

Implementing a “Predictable” Obviousness Standard Post-*KSR**

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Introduction

KSR was the Supreme Court’s first substantive pronouncement about the law of obviousness in over three decades, and was issued after years of global criticism that the U.S. standards of patentability were far too low. It is not surprising that practitioners, judges, academics, stakeholders, and even the USPTO awaited the Court’s guidance about a framework for analyzing legal obviousness in a manner that was consistent both with its precedent as well as the intuition inherent in a notionally skilled artisan. Surprisingly, *KSR* did not dispense with the Federal Circuit test for analyzing obviousness based on a combination of teachings, but rather, admonished against its use in rigid and formulaic ways. The most dramatic effects of *KSR* both in the ensuing months since its issuance and to date are seen at the USPTO, rather than in courts adjudicating patent disputes. Statistics from multiple technology centers demonstrate that BPAI affirmances rose markedly in the months immediately following *KSR* and have remained at those post-*KSR* levels. A review of court decisions applying *KSR* however, demonstrates no significant difference in the numbers of pre- and post-*KSR* adjudications of invalidity based on obviousness. Although the reasons why are not entirely clear, it is clear that (1) demonstrating nonobviousness of claims in predictable arts is more difficult post-*KSR*; and (2) the predictability of a claimed combination post-*KSR* is more important than the source of any suggestion for combining prior art teachings.

The Rule of *KSR*

Prior to the *KSR* decision, the U.S. Court of Appeals for the Federal Circuit had developed a framework for assessing the obviousness of claimed subject matter by considering whether there was some "teaching, suggestion, or motivation" (“TSM”) to combine prior art disclosures so as to render the claimed subject matter obvious.¹ Decisions long prior to *KSR* held that the teaching, suggestion or motivation to combine references had to be explicit in the references themselves, although decisions issued just prior to the Supreme Court’s decision in *KSR* softened this strict requirement.² Nevertheless, in *KSR*³, the U.S. Supreme Court held that

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¹ *Al-Site Corp. v. VSI Int’l, Inc.*, 174 F.3d 1308, 1323-1324 (Fed. Cir. 1999).

² In a trilogy of cases that preceded the *KSR* decision, the Federal Circuit held invalid as obvious patents based on *nonexpress* teachings to combine prior art disclosures. See e.g., *Dystar Textilfarben*

the Federal Circuit’s TSM test was applied much too restrictively, resulting in an approach to evaluating obviousness that did not embrace the expansive and flexible approaches established in its earlier cases.⁴ The Supreme Court made clear that “the combination of familiar elements according to known methods was likely to be obvious when it did no more than yield predictable results,⁵” citing decisions dating back at least forty years.⁶ In reaching its decision, the court hastened to provide guidance about how the question of obviousness should be evaluated.

First, a focus on the particular motivation of the patent inventors looking to solve a particular problem was too narrow; rather, the analysis must look more broadly at the recognition of a known problem for which there was an obvious solution encompassed by the patent’s claims. The Court made clear that *any* need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.

Second, persons of ordinary skill attempting to solve a problem are not led only to those elements of prior art designed to solve the same problem. Because familiar items may have obvious uses beyond their primary purposes, persons of ordinary skill will -- in many cases -- be able to fit the teachings of multiple patents together “like pieces of a puzzle.”⁷

Third, a finding of obviousness can be based on proof that a particular combination of elements would have been *obvious to try*. For example, when there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the expected result, it is likely the product of ordinary skill and common sense. In such an instance, the fact that a combination was obvious to try might show that it was legally obvious.⁸

GMBH & Co. Deutschland KG v. C.H. Patrick Co., 464 F.3d 1356, 1371 (Fed. Cir. 2006); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1289 (Fed. Cir. 2006); *In re Kahn*, 441 F.3d 977, 990 (Fed. Cir. 2006).

³ *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007)

⁴ *Id.* at 415-17.

⁵ *Id.* at 416.

⁶ *United States v. Adams*, 383 U.S. 39 (1966); *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57 (1969); *Sakraida v. AG Pro, Inc.*, 425 U.S. 273 (1976).

⁷ *KSR*, 550 U.S. at 420.

⁸ *Id.* at 421.

Finally, the need to protect against hindsight bias and *ex post* reasoning can not operate to deprive a fact finder of recourse to common sense. Acknowledging that some of the (then) more recent Federal Circuit cases recognized the availability of common knowledge and common sense in the obviousness analysis, the approach used by the Federal Circuit in *KSR* was too rigid and inflexible.⁹

The Court's opinion uses the term "predictable" five times in stating the principles underlying an obviousness inquiry -- which asks whether the patented improvement is more than the *predictable* use of prior art elements according to their established functions. The predictability of a claimed combination is therefore more central to the obviousness inquiry than the source of the suggestion to make the combination. The Court emphasized its own precedent whose flexibility permitted the use of common sense and general knowledge, the consideration of teachings beyond the particular field of the inventor's endeavor in developing the claimed invention, and the uses of familiar items beyond their primary purposes. By expanding the scope of available prior art, the sources of the suggestions for combination, and permitting evidence of common sense and general knowledge as a background against which the prior art and claimed subject matter are viewed, the Court intended that a more holistic obviousness analysis should replace the more surgical approach resulting from a rigid application of the TSM test.

The *KSR* "Bounce"

The patent community's response to *KSR* within the first several months was remarkable. The USPTO Board of Patent Appeals and Interferences ("BPAI") applied *KSR* and quickly published three precedential opinions affirming examiners' obviousness rejections in the biotechnological, electrical and mechanical arts.

In *Smith*,¹⁰ the Board upheld the rejection of a simple combination comprising an improved pocket to hold a CD inside the cover of a book because the functions of the combination were predictable, and not "uniquely challenging or difficult for one of ordinary skill in the art."¹¹

In *Catan*,¹² the Board affirmed the final rejection of claims to a consumer electronic device incorporating bio-authentication means, where each of the elements were found in one prior art reference, a second reference disclosed the bioauthentication devices in a related context, and a third disclosed that they could be substituted for each other.

⁹ *Id.* at 421-22.

¹⁰ *Ex Parte Smith*, 83 U.S.P.Q. 2d 1509 (Bd. Pat. App. & Interf., 2007).

¹¹ *Id.* at 15.

¹² *Ex Parte Catan*, 83 U.S.P.Q. 2d 1569 (Bd. Pat. App. & Interf., 2007).

Finally, in *Kubin*,¹³ the Board upheld the rejection of claims to a gene that encoded the NK Cell Activation Inducing Ligand ("NAIL") protein involved in regulating the immune system. According to the Board, it would have been *obvious to try* isolation of NAIL cDNA based on knowledge of an analogous protein in mice combined with the limited number of isolation methodologies available for the protein. These decisions demonstrated the importance of *KSR*'s impact on patent procurement, because the Board infrequently issues three separate precedential opinions applying the same Supreme Court case with such calculated urgency.

Within several months of the *Smith*, *Catan* and *Kubin* cases, the USPTO issued new examination guidelines that directed examiners to consider at least seven exemplary rationales that may support a conclusion of obviousness, including:

- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable results;
- (C) Use of known technique to improve similar devices (methods, or products) in the same way;
- (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (E) "Obvious to try" - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
- (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.¹⁴

The effect of *KSR* and the new examination guidelines became manifest in USPTO dispositions almost immediately. In 2006, the year prior to the *KSR* decision, PTO Board of Appeals affirmed in whole or in part the final rejections of patent examiners 56% of the time and

¹³ *Ex Parte Kubin*, 83 U.S.P.Q. 2d 1410 (Bd. Pat. App. & Interf., 2007).

¹⁴ USPTO guidelines for post-*KSR* consideration of obviousness (October 10, 2007) MPEP §2141 (2007).

reversed 35% of the time.¹⁵ In 2007, the affirmance rate jumped to 69% and the reversal rate dropped to 25%,¹⁶ a statistic that carried through in 2008,¹⁷ and is unchanged in 2009.¹⁸ Admittedly, other factors likely contributed to the increase in affirmances (such as pre-appeal conferences), but the co-incidence of the increased affirmance rate with the issuance of the *KSR* case cannot be purely happenstance. For example, in the first four months following *KSR*, affirmances in technology center 1600 (biotechnology) rose to almost 80%.¹⁹ Similarly, affirmances in technology center 3700 (mechanical engineering) rose from less than 50% to over 60% in the same time period.²⁰

KSR had an initial effect on district courts as well. Courts interpreting *KSR* shortly after it issued denied preliminary injunctions to pharmaceutical patent holders who failed to prove a likelihood of successfully establishing infringement by generic companies who launched products at risk.²¹ The generic companies' challenges were based on structural obviousness in view of a "lead compound" in combination with additional reference(s) that showed additional chemical modifications necessary to render the claimed subject matter obvious.²² In other cases, courts applying *KSR* granted summary judgment motions of invalidity based on obviousness,²³ upheld jury verdicts of obviousness in post-trial motions,²⁴ and granted Motions for Judgment of

¹⁵ Statistics for Board of Patent Appeals and Interferences ("BPAP") dispositions are found at <http://www.uspto.gov/web/offices/dcom/bpai/docs/receipts/fy2006.htm>. These statistics include appeals based on rejections under any provision, including those under 35 U.S.C. §103.

¹⁶ See <http://www.uspto.gov/web/offices/dcom/bpai/docs/receipts/fy2007.htm>, last visited July 21, 2009.

¹⁷ See <http://www.uspto.gov/web/offices/dcom/bpai/docs/receipts/fy2008.htm>, last visited July 21, 2009.

¹⁸ See <http://www.uspto.gov/web/offices/dcom/bpai/docs/receipts/fy2009.htm>, last visited July 23, 2009.

¹⁹ Bruce A. Stoner, Jr., "Ten Years of Board Stats: Do four months of results under *KSR* suggest anything?", APLF Annual Meeting, The Benjamin N. Cardozo School of Law, New York, N.Y., September 26, 2007 (presentation).

²⁰ *Id.*

²¹ *Altana Pharma AG v. Teva Pharms. USA, Inc.*, 532 F. Supp. 2d 666 (D.N.J. 2007); *Novartis Pharms. Corp. v. Teva Pharms. USA, Inc.*, 2007 U.S. Dist. LEXIS 65792 (D.N.J. Sept. 6, 2007).

²² *Altana* at 676-77; *Novartis* at *14-20.

²³ *Tokyo Keiso Co. v. SMC Corp.*, 533 F. Supp. 2d 1047 (C.D. Ca. 2007); *Crowd in a Box Co. v. Inflatable Crowd Co.*, 85 U.S.P.Q.2D 1510 (C.D. Ca. 2007); *PBI Performance Prods. v. NorFab Corp.*, 514 F. Supp. 2d 732 (E.D. Pa. 2007); *Craig v. Foldfast, Inc.*, 504 F. Supp. 2d 1313 (S.D. Fl. 2007);

²⁴ *TradeCard, Inc. v. SI Corp.*, 509 F. Supp. 2d 304 (S.D.N.Y. 2007).

invalidity based on obviousness notwithstanding a jury verdict to the contrary.²⁵ But over the longer term since its issuance, KSR has not significantly affected outcomes in litigation when obviousness was an asserted defense.

Authors noted that as of April, 2008, 16 of 32 district court decisions applying KSR had found patents obvious and that 11 of 16 federal circuit cases found patents obvious.²⁶ A more recent survey concluded that the federal circuit found patents obvious about half (51%) of the time and that it affirmed district court determinations of obviousness a clear majority of the time (about 67%).²⁷ Interestingly, these statistics do not appear dramatically different than those reported by Petherbridge and Wagner²⁸ in an empirical study of obviousness cases in the U.S. that spanned the fifteen year period from 1990-2005. Petherbridge et al. report an affirmance rate of 65% and an overall rate of the federal circuit finding obviousness of 57.8%.²⁹ Assuming a more studied comparison does not show a dramatic difference pre- and post-KSR, the most demonstrable effect of KSR has been seen in the USPTO, not in courts deciding *inter partes* matters.

Predictable vs. Unpredictable Arts

Given the Supreme Court's focus on the predictability of a claimed combination, it is hardly surprising that the range of KSR's effects are most acutely seen at either end of the predictability spectrum. Technologies such as pharmaceuticals and biotechnology traditionally viewed as unpredictable have suffered less under the rule of KSR as have technologies traditionally viewed as predictable, whether at the PTO or in the courts.

²⁵ *Asyst Techs., Inc. v. Empak, Inc.*, 2007 U.S. Dist. LEXIS 59100 (N.D. Ca. August 3, 2007), *affd.*, 544 F.3d 1310 (Fed. Cir. 2008).

²⁶ See [http://www.aipla.org/Content/Microsites152/IP_Practice_in_Japan/Committee_Meetings/2008-04_Japan_Trip/Presentations13/JPAA-KSR-Litigation-\(John-Johnson\).ppt](http://www.aipla.org/Content/Microsites152/IP_Practice_in_Japan/Committee_Meetings/2008-04_Japan_Trip/Presentations13/JPAA-KSR-Litigation-(John-Johnson).ppt), last visited July 21, 2009.

²⁷ See Emir Simic, *The TSM Test is Dead! Long Live the TSM Test! Aftermath of KSR, What Was All the Fuss About*, 37 AIPLA Q.J., No. 2, 227 (2009). The author studied 33 federal circuit decisions post-KSR where the court reviewed an obviousness determination of a district court. Through March 25, 2009, the authors report that the federal circuit invalidated patents for obviousness in 17 of 33 cases (about 51%) and affirmed obviousness determinations in 22 of 33 cases (about 67%). *Id.* at 249-51.

²⁸ Lee Petherbridge & R.Polk Wagner, *The Federal Circuit and Patentability: An Empirical Assessment of the Law of Obviousness*, 85 TEX. L. REV. 2051 (2007).

²⁹ *Id.* at 2087-90.

For example in *Takeda*³⁰ (the first pharmaceutical obviousness case decided by the Federal Circuit post-*KSR*), the court considered whether genus and species claims covering a compound called pioglitazone were invalid as obvious based on prior art references showing structurally similar compounds in combination with references showing the chemical modifications necessary to arrive at the claimed compound. The Federal Circuit began by stating that nothing in *KSR* changed the requirement to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish *prima facie* obviousness of a new claimed compound.³¹

Although the parties agreed that “compound b” was the closest prior art compound, the district court found that one of ordinary skill in the art would not have selected compound b as the lead compound based on other teachings about its toxicity and activity.³² Rather, the district court found and the Federal Circuit affirmed, the identification of three more structurally dissimilar compounds as the starting point based on their antidiabetic activity.³³ The court rejected Alphapharm’s post-*KSR* “obvious to try” argument because (1) the prior art disclosed a broad selection of compounds any one of which could have been selected as a lead compound for further investigation; and (2) compound b exhibited negative properties that would have directed one of ordinary skill in the art away from that compound.³⁴ The Court’s decision carefully considered *KSR* to require that the prior art narrow the scope of possible solutions to a problem (chemical compounds) before any one of them would be “obvious to try.” In that regard, *Takeda* is indeed consistent with *KSR*’s focus on predictability as a touchstone of obviousness.

Similarly in *Eisai*,³⁵ the Federal Circuit affirmed the nonobviousness of claims to an anti-ulcer drug called rabeprazole based on prior art references disclosing structurally related compounds lansoprazole and omeprazole, also used as anti-ulcer drugs. Defendants argued that lansoprazole and omeprazole were lead compounds based both on structural similarity and activity, but the Federal Circuit credited the district court’s analysis of the distinction between lansoprazole’s anti-ulcer action and the claimed compound’s gastric acid inhibition action.³⁶

³⁰ *Takeda Chem. Indus. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007).

³¹ *Id.* at 1357.

³² *Id.*

³³ *Id.* at 1358-59.

³⁴ *Id.* at 1359.

³⁵ *Eisai Co. v. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353 (Fed. Cir. 2008), reh’g denied, 2008 U.S. App. LEXIS 25264 (Fed. Cir., Sept. 16, 2008).

³⁶ The Court stated “lansoprazole's candidacy as a starting point to develop new anti-ulcer compounds versus new gastric acid inhibitors does not resolve the lead compound analysis, at least not in the absence of any contrary indications.” *Id.* at 1358.

Citing *Takeda*, the Court reinforced the assumptions *inherent* in *KSR* that (1) there exists a starting reference point in the art, prior to the time of invention, from which a skilled artisan might identify a problem and pursue potential solutions; (2) the record up to the time of invention would give some reasons, available within the knowledge of one of skill in the art, to make particular modifications to achieve the claimed compound; and (3) for narrowing the prior art universe to a "finite number of identified, predictable solutions."³⁷ Tellingly, the Court stated that "[t]o the extent an art is unpredictable, as the chemical arts often are, *KSR*'s focus on these "identified, predictable solutions" may present a difficult hurdle because potential solutions are less likely to be genuinely predictable."³⁸

In contrast, post-*KSR* cases involving claims to subject matter in more "predictable" fields of endeavor have resulted in findings of obviousness with seemingly greater frequency. For example, in *Leapfrog*,³⁹ the court affirmed the obviousness of claims directed to a toy made up of a housing, a sound production device, at least one depiction of a sequence of letters, and a reader. Finding that the application of modern electronics to an older prior art electro-mechanical toy would have been obvious, the court stated "[a]ccommodating a prior art mechanical device that accomplishes that goal to modern electronics would have been reasonably obvious to one of ordinary skill in designing children's learning devices."⁴⁰ The court specifically cited to the common sense of those skilled in the art (as directed by *KSR*) in determining the claims were obvious.⁴¹

Similarly, in *Erico*,⁴² the Federal Circuit reversed the grant of a preliminary injunction, finding that a prior art reference coupled with certain industry standards and testimonial evidence posed a serious challenge to the validity of a claim directed to a method of supporting communication cables using claimed J-hook fasteners.

To the extent that the obviousness of patent claims in post-*KSR* cases is directly related to the predictability of the combinations claimed therein, such a result was foreseen by the *KSR* Court, which stated:

Following these principles may be more difficult in other cases than it is here because the claimed subject matter may involve more than the simple substitution of one known element for

³⁷ *Id.* at 1359.

³⁸ *Id.*

³⁹ *Leapfrog Enters. v. Fisher-Price, Inc.*, 485 F.3d 11 (Fed. Cir. 2007).

⁴⁰ *Id.* at 1161.

⁴¹ *Id.*

⁴² *Erico Int'l Corp. v. Vutec Corp.*, 516 F.3d 1350 (Fed. Cir. 2008).

another or the mere application of a known technique to a piece of prior art ready for the improvement.⁴³

KSR makes clear that predictability is the lens through which obviousness considerations will be viewed, and that applicants or litigants seeking to establish or confirm the patentability of claims under Section 103 will have to demonstrate claimed combinations yield more than predictable results.⁴⁴ And while this may not represent a sea change in unpredictable arts such as pharmaceuticals or biotechnology, it will present increased challenges in arts where the predictability of a combination can be established based on the known functions of individual elements.

Is predictability a *new* standard? None of the *Adams*⁴⁵, *Anderson's*⁴⁶ or *Sakraida*⁴⁷ cases relied upon by the Supreme Court in *KSR* even mention the predictability of a claimed combination or method as a criterion for obviousness. Nor do the *Graham*⁴⁸ or *Great Atlantic & Pacific Tea Co.*⁴⁹ cases describe a standard for obviousness that is based on predictability. The question may be one of semantics, since *unexpected* properties or results have long been recognized as means for rebutting a *prima facie* showing of obviousness, and the Supreme Court in *Adams* concluded the claimed battery was nonobvious because “the operating characteristics of the Adams battery have been shown to have been *unexpected*.”⁵⁰

If, however, ‘predictability’ and ‘expectedness’ are not merely alternative formulations of the same concept, the question may be more than semantic. For example, assume that a new combination of old elements may have more than one predictable result. If the statistical probability of obtaining one of those results is extremely low, is it *expected* or *unexpected* if it is actually achieved? If it is *expected* simply because it is predictable (even with a very low probability) the threshold for proving unexpected results may now be unsurmountable. If it is *unexpected* even though it is *predictable*, an inherent and irreconcilable conflict exists between a threshold showing of obviousness and an effective rebuttal to that showing, since they will be based on the same facts -- a possible but improbable result. Further development of caselaw will

⁴³ *KSR* at 1740.

⁴⁴ *Id.* at 1739-40.

⁴⁵ *United States v. Adams*, 383 U.S. 39 (1966).

⁴⁶ *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57 (1969).

⁴⁷ *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273 (1976).

⁴⁸ *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1 (1966).

⁴⁹ *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147 (1950).

⁵⁰ *Adams*, 383 U.S. at 51 (emphasis added).

tell whether predictability is an old concept or a newly-calved standard for evaluating obviousness.

Looking Forward in a Post-KSR World

Is *KSR* much ado about nothing? Petherbridge and Wagner's empirical data show that the federal circuit found patents invalid for obviousness 58% of the time for the 15 years preceding *KSR*. The more recent Simic study of 33 post-*KSR* federal circuit obviousness cases reports that the court has found patents obvious 51% of the time, and has affirmed district courts' findings of obviousness 67% of the time.⁵¹ (These statistics do not include appeals of obviousness determinations by the BPAI, whether from *ex parte* matters involving applications or *inter partes* matters involving reexaminations or interferences).

What is clear is that when combining prior art post-*KSR*, the TSM test is still useful to show obviousness, but legitimate reasons to combine references may go beyond express or implied teachings of the prior art.⁵² Design need, market pressure and common sense may all be considered. "Obvious to try" may suffice to show legal obviousness, but only where there are a *finite* number of identified, *predictable* solutions.

At the district court level, summary judgment grants of invalidity based on obviousness are now more common, and they are considered appropriate by the Supreme Court.⁵³ Reasons for combination of a prior art reference with another reference or with knowledge available to a person of ordinary skill can be found on virtually any basis. As a result, decisions finding patents nonobvious have found elements missing from the prior art, unexpected results, or direct evidence of a teaching away.

Consistent with the *KSR* mandate, the Federal Circuit has also established a lower threshold for establishing the motivation to combine prior art disclosures. The court also accords weight to rebuttal evidence, *e.g.*, secondary considerations, unexpected results and prior art that teaches away from the claimed combination.

Going forward, the nonobviousness requirement of Section 103 will continue to pose additional hurdles to patentability after *KSR*, particularly in predictable arts or those in which

⁵¹ See n. 27, supra.

⁵² *TGIP, Inc. v. AT&T Corp.*, 527 F. Supp. 2d 561, 580-81 (Fed. Cir. 2007).

⁵³ In *KSR*, the Court confirmed the role of summary judgment in obviousness determinations by stating that "[t]o the extent the court understood the *Graham* approach to exclude the possibility of summary judgment when an expert provides a conclusory affidavit addressing the question of obviousness, it misunderstood the role expert testimony plays in the analysis. . . . Where, as here, the content of the prior art, the scope of the patent claim, and the level of ordinary skill in the art are not in material dispute, and the obviousness of the claim is apparent in light of these factors, summary judgment is appropriate." *KSR*, 550 U.S. at 426-27.

elements of a claimed combination perform no more than their ordinary function. Notwithstanding, statistics show that on average, *KSR* has not effected a sea change in the outcomes of the Federal Circuit's obviousness cases, and it is unlikely to do so at this point. The Federal Circuit will continue to analyze issues of obviousness much as it did in *Dystar*, *Khan* and *Alza*, under a moderated TSM approach that flexibly allows consideration of real-world factors known or available to a person of skill in the art. Regardless of the source of any suggestion to combine prior art teachings or the tenuousness of the suggestion itself, it is the *predictability* of the claimed combination that will be determinative in establishing patentability.