowicz & Duffy, *supra* note 14, at 1671–72.

⁵⁰ See Robbins, *supra* note 14, at 1174 (“It may be that an intervening innovation made that which the patentee accomplished obvious even though it was not obvious to prior unsuccessful researchers.”).

ensure that secondary considerations are truly informative about the invention at issue, a nexus between the secondary consideration and the invention must be established before the evidence can be considered in the obviousness analysis.

C. *KSR v. Teleflex: Increased Flexibility in Assessing Obviousness*

In 2007, the Supreme Court issued its opinion in *KSR International Co. v. Teleflex Inc.*⁵¹ The decision was highly anticipated by the patent law community because the Supreme Court had not addressed the obviousness inquiry in over thirty years.⁵² During that time, the Federal Circuit had developed its own tools for executing the obviousness analysis under *Graham*. *KSR* provided a chance for the Supreme Court to signal its views on the evolution of the doctrine and to recalibrate the inquiry if necessary.

In an effort to avoid the effects of hindsight bias, the Federal Circuit developed a teaching, suggestion, or motivation test.⁵³ To find an invention obvious, the TSM test required the identification of a specific teaching, suggestion, or motivation in the prior art to arrive at the invention at issue. For example, to find a patent invalid, a factfinder would have to point to a suggestion in the prior art, perhaps in a published trade article, that component A of an invention might be improved by combining it with component B. If the challenged patent is composed of A and B, then the suggestion in the prior art could be cited to justify finding the patent obvious and invalid. If there was no indication in the prior art that A would benefit from being combined with B, though, or if there was no documented motivation⁵⁴

⁵¹ 550 U.S. 398 (2007).

⁵² “In the forty-one years between *Graham* and *KSR*, the Court made no major refinement of the obviousness standard. Indeed, in that interval, the Court reached the merits of obviousness in just three arcane cases” Harold C. Wegner, *Making Sense of KSR and Other Recent Patent Cases*, 106 MICH. L. REV. FIRST IMPRESSIONS 39, 40 (2008), <http://www.michiganlawreview.org/assets/fi/106/wegner.pdf>. Those three cases are *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 280–83 (1976) (finding a claimed invention of a water system for cleaning dairy barns obvious using the *Graham* analysis); *Dann v. Johnston*, 425 U.S. 219, 225–30 (1976) (finding a claimed invention of a machine system for automatic recording of bank deposits and withdrawals obvious under *Graham*); and *Anderson’s-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 61–63 (1969) (finding a claimed combination patent for a method of curing asphalt obvious under *Graham*).

⁵³ See, e.g., *Ruiz v. A.B. Chance*, 234 F.3d 654, 665–66 (Fed. Cir. 2000) (applying the TSM test); *In re Dembiczak*, 175 F.3d 994, 999–1000 (Fed. Cir. 1999) (same), *abrogated on other grounds by In re Gartside*, 203 F.3d 1305 (Fed. Cir. 2000); *In re Rouffet*, 149 F.3d 1350, 1357–58 (Fed. Cir. 1998) (same).

⁵⁴ Although it became known as the TSM test, the Federal Circuit first required a teaching, suggestion, or *incentive* to combine or modify the prior art. See *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297 (Fed. Cir. 1985) (requiring the district court to elucidate “factual teachings, suggestions or incentives from th[e] prior art that

for the decision to add B to other components, then the patent could be upheld as valid.

The TSM test was developed in order to reduce the likelihood that courts would look back in time and find an invention to be obvious that was in actuality nonobvious at the time of invention. Unfortunately, the Federal Circuit started applying the TSM test in a mechanical fashion, strictly requiring a published article or patent to provide the necessary TSM before a patent could be invalidated for obviousness.⁵⁵ As a result, it became harder to prove a patent obvious because explicit teachings, suggestions, or motivations are not always easy to identify, particularly in fields where there is “little discussion of obvious techniques or combinations” or where “market demand, rather than scientific literature, . . . drive[s] design trends.”⁵⁶ This stringent application of the TSM test led to patents of questionable validity being upheld.⁵⁷ In *KSR*, the Court clarified that the Federal Circuit and lower courts should not engage in a rigid obviousness inquiry, rejecting a strict application of the TSM test.⁵⁸ Instead, the Supreme Court emphasized that the obviousness inquiry endorsed by its case law is expansive and flexible.⁵⁹

The Court acknowledged that the approach condoned in *Graham*⁶⁰ was intended to help provide uniformity and certainty to the obviousness inquiry. But it distinguished these goals from the rigidity introduced by the Federal Circuit by pointing out that *Graham* was intended to reaffirm a functional approach established by pre-*Graham* case law.⁶¹ To emphasize the difference, the Court noted that *Graham* established a broad framework for courts and particularly invited them to consider secondary considerations where

show[] the propriety of combination” when holding a patent invalid for obviousness). Three possible sources for an incentive or motivation to combine are “the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art.” *In re Rouffet*, 149 F.3d at 1357.

⁵⁵ See *KSR*, 550 U.S. at 419 (“There is no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis. But when a court transforms the general principle into a rigid rule that limits the obviousness inquiry, as the Court of Appeals did here, it errs.”).

⁵⁶ *Id.*

⁵⁷ *BURK & LEMLEY*, *supra* note 33, at 116 (“Requiring litigants to find a teaching or suggestion for every modification to the prior art, no matter how trivial, led to a number of cases in which straightforward modifications of existing technology were held patentable.”).

⁵⁸ *KSR*, 550 U.S. at 419.

⁵⁹ *Id.* at 415.

⁶⁰ See *supra* notes 21–25 and accompanying text (discussing the *Graham* framework).

⁶¹ See *KSR*, 550 U.S. at 415 (noting that *Graham* adopted the “functional approach” of *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248 (1850)).

appropriate.⁶² *KSR* establishes that the obviousness inquiry should be more flexible and allow “factfinders recourse to common sense.”⁶³ The factfinder is instructed to take into account the inferences and creative steps that a PHOSITA of ordinary creativity would undertake, as well as relevant secondary considerations, in reaching a conclusion as to obviousness.⁶⁴

Under *KSR*, because factfinders can engage in a wider, flexible inquiry and reach conclusions of obviousness without having to point to specific pieces of prior art to demonstrate a TSM, it should be easier to reach conclusions of obviousness than it was prior to the decision.⁶⁵ Against this new background, secondary considerations might provide an appealing means for patentees to present evidence in support of nonobviousness to the factfinder, who now has much more flexibility in the overall inquiry. Professors Dan Burk and Mark Lemley have predicted that after *KSR*, litigants arguing for the non-obviousness of their patented inventions will increasingly rely on secondary considerations.⁶⁶ Similarly, Lemley and Daralyn Durie believe that “[s]econdary considerations represent patentees’ best hope of demonstrating nonobviousness in the post-*KSR* world,”⁶⁷ because such evidence is generally pro-patentability, accessible to the decision maker, and a guard against hindsight bias.⁶⁸

Judges should similarly find the use of secondary-considerations evidence more helpful in the wake of *KSR*. Decision makers engaging in *KSR*’s flexible inquiry may validly turn to the economic and motivational insights of secondary-considerations evidence to provide guidance as to whether their common-sense intuitions about obviousness are, in fact, correct. For this reason, it has been suggested that secondary considerations are necessary “objective checks” to cabin *KSR*’s flexible approach and promote consistency between decisions.⁶⁹

⁶² *Id.* (“To this end, *Graham* set forth a broad inquiry and invited courts, where appropriate, to look at any secondary considerations that would prove instructive.”).

⁶³ *Id.* at 421.

⁶⁴ *Id.* at 415, 417 (reaffirming the breadth of the nonobviousness inquiry and the utility of secondary-considerations evidence and noting that “design incentives and other market forces” should be considered when determining whether an invention would have been obvious to a PHOSITA).

⁶⁵ See BURK & LEMLEY, *supra* note 33, at 117–18 (noting the likelihood of more frequent obviousness determinations under *KSR*).

⁶⁶ *Id.* at 117 (“In the wake of the Supreme Court’s decision in *KSR*, which made it harder for patentees to survive the obviousness test, it is reasonable to expect that patentees will put more reliance on secondary considerations, since they may represent the strongest possible argument for patentability in the new regime.” (footnote omitted)).

⁶⁷ Durie & Lemley, *supra* note 15, at 1004.

⁶⁸ *Id.* at 1004–06.

⁶⁹ Wieker, *supra* note 10, at 666.

II

SECONDARY CONSIDERATIONS BEFORE AND AFTER *KSR*

As discussed in Part I.C, *KSR*'s endorsement of a common-sense, flexible analysis is generally believed to have produced a heightened threshold for proving nonobviousness, thus making it harder to obtain and hold onto a patent and easier for potential infringers and competitors to argue that an issued patent is invalid due to obviousness. In this Part, I evaluate the hypothesis that, in response to this change in the obviousness inquiry, litigants and courts have increased their reliance on secondary-considerations evidence. I do this by surveying the Federal Circuit's use of secondary-considerations evidence in the years immediately following *KSR*.

A. *Secondary Considerations Before KSR*

Although my inquiry focuses on the utilization and treatment of secondary considerations following *KSR*, it is useful first to examine how the Federal Circuit employed secondary-considerations evidence in the years between *Graham* and *KSR*. The pre-*KSR* use of secondary considerations was characterized by strong endorsements of the use of such evidence,⁷⁰ but little actual reliance on such evidence to reach conclusions as to obviousness.⁷¹

Shortly after its creation in 1982, the Federal Circuit endorsed the view that secondary-considerations evidence may provide courts with the most probative and insightful evidence of obviousness or nonobviousness in the record.⁷² In one case, the court found no reversible error in a district court's conclusion that a patent was not invalid, where the district court gave weight to evidence of the commercial success, initial skepticism, and industry praise of an invention.⁷³ Similarly, the Federal Circuit endorsed a district court decision finding that an invention composed entirely of pieces of prior art was nonetheless nonobvious, based largely on the fact that the patented invention fulfilled a long-felt need, achieved commercial success, and was the sub-

⁷⁰ See, e.g., *Simmons Fastener Corp. v. Ill. Tool Works, Inc.*, 739 F.2d 1573, 1574–76 (Fed. Cir. 1984) (holding that the trial court erred in failing to consider secondary considerations as the fourth part of the *Graham* inquiry and finding evidence of commercial success sufficient to support the conclusion of nonobviousness).

⁷¹ See Christopher A. Cotropia, *Nonobviousness and the Federal Circuit: An Empirical Analysis of Recent Case Law*, 82 NOTRE DAME L. REV. 911, 945 (2007) (finding a small role for secondary-considerations evidence before *KSR*).

⁷² *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983).

⁷³ *Vulcan Eng'g, Co. v. Fata Aluminium, Inc.*, 278 F.3d 1366, 1373 (Fed. Cir. 2002).

ject of skepticism on the part of experts, which the court called “strong evidence of nonobviousness.”⁷⁴

Despite the endorsement of such evidence, in the years prior to *KSR* the Federal Circuit did not give much weight to secondary-considerations evidence that ran counter to an obviousness conclusion based on the prior art and skill level of the PHOSITA. In his study of Federal Circuit decisions on nonobviousness between 2002 and 2005, Professor Chris Cotropia observed that secondary considerations played a “miniscule role” in nonobviousness decisions.⁷⁵ In a survey of district court and Federal Circuit opinions between 2004 and 2005, Professor Gregory Mandel discovered that secondary-considerations evidence was found sufficient to rebut a *prima facie* case of obviousness in only one case out of ninety-three.⁷⁶ Additionally, the Federal Circuit provided little guidance to district courts regarding how much weight to accord particular secondary considerations.⁷⁷

⁷⁴ *Env'tl. Designs, Ltd. v. Union Oil Co. of Cal.*, 713 F.2d 693, 697–98 (Fed. Cir. 1983).

⁷⁵ Cotropia, *supra* note 71, at 945.

⁷⁶ Mandel, *supra* note 29, at 1422–23.

⁷⁷ *See Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1539 (Fed. Cir. 1983) (“Enroute to a conclusion on obviousness, a court must not stop until *all* pieces of evidence on that issue have been fully considered and each has been given its appropriate weight. Along the way, some pieces will weigh more heavily than others, but decision should be held in abeyance, and doubt maintained, until all the evidence has had its say.”). District courts following Federal Circuit precedent were instructed to consider secondary considerations when they were in the record as part of the initial obviousness analysis. The district court was to weigh any secondary considerations submitted into evidence with the other *Graham* factors to determine if a *prima facie* case of obviousness had been established, and to ensure that the requisite nexus between the secondary considerations evidence and the claimed invention was present. *See, e.g., Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1574 (Fed. Cir. 1996) (noting that factfinders must ascertain whether a nexus connects commercial success to a claimed invention and determine the probative value of secondary-considerations evidence for rebutting a *prima facie* case of obviousness); *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1391–94 (Fed. Cir. 1988) (noting that secondary-considerations evidence must be considered despite a strong case for obviousness based on prior art, and laying out an “evidentiary routine” where a patentee must establish a *prima facie* case of a nexus between commercial success and the claimed invention); *Simmons Fastener Corp. v. Ill. Tool Works, Inc.*, 739 F.2d 1573, 1575 (Fed. Cir. 1984) (explaining that the weight accorded to secondary-considerations evidence depends on a demonstration of “[a] nexus between the merits of the claimed invention and the evidence of secondary considerations”).

However, the Federal Circuit gave little guidance on how much weight to accord particular secondary considerations beyond somewhat confusing statements supporting the proposition that secondary considerations could be sufficient to support a finding of non-obviousness but insufficient to rebut a *prima facie* case of obviousness. *See, e.g., Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 719 (Fed. Cir. 1991) (stating that courts may contemplate secondary-considerations evidence and yet still find such evidence insufficient to overcome a *prima facie* case); *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988) (noting that secondary considerations must be considered but do not control the obviousness determination).

This lack of guidance may explain the relatively limited role that secondary considerations appear to have played in the years immediately prior to *KSR*. Because the TSM test generally made it easier to uphold patent validity and most secondary considerations are used to help prove nonobviousness, litigants may have felt less pressure to introduce secondary-considerations evidence in order to prove nonobviousness. Similarly, since the TSM test already provided a structured inquiry designed to avoid hindsight bias, decision makers might not have felt the need to take into account or explicitly address secondary-considerations evidence, even when litigants presented such evidence. In sum, although the Federal Circuit required the inclusion of secondary considerations in the obviousness inquiry prior to *KSR*, the court accorded such evidence varying weight, only occasionally finding secondary-considerations evidence sufficient to support a finding of nonobviousness.

B. A Survey of the Use of Secondary Considerations Under the Revised Obviousness Inquiry

In order to characterize the initial role that secondary considerations have played post-*KSR*, I examined thirty-one precedential decisions issued by the Federal Circuit where the nonobviousness of a patent or patent application was contested and secondary-considerations evidence was addressed.⁷⁸ Secondary considerations were virtually never sufficient to counter evidence found to be indicative of obviousness under the first three steps of the *Graham* inquiry. In eight of the cases, the court reversed a lower court finding of nonobviousness, despite the presence of secondary-considerations evidence in support of nonobviousness.⁷⁹ These decisions acknowl-

⁷⁸ For a list of the cases examined and their outcomes, see *infra* Appendix.

⁷⁹ See *Ball Aerosol & Specialty Container, Inc. v. Ltd. Brands, Inc.*, 555 F.3d 984, 994 (Fed. Cir. 2009) (“[T]he secondary consideration of commercial success . . . do[es] not outweigh the clear indication of obviousness apparent from the prior art.”); *Bos. Scientific Scimed, Inc. v. Cordis Corp.*, 554 F.3d 982, 991–92 (Fed. Cir. 2009) (“[G]iven the strength of the prima facie obviousness showing, the evidence on secondary considerations was inadequate to overcome a final conclusion that [the claim] would have been obvious.” (quoting *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007) (internal quotation marks omitted))); *Agrizap, Inc. v. Woodstream Corp.*, 520 F.3d 1337, 1344 (Fed. Cir. 2008) (“[T]he objective evidence of nonobviousness simply cannot overcome such a strong prima facie case of obviousness.”); *Commonwealth Scientific & Indus. Research Org. v. Buffalo Tech., Inc.*, 542 F.3d 1363, 1377 (Fed. Cir. 2008) (concluding that secondary-considerations evidence “d[id] not justify the entry of summary judgment in CSIRO’s favor in light of the evidence Buffalo introduced as to the primary considerations bearing on obviousness”); *Erico Int’l Corp. v. Vutec Corp.*, 516 F.3d 1350, 1357 (Fed. Cir. 2008) (vacating a preliminary injunction after finding a question as to obviousness after the district court had found the patent nonobvious); *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1327–28 (Fed. Cir. 2008) (“[A]t least some of the factors argued by Muniauction

edged the presence of secondary-considerations evidence in favor of a finding of nonobviousness, but either found such evidence insufficient to outweigh the evidence in favor of a finding of obviousness or dismissed the evidence for lacking a sufficient nexus to the invention. In nine other cases, the Federal Circuit affirmed a district court (or PTO Board) finding of obviousness, noting that the secondary-considerations evidence was insufficient to outweigh the evidence of obviousness.⁸⁰ In more than half of these cases, secondary-considerations evidence was dismissed as insufficient or too remote to have any real weight in the obviousness analysis. While secondary-considerations evidence was predicted to be important to patentees and patent applicants following *KSR*,⁸¹ this prediction has not been reflected in practice. In the cases examined, the court explicitly reversed a finding of obviousness based on secondary considerations only once, though it did vacate and remand two decisions that found a patent obvious because the district court failed to explicitly examine secondary-considerations evidence.⁸² These observations somewhat diverge from an early assessment of the use of secondary considera-

lack the requisite nexus to the claims. . . . [T]o the extent that some of the factors arguably meet the nexus requirement, their relationship to the claims is simply too attenuated to overcome the strong prima facie demonstration . . . that the claims are obvious.”); *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1368 (Fed. Cir. 2008) (“Secondary considerations of nonobviousness . . . simply cannot overcome this strong prima facie case of obviousness.”); *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1365–66 (Fed. Cir. 2007) (holding that the patents were obvious despite evidence that “the inventors were widely recognized as pioneers” and “that physicians began performing human transplants only after the inventors conducted their mouse experiments,” and despite the decision of the PTO to issue the patents).

⁸⁰ See *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1289, 1299–1300 (Fed. Cir. 2010); *Fresenius USA, Inc. v. Baxter Int’l, Inc.*, 582 F.3d 1288, 1302 (Fed. Cir. 2009); *In re Mettke*, 570 F.3d 1356, 1361 (Fed. Cir. 2009); *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1332–33 (Fed. Cir. 2009); *Rothman v. Target Corp.*, 556 F.3d 1310, 1322 (Fed. Cir. 2009); *Asyst Techs., Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1316 (Fed. Cir. 2008); *In re DBC*, 545 F.3d 1373, 1384 (Fed. Cir. 2008); *Forest Labs., Inc. v. Ivax Pharm., Inc.*, 501 F.3d 1263, 1269 (Fed. Cir. 2007); *Leapfrog*, 485 F.3d at 1162.

⁸¹ See Kenneth R. Adamo et al., *The Curse of “Copying,”* 7 J. MARSHALL REV. INTEL. PROP. L. 296, 322 (2008) (“In view of [*KSR*], a larger percentage of patents may be deemed prima facie obvious, making objective evidence . . . more important than ever. . . . [O]ne should expect that . . . patent owners will conjure up evidence of ‘copying’ whenever possible, and try to use it aggressively to maintain the validity of their patents.” (footnote omitted)); *supra* note 66 and accompanying text (noting such a prediction by Burk and Lemley).

⁸² See *Cross, Inc. v. Int’l Trade Comm’n*, 598 F.3d 1294, 1311 (Fed. Cir. 2010) (reversing a determination that a footwear product patent was obvious on the grounds that commercial success evidence with a sufficient nexus to the claimed invention was demonstrated); *Süd-Chemie, Inc. v. Multisorb Techs., Inc.*, 554 F.3d 1001, 1009 (Fed. Cir. 2009) (vacating a summary judgment ruling due to a different reading of the prior art and instructing the district court to explicitly examine secondary-considerations evidence on remand); *In re Sullivan*, 498 F.3d 1345, 1351 (Fed. Cir. 2007) (vacating and remanding a PTO Board deci-

tions at the district court level post-*KSR*. In 2008, Kenneth Adamo, Ryan McCrum, and Susan Gerber concluded that district courts were giving increased attention to secondary-considerations evidence.⁸³ However, their study regarded district court cases that rejected secondary-considerations evidence (based on either an insufficient nexus between the evidence and the invention, or a strong *prima facie* case of obviousness) as giving attention to secondary considerations.⁸⁴ While technically giving attention to secondary considerations, these decisions appeared to discount their role. The study cited one case where a district court found a patent nonobvious in part because of secondary-considerations evidence, but that decision was overturned on appeal by the Federal Circuit.⁸⁵ Thus, while illuminating district court practice, this study does not indicate a paradigm shift in the use of secondary considerations.

The court affirmed a finding of nonobviousness in eleven of the cases involving secondary considerations. Seven of these cases dealt with pharmaceutical patents,⁸⁶ two dealt with medical devices,⁸⁷ and

sion, which had affirmed the rejection of a patent application due to the PTO Board's failure to consider rebuttal evidence concerning secondary considerations).

⁸³ Adamo et al., *supra* note 81, at 296.

⁸⁴ *Id.* at 296–97 & 296 n.9.

⁸⁵ *Id.* (citing *Muniauction, Inc. v. Thomson Corp.*, 502 F. Supp. 2d 477, 490 (W.D. Pa. 2007), *rev'd in part*, 532 F.3d 1318 (Fed. Cir. 2008)).

⁸⁶ See *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 997–98 (Fed. Cir. 2009) (affirming the district court's finding of nonobviousness and describing the district court's examination of unexpected results, commercial success, and satisfaction of a long-felt need); *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1352–53 (Fed. Cir. 2008) (upholding the district court's grant of a preliminary injunction based on the likelihood of the patent's validity); *Eisai Co. v. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353, 1355 (Fed. Cir. 2008) (“[T]he district court correctly determined that the . . . patent [was] non-obvious over the proffered prior art”); *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1365 (Fed. Cir. 2008) (“Of particular importance beyond the *prima facie* analysis, this court also detects evidence of objective criteria showing nonobviousness. Specifically, the record shows powerful unexpected results The record also shows skepticism of experts and copying—other respected sources of objective evidence of nonobviousness—as well as commercial success.”); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1378–80 (Fed. Cir. 2006) (affirming the district court's finding of nonobviousness and noting the district court's consideration of unexpected results), *aff'd*, 550 F.3d 1075 (Fed. Cir. 2008); *Forest Labs., Inc. v. Ivax Pharm., Inc.*, 501 F.3d 1263, 1269 (Fed. Cir. 2007) (upholding the district court's determination of nonobviousness and describing the patentee's evidence of unexpected results); *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1360 (Fed. Cir. 2007) (affirming the nonobviousness of a pharmaceutical patent).

⁸⁷ See *Pressure Prods. Med. Supplies, Inc. v. Greatbatch Ltd.*, 599 F.3d 1308, 1319 (Fed. Cir. 2010) (affirming a finding of nonobviousness after considering the secondary-considerations evidence of “commercial success, long felt need, skepticism of experts, and unexpected results”); *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1328 (Fed. Cir. 2009) (finding a patented spinal implant device nonobvious with secondary considerations supporting the finding).

two dealt with computers or electronics.⁸⁸ In the cases where nonobviousness was affirmed, secondary considerations were found to support a *prima facie* finding of nonobviousness.⁸⁹ The court devoted the most attention to secondary considerations in these cases,⁹⁰ most likely because they provided additional evidence that the court could point to in order to demonstrate to the public—and reassure itself—that the conclusion it had reached on obviousness was the correct one. The pharmaceutical patent cases did not involve secondary-considerations evidence based solely on evidence of commercial success. In all of the pharmaceutical cases where the nonobviousness of the invention was upheld on appeal, the secondary-considerations evidence included evidence of unexpected results combined with commercial success, long-felt but unmet need, or copying.⁹¹ One of the medical device cases, *DePuy Spine, Inc. v. Medtronic*, involved a spinal implant screw, which both the district court and the Federal Circuit found to be a nonobvious invention, largely because the prior art taught away from the combination that the invention embodied.⁹² The Federal Circuit, agreeing with the district court, also noted that both the failure of others and copying supported the finding of nonobviousness.⁹³

In the other medical device case, *Pressure Products Medical Supplies, Inc. v. Greatbatch Ltd.*, the Federal Circuit found that substantial evidence supported the jury's finding that the patent was not invalid for obviousness, and that the district court did not err in denying the patent challenger's motion for judgment as a matter of

⁸⁸ See *Power-One, Inc. v. Artesyn Techs., Inc.*, 599 F.3d 1343, 1352 (Fed. Cir. 2010) (affirming the district court's denial of a motion for judgment as a matter of law on the question of patent invalidity for obviousness after noting evidence of copying and praise by competitors); *i4i Ltd. P'ship v. Microsoft Corp.*, 589 F.3d 1246, 1261–62 (Fed. Cir. 2009) (affirming "the district court's legal conclusion of nonobviousness" for a software patent).

⁸⁹ See, e.g., *Ortho-McNeil*, 520 F.3d at 1365 ("Of particular importance beyond the *prima facie* analysis, this court also detects evidence of objective criteria showing nonobviousness.").

⁹⁰ The exception to this statement is *i4i Ltd. Partnership*, where the court noted the secondary-considerations evidence presented at trial but did not explicitly engage with such evidence during its deferential review of the jury's factual findings on appeal. See *infra* notes 99–101 and accompanying text (describing the posture of the case and the limited judicial treatment of secondary-considerations evidence on appeal).

⁹¹ See *infra* Part II.C.3–4 (discussing unexpected-results evidence and the treatment of secondary considerations in pharmaceutical cases); see also cases collected *infra* Appendix.

⁹² 567 F.3d at 1328 ("[T]he district court correctly found that Puno, viewed against the backdrop of the collective teachings of the prior art, teaches away from a rigid pedicle screw encompassed by the hypothetical claim, such that a person of ordinary skill would have been deterred from combining Puno and Anderson . . .").

⁹³ *Id.* at 1328 ("We also believe that certain secondary considerations—'failure by others' and 'copying'—support the view that this combination would not have been obvious at the time of invention.").

law on obviousness.⁹⁴ The court noted that secondary-considerations evidence, including commercial success, long-felt but unmet need, skepticism of experts, and unexpected results, also supported a finding of nonobviousness and served as independent, not just cumulative, evidence of nonobviousness.⁹⁵

Power-One, Inc. v. Artesyn Technologies, Inc. also involved the affirmance of a district court's denial of a motion for judgment as a matter of law on obviousness.⁹⁶ The court found that sufficient evidence supported the lower court's finding that the scope of the prior art was limited and that there were differences between the invention disclosed and the prior art.⁹⁷ The court also noted that secondary-considerations evidence supported the jury's conclusion that the patent was not invalid. Specifically, the court noted that there was evidence that the patent challenger touted its own infringing product as an "advancement in the industry," as well as evidence of industry praise and copying.⁹⁸

In the software case, *i4i Ltd. Partnership v. Microsoft Corp.*, the Federal Circuit upheld a jury finding of nonobviousness for a software patent on an improved method of editing documents containing markup language.⁹⁹ The review on appeal was deferential because the court was reviewing jury findings of obviousness where no pre-verdict motion for judgment as a matter of law on obviousness had been filed.¹⁰⁰ As a result, the Federal Circuit did not specifically examine the secondary-considerations evidence, but did note that i4i had presented at trial evidence of commercial success, long-felt need, and failure of others.¹⁰¹

Overall, the majority of patent cases where secondary considerations were found to support a finding of nonobviousness involved a specific industry (pharmaceutical) and a particular type of evidence traditionally categorized as secondary (unexpected results).¹⁰²

⁹⁴ *Pressure Prods. Med. Supplies, Inc. v. Greatbatch Ltd.*, 599 F.3d 1308, 1319 (Fed. Cir. 2010).

⁹⁵ *Id.*

⁹⁶ 599 F.3d 1343, 1352 (Fed. Cir. 2010).

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ 589 F.3d at 1262.

¹⁰⁰ *Id.* at 1261 (finding that Microsoft had waived its right to appeal the jury's implicit obviousness verdict and holding that the Federal Circuit was to review only the district court's legal conclusion of nonobviousness based on presumed factual findings).

¹⁰¹ *Id.* at 1260.

¹⁰² See *infra* Appendix (tabulating obviousness holdings, case outcomes, and the use of secondary considerations).

C. *The Current Use of Secondary-Considerations Evidence*

Analysis of how the Federal Circuit has utilized secondary-considerations evidence when considering challenges to the nonobviousness of patents reveals several qualities of the current state of secondary considerations in patent law. First, the Federal Circuit has retained a high bar for relevancy, allowing only the most relevant secondary-considerations evidence to factor into the nonobviousness calculus. Second, the Federal Circuit has begun to place an increased emphasis on the secondary consideration of unexpected results. Third, despite the fact that secondary-considerations evidence was predicted to rise in prominence post-*KSR*,¹⁰³ the cases examined indicate that the Federal Circuit has thus far given such evidence little weight in the obviousness analysis.¹⁰⁴ Instead, secondary-considerations evidence remains a formal requirement that the Federal Circuit requires district courts and the PTO Board to explicitly address, but one without any real bite outside of the pharmaceutical arts. As a result, presentation of secondary-considerations evidence appears to be an attractive litigation strategy for pharmaceutical patentees, but a less fruitful one for patentees working in other technology areas, particularly the mechanical arts.

1. *Stringent Relevancy Requirements*

The Federal Circuit has continued to impose rigorous demands on secondary-considerations evidence, requiring a clear nexus between the proffered evidence and the invention at issue. In an appeal from an obviousness rejection of a patent application for a nutraceutical fruit juice composition, the patent applicant argued that the PTO Board improperly found a lack of a nexus between the commercial-success evidence and the claimed invention.¹⁰⁵ The inventors had supplied evidence of \$130 million in sales of the juice composition over two years; while the Board acknowledged the sales were substantial, it still rejected the evidence, finding that it “[might] be attributable to other factors, such as aggressive network marketing.”¹⁰⁶ Emphasizing that there was no evidence tying the sales to the claimed invention, the Board speculated that the commercial suc-

¹⁰³ See *supra* note 66 and accompanying text (discussing the anticipated increased patentee reliance on secondary considerations).

¹⁰⁴ However, it must be acknowledged that courts’ decisions are “dependent . . . on the amount of secondary consideration evidence presented by the parties.” Jonathan J. Darrow, *Secondary Considerations: A Structured Framework for Patent Analysis*, 74 ALB. L. REV. 47, 53 (2011).

¹⁰⁵ *In re DBC*, 545 F.3d 1373, 1384 (Fed. Cir. 2008).

¹⁰⁶ *Id.*

cess might simply be due to the rise in popularity of the juice in general or the commission-based network marketing structure used by the company. The Federal Circuit agreed, stressing that evidence of commercial success without proof that sales are the direct result of unique characteristics of the invention does not demonstrate nonobviousness.¹⁰⁷

The Federal Circuit's criticism of the applicants' evidence demonstrates how difficult it can be to make a case for nonobviousness based on commercial success. It might be hard for patent applicants to demonstrate why they were able to sell significant amounts of their product. For instance, what type of available proof would demonstrate that a product's sales were due to the product's unique properties and not due to marketing efforts? Certainly it would be hard (and expensive) to determine why consumers purchased the product and for a patentee to demonstrate a nexus between the product's sales and its innovativeness. Even if the marketing tactics were aggressive, it would be difficult to determine if the correct conclusion was that consumers bought the juice due to marketing, as opposed to the product's uniqueness.

It may also be difficult for patentees to demonstrate a connection between commercial success and the patent claims at issue. This difficulty is especially present where a patentee seeks to defend a patent that claims a component in a product. Unlike a patentee defending a patent that directly embodies an entire product, a patentee defending a patent that claims a component in a product may be unable to demonstrate that the improved product's commercial success was due to the patented component.¹⁰⁸ This is especially the case if the product was sold in the marketplace prior to the incorporation of the patented component.¹⁰⁹

¹⁰⁷ *Id.* (“[E]vidence of commercial success alone is not sufficient to demonstrate nonobviousness of a claimed invention.”).

¹⁰⁸ Brian Kahin notes that, while the relationship between products and patents is “relatively close” in the pharmaceutical, chemical, and medical industries, the IT sector contains a “large volume of patents relative to products.” Brian Kahin, *Patents and Diversity in Innovation*, 13 MICH. TELECOMM. & TECH. L. REV. 389, 389–90 (2007).

¹⁰⁹ A recent case before the Federal Circuit demonstrates this tension. In *Tokai Corp. v. Easton Enterprises*, the patentee had claimed a lighter with an automatic locking feature. 632 F.3d 1358, 1361 (Fed. Cir. 2011). The court dismissed the evidence of commercial success provided by the patentee, finding “no evidence from which one could reasonably infer a nexus between its sales data and its utility lighters’ automatic-locking features.” *Id.* at 1370. Judge Newman criticized the majority for ignoring the fact that a modification can lead to a marketplace response, particularly given the fact that the defendants had not challenged Tokai’s evidence suggesting that the commercial success was due to the lighter’s “improved child-safety mechanism.” *Id.* at 1379 (Newman, J., dissenting).

Perhaps the risk of finding a small number of nonobvious inventions obvious, because of a need to prove a nexus between commercial success and a claimed invention and the difficulty some patentees may face in attempting to do so, is outweighed by the goal of avoiding upholding obvious inventions based on evidence only tangentially related (or not related at all) to the actual inventive contribution.¹¹⁰ Since these drawbacks appear to be inherent in the use of commercial success as a secondary consideration, patentees will likely find more success if they can provide evidence of other secondary considerations along with commercial success.¹¹¹

The Federal Circuit has been similarly demanding of other types of secondary-considerations evidence.¹¹² It requires close ties between legally appropriate or cognizable praise and the specific inventive contribution claimed in order to establish the required nexus.¹¹³ For example, in order to prove the nonobviousness of a patent for a method of auctioning municipal bonds via the internet, the patentee in *Muniauction, Inc. v. Thomson Corp.* offered evidence that a municipality utilizing the method was given an Innovation in American Government award for its use of the system.¹¹⁴ The evidence was rejected, however, because the court found that the press coverage of the award focused on the fact that the system offered a new type of bidding that was different from what had been used previously.¹¹⁵ Because the patentee's claims included a means to implement a previous method of conducting auctions via web browsers, the court concluded that the award lacked a nexus to the full scope of the claims at

¹¹⁰ See *Merges, supra* note 36, at 859–61, 874 (outlining the perceived costs of reliance on commercial success evidence without a strict nexus requirement and the risk that courts will reward inventions that the patent system was not meant to encourage).

¹¹¹ See *id.* at 874 (suggesting that patentees provide additional secondary-considerations evidence); Jay Jongjitirat, Note, *Leapfrog Enterprises v. Fisher-Price: Secondary Considerations in Nonobviousness Determinations*, 42 U.C. DAVIS L. REV. 599, 626–27 (2008) (noting that courts have given less weight to evidence of commercial success absent other secondary-considerations evidence); Robbins, *supra* note 14, at 1176–77 (contending that a showing of both commercial success and long-felt demand presents a strong case of nonobviousness).

¹¹² See *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1332–33 (Fed. Cir. 2009) (requiring specific proof in a nonobviousness analysis that the problems created by bulk e-mail marketing comprised a distinct long-felt need, proof of the length of time that the need remained unmet, and proof of how the invention addressed the need).

¹¹³ See *In re Mettke*, 570 F.3d 1356, 1361 (Fed. Cir. 2009) (finding evidence that a patent had been cited as prior art by almost 100 other patents to be insufficient to rebut a prima facie case of obviousness, and similarly rejecting evidence of the widespread use of the invention's elements in competing products as evidence of commercial success).

¹¹⁴ 532 F.3d 1318, 1328 (Fed. Cir. 2008).

¹¹⁵ See *id.* (“The press coverage of the award in the record, however, focuses on the availability of maturity-by-maturity bidding in the Muniauction system, as compared to the conventional all-or-none bidding.”).

issue.¹¹⁶ While the patentee might have encountered problems because the prior method of bidding may have been obvious to implement via a web browser, it is worth considering whether it was appropriate to dismiss the evidence completely. Assuming that the other method was not previously known, it is unclear that praise for one component of an invention should not qualify as judicially cognizable contemporaneous praise simply because it does not also highlight the other components of an invention.¹¹⁷ While the court was right to examine the relevance of secondary considerations prior to weighing such evidence against the case for obviousness, there is cause for concern if courts screen secondary-considerations evidence too rigidly. Excessive exclusion of secondary-considerations evidence potentially eliminates some of the most illuminating and accessible evidence about the situation faced by a PHOSITA at the time of invention.

2. *Shifting the Patentability Threshold by Declining To Examine Significant Secondary-Considerations Evidence*

In the cases surveyed, post-*KSR* litigants who have relied on the secondary considerations explicitly listed in the *Graham* decision¹¹⁸ (such as long-felt but unmet need and commercial success) have found little success before the Federal Circuit, particularly outside of the pharmaceutical realm.¹¹⁹ In fact, the Federal Circuit has now adopted the position that “evidence of secondary considerations does not always overcome a strong *prima facie* showing of obviousness.”¹²⁰

¹¹⁶ See *id.* (“Although both auction types are disclosed . . . , claims 1 and 31 include conventional all-or-none bidding, as well as maturity-by-maturity bidding. Thus, the 1999 award lacks the required nexus . . .”).

¹¹⁷ The rejection of secondary-considerations evidence because it fails to match the full scope of the claims is reminiscent of *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, where the court rejected expert testimony about surprise on the part of competitors in the field, because the expert failed to prove that he and the competitors had knowledge of all of the prior art at issue. 491 F.3d 1342, 1365 (Fed. Cir. 2007); see also *infra* Part II.D (describing the *PharmaStem* decision and the potential flaws in the court’s approach to secondary considerations).

¹¹⁸ See *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966) (listing commercial success, long-felt but unsolved need, and failure of others as secondary considerations).

¹¹⁹ See, e.g., *Muniauction*, 532 F.3d at 1327–28 (finding secondary considerations, including industry praise, skepticism, copying, and commercial success, to be insufficient due to a lack of a clear nexus or an inability to overcome a strong *prima facie* demonstration of obviousness).

¹²⁰ *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1333 (Fed. Cir. 2009) (quoting *Asyst Techs., Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1316 (Fed. Cir. 2008)); see also *Ball Aerosol & Specialty Container, Inc. v. Ltd. Brands, Inc.*, 555 F.3d 984, 994 (Fed. Cir. 2009) (finding that evidence of commercial success of a combination candle stand/lid failed to outweigh the clear indication of obviousness from prior art); *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1368 (Fed. Cir. 2008) (holding that secondary considerations were insufficient to overcome a strong *prima facie* case of obviousness).

Leapfrog Enterprises, Inc. v. Fisher-Price, Inc. provides one example of how this standard has been applied.¹²¹ In *Leapfrog*, the district court found a strong prima facie case of obviousness for an invention that updated a mechanical reader toy for children by developing an electronic form of the reader toy.¹²² The Federal Circuit affirmed the district court's finding that the patent was invalid for obviousness despite the admitted presence of considerable secondary-considerations evidence that suggested nonobviousness.¹²³ The district court had largely relied on expert testimony to find the patented invention prima facie obvious and gave only cursory attention to secondary considerations: "As to the secondary considerations tending to show non-obviousness, Leapfrog points to only three: commercial success, praise, and long-felt need. While it is true that Leapfrog adduced substantial evidence of these three factors, the court is not convinced that they overcome the very strong case of obviousness" ¹²⁴ Because the district court had found a strong case of obviousness based on the first three steps of the *Graham* analysis, the court declined to further examine the proffered evidence of commercial success, industry praise, and long-felt but unmet need.

By affirming the district court, the Federal Circuit accepted the district court's choice not to discuss in detail the inapplicability of each secondary consideration introduced by Leapfrog in light of a strong prima facie case of obviousness. However, the district court's approach may have failed to adequately consider secondary-considerations evidence as part of the obviousness inquiry under Supreme Court and Federal Circuit precedent.¹²⁵ Secondary considerations can offer courts unique insight into the situation confronted by a PHOSITA at the time of invention,¹²⁶ and diminishing their role

¹²¹ 485 F.3d 1157 (Fed. Cir. 2007).

¹²² *Id.* at 1162.

¹²³ *Id.*

¹²⁴ *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, No. 03-927-GMS, 2006 WL 891001, at *8 (D. Del. Mar. 30, 2006).

¹²⁵ See *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007) (noting that the *Graham* inquiry extends to secondary considerations); *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1365 (Fed. Cir. 2008) (explaining that secondary-considerations evidence does not act as a "cumulative or confirmatory part of the obviousness calculus but constitutes independent evidence of nonobviousness"); *In re Piasecki*, 745 F.2d 1468, 1471 (Fed. Cir. 1984) (noting that all evidence relating to the obviousness inquiry must be considered, including secondary considerations); *In re Sernaker*, 702 F.2d 989, 996 (Fed. Cir. 1983) (noting that evidence of secondary considerations must be considered when put forward by a patent applicant).

¹²⁶ Sarah A. Geers, Comment, *Common Sense and the Fact Finder Without Skill in the Art: The Role of Objective Evidence in Achieving Proper Technology Specificity*, 40 SETON HALL L. REV. 225, 246 (2010) (suggesting that courts increase the use of secondary-considerations evidence in understanding the viewpoint of a PHOSITA); see Darrow,

may in effect heighten the nonobviousness bar for patentability.¹²⁷ Courts increase the robustness of their inquiry by deliberately examining secondary-considerations evidence and justifying reliance on it, dismissing it due to a lack of a nexus to the invention, or weighing it against the prior art.

Disregarding substantial secondary-considerations evidence in the face of a strong case of obviousness also places additional weight on the determination of whether or not the case for obviousness is strong. If a factfinder's subjective obviousness determination controls the relevance of secondary-considerations evidence, obviousness determinations might suffer from increased variability.¹²⁸ Accepting that secondary-considerations evidence may be more objective than evidence of obviousness from the standpoint of the PHOSITA, a factfinder's subjective determination of obviousness could become untethered from objective facts. Despite this concern, following *Leapfrog*, the Federal Circuit has continued to express the opinion that a strong *prima facie* case of obviousness may overcome substantial evidence of secondary considerations.¹²⁹

3. *Shifting the Emphasis on Unexpected Results*

The classification of unexpected-results evidence as a secondary consideration existed prior to *KSR* and has continued since then.¹³⁰ In *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.*, the Federal Circuit found that secondary-considerations evidence provided considerable independent support for the nonobviousness of the

supra note 104, at 56 (summarizing the appropriateness of secondary considerations for obviousness determinations); Wieker, *supra* note 10, at 673–74, 681 (recommending greater use of secondary considerations and arguing that such evidence is “more telling of the state of the art at the time of invention than is common sense”).

¹²⁷ See Jongjitirat, *supra* note 111, at 625–27 (arguing that the Federal Circuit's decision in *Leapfrog* both erroneously interpreted *KSR* as requiring a stricter evaluation of nonobviousness and failed to account for secondary considerations, creating a heightened nonobviousness standard).

¹²⁸ See Wieker, *supra* note 10, at 679–80 (arguing that courts may reach inconsistent results if allowed to ignore secondary-considerations evidence where a strong case of obviousness is made).

¹²⁹ See *Rothman v. Target Corp.*, 556 F.3d 1310, 1322 (Fed. Cir. 2009) (“[A] strong *prima facie* obviousness showing may stand even in the face of considerable evidence of secondary considerations.”); *cf.* *Bos. Scientific Scimed, Inc. v. Cordis Corp.*, 554 F.3d 982, 991–92 (Fed. Cir. 2009) (finding that “weak secondary considerations” could not overcome a “strong *prima facie* showing” of obviousness).

¹³⁰ See, e.g., *Ortho-McNeil*, 520 F.3d at 1365 (describing unexpected results as an objective criterion showing nonobviousness); *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1369–72 (Fed. Cir. 2007) (discussing unexpected results as a secondary consideration); *Eli Lilly & Co. v. Zenith Goldline Pharm., Inc.*, 471 F.3d 1369, 1380 (Fed. Cir. 2006) (noting the plaintiff's secondary-considerations evidence of long-felt but unmet need, failure of others, industry praise, and unexpected results).

patented anticonvulsive compound.¹³¹ Although the record also contained evidence of commercial success, skepticism of experts, and copying, the court highlighted unexpected results in its discussion of objective indicia of nonobviousness.¹³² Consistent with this trend, district courts have treated unexpected results as an unquestioned and commonly cited embodiment of secondary-considerations evidence.¹³³

Professor Rebecca Eisenberg has criticized the categorization of evidence of unexpected results as a secondary consideration. Eisenberg argues that evidence of unexpected results is inherently different from other market-based secondary-considerations evidence in that it is “primary, technological evidence going directly to the statutory inquiry as to ‘the differences between the subject matter sought to be patented and the prior art.’”¹³⁴ Eisenberg argues that categorizing unexpected-results evidence as a secondary consideration may cause decision makers to improperly discount such evidence.¹³⁵ If secondary-considerations evidence is not as rigorously examined as “primary” evidence concerning obviousness, this danger is certainly more than a possibility. However, *KSR* specifically implicates the need for courts to consider unexpected results: “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”¹³⁶ The resulting emphasis on demonstrating that a combination of elements produced unpredictable or unexpected results appears to have led to an increased utilization of unexpected-results evidence in the initial technical determination of whether the claimed invention would have been obvious to a PHOSITA. This “recategorization” of unexpected-results evidence has been observable in several cases.¹³⁷

¹³¹ 520 F.3d at 1365.

¹³² *Id.* (“Of particular importance beyond the prima facie analysis this court also detected evidence of objective criteria showing nonobviousness. Specifically, the record shows powerful unexpected results . . . for topiramate. The record also shows skepticism of experts and copying—other respected sources of objective evidence of nonobviousness—as well as commercial success.”).

¹³³ See *Daiichi Sankyo Co. v. Mylan Pharm. Inc.*, 670 F. Supp. 2d 359, 381–83 (D.N.J. 2009) (stating that objective indicia of nonobviousness include unexpected results and discussing evidence of unexpected results); *Everett Labs., Inc. v. Breckenridge Pharm., Inc.*, 573 F. Supp. 2d 855, 860 (D.N.J. 2008) (listing various secondary considerations, including unexpected results); *Friskit, Inc. v. RealNetworks, Inc.*, 499 F. Supp. 2d 1145, 1153–54 (N.D. Cal. 2007) (same).

¹³⁴ Rebecca S. Eisenberg, *The Shape of Things To Come: Pharma's Nonobviousness Problem*, 12 LEWIS & CLARK L. REV. 375, 418 (2008) (quoting 35 U.S.C. § 103(a) (2006)).

¹³⁵ *Id.*

¹³⁶ *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

¹³⁷ See *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 997–98 (Fed. Cir. 2009) (analyzing unexpected results apart from a discussion of secondary considerations, but describing evidence of unexpected results as a rebuttal to a prima facie case of obvi-

4. *A Continuing Exception for Pharmaceutical Patents*

Although the utility of secondary-considerations evidence for litigants seeking to demonstrate the nonobviousness of their invention seems to be diminishing under current Federal Circuit precedent, it appears that this trend has not affected pharmaceutical patent litigants. While secondary considerations are facially applicable to every patent case, they are actually slightly biased in their applicability to particular types of patents and industries.¹³⁸ In patent cases following *KSR*, litigants defending pharmaceutical patents have been more successful in utilizing secondary-considerations evidence to establish non-obviousness.¹³⁹ For example, these litigants may be able to highlight the research expenditures invested in the development of a new lead compound as a secondary consideration of nonobviousness. Burk and Lemley have suggested that using research costs as secondary-considerations evidence may be a means to encourage high-cost, high-risk, but presumably socially beneficial, innovation.¹⁴⁰ And the Federal Circuit has accepted such evidence as indicative of the nonobviousness of the compound claimed. In *Sanofi-Synthelabo v. Apotex, Inc.*, the Federal Circuit endorsed the district court's reliance on evi-

ousness); *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1088–90 (Fed. Cir. 2008) (addressing unexpected results in the context of whether the PHOSITA would have found the invention obvious, given the prior art); *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1361–63 (Fed. Cir. 2007) (addressing unexpected results separately from secondary considerations).

¹³⁸ For example, secondary considerations are more likely to apply in a pharmaceutical patent case than a software patent case. See BURK & LEMLEY, *supra* note 33, at 117–18 (observing that secondary considerations are more likely to support patents on entire products, rather than components, and that secondary considerations work best for products sold directly to consumers, rather than for upstream research tools or intermediary products).

¹³⁹ See, e.g., *Procter & Gamble*, 566 F.3d at 998 (finding that secondary-considerations evidence supported a finding of nonobviousness in a pharmaceutical patent case); see also Katherine M.L. Hayes, Note, *Three Years Post-KSR: A Practitioner's Guide to "Winning" Arguments on Obviousness and a Look at What May Lay Ahead*, 9 NW. J. TECH. & INTELL. PROP. 243, 254 (2010) (observing in the context of pharmaceutical patent cases that "[a]lthough secondary considerations operate primarily to negate a *prima facie* case of obviousness, many district courts, while finding against the challenger on the basis of the *prima facie* case, write lengthy opinions explaining why secondary considerations also support the initial finding of non-obviousness"); *infra* Appendix (collecting cases and summarizing the dispositions and treatment of secondary-considerations evidence); cf. *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007) (upholding the district court's finding that a patent for an electronic reader was invalid as obvious despite the fact that the district court acknowledged the existence of substantial secondary-considerations evidence).

¹⁴⁰ *Id.* at 132 (proposing the cost and uncertainty of an innovation as a secondary consideration). Professors Meurer and Strandburg have also suggested that nonobviousness doctrine should pay attention to research costs in order to encourage research that provides benefits to society at large. Meurer & Strandburg, *supra* note 19, at 576–77.

dence that Sanofi had spent “extensive time and money” to develop the racemate (a mixture of two different forms) of a previously known pharmaceutical compound before deciding to focus on developing only one form of the compound instead.¹⁴¹

However, the utility of this evidence as a secondary consideration is likely to be case-specific and dependent on detailed information about the inventor’s motivations. Research expenditures are only relevant if one assumes that inventors are rational PHOSITAs who would not waste money exploring unreasonable leads, as their expenditures would otherwise not be a useful metric. Following this assumption, researchers are presumed to spend large amounts of research funds to pursue only those nonobvious research paths with correspondingly large payoffs. Were the research path obvious, the danger of competitors beating them to market via the same obvious research path would not justify the expenditure.¹⁴² If the inventors ultimately change course after such a significant investment—for example, millions of dollars over four years in *Sanofi-Synthelabo*¹⁴³—one would assume they shifted in favor of another option that was also not obvious. Yet the intuition that research expenditures signal nonobviousness may not hold true when a company decides to pursue a technically challenging research path toward an obvious invention. In such a situation, the technical barriers may be enough to encourage a company, believing it has sufficient technical expertise, to risk investing in a project that should be an obvious target for competitors.

D. Burdensome Conditions on Introducing Secondary-Considerations Evidence—The Example of PharmaStem

A survey of decisions following *KSR* indicates that decision makers have not increased their reliance on secondary-considerations evidence. Post-*KSR* litigants have continued to present secondary-considerations evidence, but decision makers have often given secondary-considerations evidence little weight. In some cases, the evidence may correctly be discounted because it lacks a nexus to the claimed invention. However, because of the potential value of secondary considerations in combating hindsight bias post-*KSR*, courts should be careful to avoid excessively ruling out such evidence. *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*¹⁴⁴ provides a helpful

¹⁴¹ *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1378–79 (Fed. Cir. 2006).

¹⁴² Cf. BURK & LEMLEY, *supra* note 33, at 132 (explaining that, since high-cost innovation correlates with high risk, rational entrepreneurs will not invest in “high-cost projects unless the expected reward is correspondingly greater”).

¹⁴³ 470 F.3d at 1378.

¹⁴⁴ 491 F.3d 1342 (Fed. Cir. 2009).

illustration of the barriers to using secondary-considerations evidence. PharmaStem, a biotechnology company, held two patents on a method for using hematopoietic stem cells (HSCs) from cryopreserved umbilical cord blood to reconstitute a compromised blood or immune system.¹⁴⁵ In an infringement suit challenging PharmaStem's patents, the jury found that both patents were valid and infringed by the defendants, who were offering cord blood collection and cryopreservation services.¹⁴⁶ However, the district court subsequently entered a judgment as a matter of law that both patents were not infringed, while denying the defendants' motions regarding the invalidity of the patents.¹⁴⁷ On appeal, the Federal Circuit reversed the district court on the obviousness issue, holding that PharmaStem's patents were invalid for obviousness.¹⁴⁸

To reach its decision, the district court had relied on testimony from PharmaStem's expert, who stated that he had previously doubted that cord blood transplantations would work in humans and that the prior art did not demonstrate that cord blood contained HSCs.¹⁴⁹ The district court also used secondary-considerations evidence to uphold the jury's verdict as to the patents' validity.¹⁵⁰ The Federal Circuit rejected this position, finding that the expert's statements were contradicted by the patent specification,¹⁵¹ where the inventors acknowledged that HSCs resided in cord blood and cited prior art references.¹⁵² The court also rejected the suggestion that the inventors might have carelessly included such a statement in the specification by inappropriately referring to HSCs, instead of progenitor

¹⁴⁵ *Id.* at 1347–48. The method provides for the collection and preservation of hematopoietic stem cells (HSCs) from the blood found within an infant's umbilical cord for later use in repopulating a recipient's blood and immune systems, which have been compromised due to chemotherapy or disease. *See id.* HSCs are stem cells capable of giving rise to the blood and immune system cell lineages. The HSCs from an infant's umbilical cord blood may provide the infant (or even a closely related person) a source of stem cells to treat an illness causing the depletion of the immune or blood systems.

¹⁴⁶ *Id.* at 1346.

¹⁴⁷ *Id.* at 1346–47.

¹⁴⁸ *Id.* at 1347.

¹⁴⁹ *Id.* at 1360–61.

¹⁵⁰ *Id.*

¹⁵¹ The patent specification constitutes the majority of the patent document and contains the written description of the invention, "the manner and process of making and using it," the best mode for carrying out the claimed invention, and the patent claims. *See* 35 U.S.C. § 112 (2006).

¹⁵² *PharmaStem*, 491 F.3d at 1362 ("Contrary to Dr. Bernstein's contention that the prior art did not disclose the presence of stem cells in cord blood, the inventors cited several prior art references and stated flatly that 'hematopoietic stem cells have been demonstrated in human umbilical cord blood.'").

cells generally.¹⁵³ The court found that a more natural reading of the specification suggested that it was not careless error to include such statements, that such a characterization of the prior art was not unreasonable given that the authors of prior references could have reasonably inferred that HSCs were present even if they could not directly prove it, and that regardless, statements in the specification were binding on the inventors.¹⁵⁴ Although the inventors conclusively demonstrated that these stem cells existed in cord blood and could be used to achieve hematopoietic reconstitution, the court found that the inventors did not discover anything nonobvious.¹⁵⁵ Instead, the court found the subject matter not patentable and described PharmaStem's efforts as routine research efforts used to confirm what other researchers would have suspected based on the prior art.¹⁵⁶

PharmaStem claimed that secondary considerations demonstrated that the use of cord blood HSCs for immune and blood system reconstitution was not obvious to a PHOSITA, citing evidence of professional approval, surprise on the part of researchers at their success, and the subsequent performance of human cord blood transplants by physicians *after* the inventors' experimental demonstration.¹⁵⁷ The Federal Circuit dismissed these secondary considerations, reasoning that they were not persuasive as evidence of nonobviousness. For instance, the court pointed out that PharmaStem did not demonstrate that they received professional praise for their inventive contribution instead of for confirmatory "proof, through laboratory work."¹⁵⁸ The court also dismissed evidence that other researchers were surprised at the success of the inventors, noting a lack of evidence that the research group knew of all the specific prior art references that supposedly were foundational to the claimed invention and that the group's surprise was directly related to the contents of the patent specification.¹⁵⁹ The researchers' surprise, the court noted, was over the success of the human cord blood transplant and not the particular results within the specification, although the transplant was based on the inventors' work (contained in the specification).¹⁶⁰ Finally, the

¹⁵³ *Id.*

¹⁵⁴ *Id.* at 1362–63.

¹⁵⁵ *Id.* at 1363.

¹⁵⁶ *Id.*

¹⁵⁷ *Id.* at 1365.

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*

¹⁶⁰ The transplant took place after the application for the first of the two patents was filed and just prior to the filing of the application for the second patent. The first patent application does not mention the transplant, and the second patent application mentions the transplant attempt but not the results. *Id.*

court dismissed the evidence that physicians did not attempt human cord blood transplants until after the inventors' work, reasoning instead that physicians would attempt a new procedure on a patient only after finding extremely strong scientific support for the procedure.¹⁶¹

Although the Federal Circuit found a strong case for obviousness based on the prior art, the court's reasons for dismissing secondary considerations do not appear to necessarily conform to the actual process of scientific discovery. Many, if not most, scientific discoveries and research projects build upon prior research, and indeed, scientific progress is often viewed as incremental.¹⁶²

Judge Newman's dissent in the case criticized the majority for allowing hindsight to affect the obviousness determination. She emphasized the fact that PharmaStem's contribution had received professional praise and met a long-felt need.¹⁶³ The majority, she argued, should have made greater use of such secondary considerations in this context:

[T]he processes of discovery in complex science make it particularly necessary to view the achievement in the context of the knowledge at the time the invention was made, and to judge it as it was judged by scientific peers at that time, with the assistance of the hard fact of commercial success in a field in which the need was great and success had long been eluded.¹⁶⁴

According to the dissent, the PharmaStem scientists had not simply been carrying out routine experimentation. Instead, they had discovered an answer to two elusive questions: whether there were hematopoietic stem cells in cord blood and whether these cells could be used to reconstitute a compromised hematopoietic system.¹⁶⁵

Without paying due regard to secondary considerations, it arguably will become more difficult to patent methods developed in the laboratory under a method or product patent for the purposes of commercialization. Given the Federal Circuit's distaste for results acquired via routine experimentation, combined with the fact that most science comes from hypotheses that build upon prior work,¹⁶⁶ it

¹⁶¹ *Id.* at 1365–66.

¹⁶² See JOHN LOSEE, *THEORIES OF SCIENTIFIC PROGRESS: AN INTRODUCTION* 1 (2004) (describing the two primary theories of scientific progress); Christine MacLeod, *Concepts of Invention and the Patent Controversy in Victorian Britain*, in *TECHNOLOGICAL CHANGE* 137, 145–47 (Robert Fox ed., 2008) (explaining the deterministic conception of invention).

¹⁶³ *PharmaStem*, 491 F.3d at 1367 (Newman, J., dissenting).

¹⁶⁴ *Id.* at 1368.

¹⁶⁵ *Id.* at 1378.

¹⁶⁶ See A. Rupert Hall, *Scientific Method and the Progress of Techniques*, in 4 *THE CAMBRIDGE ECONOMIC HISTORY OF EUROPE* 96, 96 (E.E. Rich & C.H. Wilson eds., 1967)

may become exceedingly difficult to satisfy the nonobviousness requirement unless one is working in a field with little previous work. The resulting difficulty in patenting discoveries might reduce the incentive for scientists like those at PharmaStem to find solutions to long unanswered questions, since competitors could quickly access new discoveries if they were unpatented.

The *PharmaStem* decision has also been criticized due to the Federal Circuit's discounting of professional praise by a research group where the group did not prove that it knew of all the prior art.¹⁶⁷ Screening expert testimony based on all prior art, in contrast to the expert's actual knowledge of prior art, prevents secondary considerations from contributing nontechnical evidence of how the invention was actually developed and received by PHOSITAs at the time of invention. Instead, courts determining whether to give weight to secondary considerations should take into account only the actual knowledge possessed by the expert at the time of invention, not the knowledge that becomes apparent in hindsight with all prior art collected for examination.

III

THE POTENTIAL FOR A REINVIGORATED USE OF SECONDARY-CONSIDERATIONS EVIDENCE

In this Part, I consider the implications of the observation that secondary-considerations evidence is frequently dismissed (outside of the pharmaceutical realm) as insufficient without a thorough explanation of the reasons for reaching such a conclusion. This practice may lead to a general tendency to dismiss such evidence as insufficient before thoroughly considering the evidence in the context of mechanical arts patents.¹⁶⁸ I conclude that the current practice must be considered when contemplating recently advanced proposals for the tailoring of secondary-considerations evidence to different industries. I also suggest that the Federal Circuit should engage with such evidence in order to serve a teaching function to enhance the doctrine during the transition period post-*KSR*.

(describing gradual scientific progress from the Middle Ages to the modern day); Adam Mossoff, *The Incremental Invention of the Sewing Machine (Part 2 of 2)*, THE VOLOKH CONSPIRACY (Apr. 30, 2009, 11:46 AM), <http://volokh.com/posts/1241038408.shtml>.

¹⁶⁷ See Durie & Lemley, *supra* note 15, at 1017–18 & 1018 n.151 (arguing that the construct of an all-knowing PHOSITA infects the analysis of secondary considerations and prevents secondary considerations from providing a dose of realism to the obviousness inquiry).

¹⁶⁸ Although there is no requirement that a court reduce to words every mental step involved in reaching a conclusion, and although the need for judicial economy is recognized, the process may serve to maintain and promote an analytic approach.

A. *Critiquing Proposals for Industry-Tailored Use of Secondary Considerations in Light of Current Practice*

KSR has renewed proposals for reshaping the obviousness inquiry generally, as well as for changing the role of secondary considerations.¹⁶⁹ Some proposals have suggested moving toward a patent system tailored to specific industries, replacing the current one-size-fits-all patent regime with a set of industry-specific provisions.¹⁷⁰ These proposals assume that the patent system offers better protection to certain industries, such as the pharmaceutical industry, than to others, such as the software industry.¹⁷¹ This starting point is consistent with pharmaceutical patentees' successful utilization of secondary considerations in the wake of *KSR* and the limited success had by patentees in other industries or technological fields.¹⁷²

Other proposals would specifically modify the obviousness inquiry, including the weighing of secondary considerations, instead of moving toward industry-tailored patent regimes on a broader scale. Current practice regarding judicial treatment of secondary considerations, as well as litigant utilization of secondary considerations, should aid in evaluating proposals for reshaping the obviousness inquiry, including altering the use of secondary considerations. Since some courts have cursorily dismissed secondary-considerations evidence, tailoring proposals might remove or add barriers to proving nonobviousness for specific classes of patentees with potentially negative implications for innovation policy. For example, a proposal that assumes that we need patents to promote innovation in the chemical arts (or pharmaceutical industry) might suggest that it should be easier to demonstrate nonobviousness in the relatively unpredictable

¹⁶⁹ See, e.g., Abramowicz & Duffy, *supra* note 14, at 1596–1602, 1655–57 (proposing an inducement standard of patentability and noting the role of secondary-considerations evidence in implementing this standard); Darrow, *supra* note 104, at 59 (proposing a statutory amendment that would insert secondary considerations into the Patent Act's text concerning patentability determinations).

¹⁷⁰ See BURK & LEMLEY, *supra* note 33, at 95 (arguing that courts should account for differences between industries when making patent decisions).

¹⁷¹ See Geers, *supra* note 126, at 241–43 (describing the significant structural differences in how the pharmaceutical industry and software industry innovate and the resulting differences in these industries' patent needs); see also BURK & LEMLEY, *supra* note 33, at 65 (noting the different economic effects patents create in the software and biotechnology industries); FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY ch. 3 (2003), available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf> (outlining the reported differences in investment, product life cycle, impetus for innovation, and the role of patents in the software, computer, and pharmaceutical industries).

¹⁷² See *supra* Part II.C.4 (discussing the successful use of secondary-considerations evidence in the context of pharmaceutical patents).

chemical arts. Such a proposal might include a presumption or thumb on the scale toward a finding of nonobviousness. Such a presumption would place less pressure on the patent applicant or patentee to come forward with sufficient secondary-considerations evidence, and any judicial tendency to dismiss such evidence would be of limited effect given the presumption. In contrast, if courts generally dismiss secondary-considerations evidence in the context of mechanical arts patents, adopting a tailoring proposal that presumes that such inventions are obvious until rebutted with sufficient secondary-considerations evidence could create a barrier to patentability.

As noted above, while some proposals would change the overall patent system—with the goal of creating a system designed to meet the needs of patentees in different industries, as well as to better promote innovation generally in different industries—other proposals focus only on reshaping the nature of the obviousness inquiry. Some of these proposals would alter the obviousness inquiry by tailoring it to different industries, each of which has “different needs and experience[s] the patent system differently.”¹⁷³ For example, Sarah Geers has proposed a flexible approach for employing secondary-considerations evidence, including the use of such evidence to develop “[i]ndustry-[s]pecific [f]actual [p]resumptions.”¹⁷⁴ Geers suggests that there should be a strong, pre-inventive presumption of obviousness in the mechanical arts and a presumption of nonobviousness in the pharmaceutical arts.¹⁷⁵ These presumptions could then either be rebutted or further supported using secondary-considerations evidence.¹⁷⁶

This proposal appears to be consistent with the Federal Circuit opinions examined.¹⁷⁷ Courts may have already internalized the proposed presumptions based on industrial characteristics, perhaps due to the fact that the mechanical arts are inherently more intuitive than the pharmaceutical arts to a factfinder applying common sense judgments

¹⁷³ BURK & LEMLEY, *supra* note 33, at 65.

¹⁷⁴ Geers, *supra* note 126, at 260.

¹⁷⁵ *Id.* at 262, 266.

¹⁷⁶ *Id.* at 262–69 (describing how patentees may rebut industry-specific presumptions with secondary-considerations evidence). Geers contends, for example, that industry praise should be considered particularly persuasive for mechanical arts patents as, “given the lower complexity and uncertainty of the field, laudatory statements by peers are likely to be rare unless a solution is nonobvious.” *Id.* at 262–63.

¹⁷⁷ In each of the pharmaceutical patent cases studied, the invention was upheld as non-obvious, with secondary-considerations evidence supporting the conclusion. In contrast, most of the mechanical arts cases examined found the claimed invention obvious and the proffered secondary-considerations evidence insufficient to rebut a strong *prima facie* case. This insufficiency was frequently due to a lack of a nexus between the secondary-considerations evidence and the claimed invention. See *infra* Appendix (listing cases and reasoning based on secondary-considerations evidence).

about obviousness. Indeed, in the opinions examined, pharmaceutical patents were found obvious far less often than mechanical arts patents.¹⁷⁸ Courts have not heeded the second part of the proposal, however, by allowing post-invention evidence of commercial success, industry praise, and copying (among other secondary considerations) to rebut the presumption of obviousness in the mechanical arts. Instead, the courts have often summarily dismissed such evidence.¹⁷⁹ Relatedly, the stringent requirements for secondary-considerations evidence suggests that it will be difficult for most patentees to rebut a strong presumption against a finding of obviousness in the mechanical arts, particularly given that unexpected-results evidence is invoked much less frequently in the mechanical arts. Given current practice, a proposal that endorses a virtually irrebuttable presumption has the potential to raise the nonobviousness threshold to impossible heights. Ultimately, whether this is a favorable development depends on one's assessment of the need for patents to promote innovation in the mechanical arts.

Evidence suggests that not all members of the Federal Circuit are content with the current trend of disregarding secondary considerations or with this pattern's potential impact on the availability of mechanical arts patents. In *Media Technologies Licensing, LLC v. Upper Deck Co.*,¹⁸⁰ Judge Rader's dissent contended that the court had shortchanged a mechanical arts patentee in giving little weight to secondary-considerations evidence: "[I]gnoring significant objective indicia of non-obviousness, this court substitutes its judgment on patentability for that of a jury. Lurking just beneath the surface of this court's blindness to the underlying facts supporting non-obviousness is a bias against non-technical arts."¹⁸¹ While the disputed patent—which covered a baseball trading card with a portion of a memorabilia item attached—did not concern an advancement in “rocket science or cancer medicine,” investments made by individuals working in non-technical fields should receive “the same protection as any other advances.”¹⁸² Absent attention to secondary-considerations evidence,

¹⁷⁸ See *infra* Appendix (listing cases and their respective evaluations of secondary-considerations evidence and obviousness).

¹⁷⁹ See, e.g., *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007) (affirming the district court's conclusion that substantial secondary considerations were insufficient to overcome a *prima facie* showing of obviousness).

¹⁸⁰ 596 F.3d 1334 (Fed. Cir. 2010).

¹⁸¹ *Id.* at 1339–40 (Rader, J., dissenting).

¹⁸² *Id.* at 1340.

some nonobvious mechanical arts patents may fail to overcome a general presumption of obviousness.¹⁸³

B. Promoting Greater Utilization of Secondary-Considerations Evidence

Both current practice and proposals to improve current practice could benefit from courts conducting a more thorough examination of all proffered secondary-considerations evidence.¹⁸⁴ Although scholars had predicted that secondary-considerations evidence would become more important to litigants and more helpful to courts engaging in the obviousness inquiry post-*KSR*, the courts have largely continued their pre-*KSR* practices, giving little attention to secondary-considerations evidence.¹⁸⁵ Because of the obviousness inquiry's uncertain bounds in the post-*KSR* transition period, there is a need for courts to expressly discuss secondary-considerations evidence. While *KSR* endorsed a flexible, common sense approach to the obviousness analysis, the opinion does not reveal an intention to skew the availability of secondary-considerations evidence in support of the nonobviousness of an invention. The *KSR* Court supported a return to the functional inquiry established in *Graham*, which included the use of secondary-considerations evidence.¹⁸⁶

If the Federal Circuit were to address the secondary considerations introduced by litigants, even in cases where the court considered the evidence insufficient to rebut a prima facie case of obviousness, it would help to clarify the applicability of secondary considerations post-*KSR*. As Professors Michael Abramowicz and John Duffy have noted, *KSR* has presented the opportunity to create a more coherent and “pragmatic obviousness doctrine that yields predictable answers.”¹⁸⁷ According to the *KSR* Court, secondary considerations are part of the obviousness inquiry where “instructive.”¹⁸⁸ By evaluating secondary-considerations evidence, the Federal Circuit can provide guidance to factfinders as to what forms of secondary-

¹⁸³ In addition, it is unclear how the presumption of patent validity that attaches to issued patents would interact with any proposed factual presumption of obviousness. See 35 U.S.C. § 282 (2006) (“A patent shall be presumed valid.”).

¹⁸⁴ See Abramowicz & Duffy, *supra* note 14, at 1656 (“[C]ourts ideally should offer further guidance on the secondary considerations.”).

¹⁸⁵ See *supra* Part II (discussing pre-*KSR* and current use of secondary-considerations evidence).

¹⁸⁶ See *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007) (“*Graham* set forth a broad inquiry and invited courts, where appropriate, to look at any secondary considerations that would prove instructive.”).

¹⁸⁷ Abramowicz & Duffy, *supra* note 14, at 1596.

¹⁸⁸ *KSR*, 550 U.S. at 415.

considerations evidence are “instructive” within the context of specific cases. Even though the obviousness inquiry involves factual issues, it remains a question of law.¹⁸⁹ As such, the Federal Circuit has the authority to review such determinations *de novo*,¹⁹⁰ including conclusions based on secondary-considerations evidence. If the Federal Circuit continues to summarily dismiss secondary-considerations evidence, the doctrine surrounding the obviousness inquiry will lose a source of potential clarity, to the detriment of patent litigants. Accordingly, litigants should continue to offer secondary-considerations evidence when available in order to increase the chances that courts will include such considerations in the obviousness inquiry.

Regardless of the post-*KSR* trend against giving weight to secondary considerations in the obviousness inquiry, Federal Circuit precedent still requires district courts and the PTO to take secondary considerations into account. Thus, the foundation for expanding the role of secondary considerations is already in place. In *Süid-Chemie, Inc. v. Multisorb Technologies, Inc.*, the Federal Circuit vacated the district court’s summary judgment of obviousness.¹⁹¹ In contrast to the district court’s conclusion, the Federal Circuit found that the prior art did not teach all of the claim limitations at issue.¹⁹² In other words, the prior art did not completely cover the claimed invention. The Federal Circuit noted that the district court failed to explicitly address secondary-considerations evidence of unexpected results, copying, and commercial success.¹⁹³ In remanding based on its alternative reading of the prior art, the Federal Circuit instructed the district court to carefully weigh any evidence of secondary considerations of nonobviousness that might arise on remand.¹⁹⁴ Similarly, the Federal Circuit has vacated and remanded PTO Board decisions for failing to consider secondary-considerations evidence presented as rebuttal evidence following the rejection of a patent application.¹⁹⁵ The Federal Circuit’s vigilance in requiring formal consideration of secondary-considerations evidence suggests that the groundwork for a more

¹⁸⁹ *Meurer & Strandburg*, *supra* note 19, at 565–67.

¹⁹⁰ *Media Techs. Licensing, LLC v. Upper Deck Co.*, 596 F.3d 1334, 1337 (Fed. Cir. 2010) (“Whether an invention would have been obvious at the time the invention was made is a question of law, which we review *de novo* . . .”).

¹⁹¹ 554 F.3d 1001, 1004 (Fed. Cir. 2009).

¹⁹² *Id.* at 1009.

¹⁹³ *Id.* at 1008.

¹⁹⁴ *Id.*

¹⁹⁵ *See In re Sullivan*, 498 F.3d 1345, 1350–53 (Fed. Cir. 2007) (vacating and remanding the Board of Patent Appeals decision for failing to consider secondary-considerations evidence against a *prima facie* case of obviousness).

robust obviousness inquiry already exists. The Federal Circuit's next step should be to expand the evaluation of secondary considerations from a formal requirement to a robust tool.

CONCLUSION

The concern after *KSR* is that courts engaging in a more flexible obviousness inquiry will be more likely to arrive at a prima facie case of obviousness and, as a result, be less likely to fully account for secondary considerations. A review of post-*KSR* cases suggests that this prediction has been borne out in practice (with the possible exception of pharmaceutical patents). Stringent relevancy requirements for secondary considerations and cursory review of relevant secondary-considerations evidence limit the role of such evidence in most obviousness determinations. A more rigorous review of secondary-considerations evidence would reverse this trend and help clarify the instructive role of secondary considerations for decision makers evaluating the obviousness of an invention.

APPENDIX: ANALYSIS OF SECONDARY-CONSIDERATIONS EVIDENCE
IN SELECTED CASES

<i>Case</i>	<i>Citation</i>	<i>Prior decision on obviousness (of district court unless noted)</i>	<i>Federal Circuit decision on obviousness</i>	<i>Secondary considerations</i> ¹⁹⁶	<i>Technology category</i> ¹⁹⁷
Süd-Chemie, Inc. v. Multisorb Technologies, Inc.	554 F.3d 1001 (Fed. Cir. 2009)	Obvious	Vacated and remanded	Failure to consider secondary-considerations evidence	Chemical (gas)
Therasense, Inc. v. Becton, Dickinson & Co.	593 F.3d 1289 (Fed. Cir. 2010)	Obvious	Affirmed	Lacking nexus	Chemical (miscellaneous)
Fresenius USA, Inc. v. Baxter International, Inc.	582 F.3d 1288 (Fed. Cir. 2009)	Obvious	Affirmed	Deferential review of jury decision; implicit rejection of secondary considerations as insufficient	Chemical (miscellaneous)
<i>In re Mettke</i>	570 F.3d 1356 (Fed. Cir. 2009)	Obvious (PTO Board)	Affirmed	Insufficient; lacking nexus	Computers & Communications (communications)
Power-One, Inc. v. Artesyn Technologies, Inc.	599 F.3d 1343 (Fed. Cir. 2010)	Nonobvious	Affirmed	Supported finding of nonobviousness; nexus demonstrated	Computers & Communications (computer hardware & software)
i4i Ltd. Partnership v. Microsoft Corp.	589 F.3d 1246 (Fed. Cir. 2009)	Nonobvious; jury found the patent not invalid	Affirmed	Deferential review of jury decision; implicit acceptance of secondary considerations	Computers & Communications (computer hardware & software)
Perfect Web Technologies, Inc. v. InfoUSA, Inc.	587 F.3d 1324 (Fed. Cir. 2009)	Obvious	Affirmed	Insufficient	Computers & Communications (computer hardware & software)
Asyst Technologies, Inc. v. Emtrak, Inc.	544 F.3d 1310 (Fed. Cir. 2008)	Obvious	Affirmed	Insufficient; lacking nexus	Computers & Communications (computer hardware & software)

¹⁹⁶ Discussion of unexpected results is summarized within this category, even if such analysis was not grouped with the analysis of secondary considerations proper. *See supra* Part II.C.3 (discussing the shifting use of unexpected results as a secondary consideration). Cases containing consideration of unexpected results are specifically noted.

¹⁹⁷ Technology category and subcategory classifications are based upon the technology categorization system for patent classes developed by the National Bureau of Economic Research Patent Data Project. *See* Bronwyn H. Hall, Adam B. Jaffe & Manuel Trajtenberg, *The NBER Patent Citations Data File: Lessons, Insights and Methodological Tools* 12–13, 41–42 (Nat'l Bureau of Econ. Research, Working Paper No. 8498, 2001) (describing the categories).

<i>Case</i>	<i>Citation</i>	<i>Prior decision on obviousness (of district court unless noted)</i>	<i>Federal Circuit decision on obviousness</i>	<i>Secondary considerations</i>	<i>Technology category</i>
Muniauction, Inc. v. Thomson Corp.	532 F.3d 1318 (Fed. Cir. 2008)	Nonobvious	Obvious	Insufficient; lacking nexus	Computers & Communications (computer hardware & software)
DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.	567 F.3d 1314 (Fed. Cir. 2009)	Nonobvious	Affirmed	Supported finding of nonobviousness	Drugs & Medical
Boston Scientific Scimed, Inc. v. Cordis Corp.	554 F.3d 982 (Fed. Cir. 2009)	Nonobvious	Obvious	Insufficient	Drugs & Medical
<i>In re Sullivan</i>	498 F.3d 1345 (Fed. Cir. 2007)	Obvious (PTO Board)	Vacated and remanded	Failure to consider secondary-considerations evidence	Drugs & Medical (biotechnology)
PharmaStem Therapeutics, Inc. v. Viacell, Inc.	491 F.3d 1342 (Fed. Cir. 2007)	Nonobvious	Obvious	Lacking nexus	Drugs & Medical (biotechnology)
Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.	566 F.3d 989 (Fed. Cir. 2009)	Nonobvious	Affirmed	Supported finding of nonobviousness; unexpected results	Drugs & Medical (drugs)
Sanofi-Synthelabo v. Apotex, Inc.	550 F.3d 1075 (Fed. Cir. 2008)	Nonobvious	Affirmed	Supported finding of nonobviousness; unexpected results	Drugs & Medical (drugs)
<i>In re DBC</i>	545 F.3d 1373 (Fed. Cir. 2008)	Obvious (PTO Board)	Affirmed	Insufficient; lacking nexus	Drugs & Medical (drugs)
Abbott Laboratories v. Sandoz, Inc.	544 F.3d 1341 (Fed. Cir. 2008)	Nonobvious	Affirmed	Supported finding of nonobviousness; unexpected results	Drugs & Medical (drugs)
Eisai Co. v. Dr. Reddy's Laboratories, Ltd.	533 F.3d 1353 (Fed. Cir. 2008)	Nonobvious	Affirmed	Supported finding of nonobviousness; unexpected results	Drugs & Medical (drugs)
Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.	520 F.3d 1358 (Fed. Cir. 2008)	Nonobvious	Affirmed	Supported finding of nonobviousness; unexpected results	Drugs & Medical (drugs)
Forest Laboratories, Inc. v. Ivax Pharmaceuticals, Inc.	501 F.3d 1263 (Fed. Cir. 2007)	Nonobvious	Affirmed	Supported finding of nonobviousness; unexpected results	Drugs & Medical (drugs)
Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.	492 F.3d 1350 (Fed. Cir. 2007)	Nonobvious	Affirmed	Supported finding of nonobviousness; unexpected results	Drugs & Medical (drugs)

<i>Case</i>	<i>Citation</i>	<i>Prior decision on obviousness (of district court unless noted)</i>	<i>Federal Circuit decision on obviousness</i>	<i>Secondary considerations</i>	<i>Technology category</i>
Pressure Products Medical Supplies, Inc. v. Greatbatch Ltd.	599 F.3d 1308 (Fed. Cir. 2010)	Nonobvious	Affirmed	Supported jury finding of nonobviousness	Drugs & Medical (surgery & medical instruments)
Commonwealth Scientific & Industrial Research Organisation v. Buffalo Technology (USA), Inc.	542 F.3d 1363 (Fed. Cir. 2008)	Nonobvious; summary judgment granted	Vacated and remanded	Insufficient	Electrical & Electronics (power systems)
Agrizap, Inc. v. Woodstream Corp.	520 F.3d 1337 (Fed. Cir. 2008)	Nonobvious	Obvious	Insufficient	Electrical & Electronic (power systems)
Sundance, Inc. v. DeMonte Fabricating Ltd.	550 F.3d 1356 (Fed. Cir. 2008)	Nonobvious; judgment as a matter of law	Obvious	Insufficient	Mechanical (transportation)
Crocs, Inc. v. International Trade Commission	598 F.3d 1294 (Fed. Cir. 2010)	Obvious (International Trade Commission)	Nonobvious	Nexus demonstrated	Other (apparel & textile)
Rothman v. Target Corp.	556 F.3d 1310 (Fed. Cir. 2009)	Obvious	Affirmed	Deferential review of jury decision; insufficient	Other (apparel & textile)
Ball Aerosol & Specialty Container, Inc. v. Ltd. Brands, Inc.	555 F.3d 984 (Fed. Cir. 2009)	Nonobvious	Obvious	Insufficient	Other (heating)
Media Technologies Licensing, LLC v. Upper Deck Co.	596 F.3d 1334 (Fed. Cir. 2010)	Obvious	Affirmed	Insufficient; lacking nexus	Other (miscellaneous)
Erico International Corp. v. Vutec Corp.	516 F.3d 1350 (Fed. Cir. 2008)	Nonobvious; preliminary injunction granted	Vacated and remanded	Insufficient	Other (miscellaneous)
Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.	485 F.3d 1157 (Fed. Cir. 2007)	Obvious	Affirmed	Insufficient	Other (miscellaneous)

