

KSR-Induced PTO Obviousness Practice Changes*

Harold C. Wegner**

I. OVERVIEW

*KSR*¹ represents the most important Supreme Court obviousness case in the more than forty years. The changes brought about by *KSR* have been fundamental and are still being felt.

As the Court's first major revisit to the fundamental question of obviousness since 1966, it necessarily has a major impact on practice as the what is likely to be the only major decision interpreting obviousness for quite some time. *See* § II, *Successive Shock Waves at the Court and the PTO*. Changes are coming in two waves. First, the Federal Circuit itself restructured the law of obviousness more than a year ago in reaction to the filing of the *certiorari* petition in 2005 so that the major course correction needed by *KSR* has *already* been accomplished. Thus, it may not have been incorrect to say that, *measured by the state of the law at the time of the decision itself*, *KSR* brought about no "great change" and that the first post-*KSR* opinion "did not require one iota of change" from the draft finished before *KSR* was decided. *See* § II-A, *The 2006 Change in Federal Circuit practice*. During the more than two year pendency of the Supreme Court proceedings in *KSR*, the U.S. Patent and Trademark Office (PTO) has done little to adapt its policies but instead has prudently waited to see what the Supreme Court would say. Only now are the changes at the PTO starting to emerge. *See* § II-B, *Evolving Changes at the PTO*.

While there has been a handful of Supreme Court obviousness cases over the past forty years, *KSR* is the first fundamental, comprehensive Supreme Court treatment of the standard of obviousness in this period. *See* § III, *The KSR Redraft*

* *KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007)(Kennedy, J.). This paper represents the personal views of the writer and does not necessarily reflect the views of any colleague, organization or client thereof.

** Former Director of the Intellectual Property Law Program and Professor of Law, George Washington University Law School. Partner, Foley & Lardner LLP. [hwegner@foley.com]

¹*Supra* p. 1, n.*.

of Graham Obviousness Standards. Already, there are clear changes in practice that must be anticipated in drafting and procurement of patents at the PTO:

First, a greater emphasis must be placed on establishing unexpected or nonobvious results for a claimed combination or product versus the prior art. *See § III-A, Unpredictable Results to Establish Nonobviousness.* Second, the Court has restated the law of obviousness in subtle shadings and emphasis. This requires strategic reconsideration of how to approach the issue of obviousness at the PTO, including “design incentives” and “market forces”; “improvements” in similar devices; and special considerations in areas of complex technology. *See § III-B, Restated Law of Combination Invention Obviousness.*

The burden placed on the Office to provide an explicit evidentiary framework for an obviousness rejection is a plus for patent applicants. *See § IV, An Explicit Evidentiary Framework.* The Examiner bears the burden of providing an “explicit” analysis. *See § IV-A, An “Explicit” Analysis.* Yet, this does not mean that express teachings for every missing piece must be found. *See § IV-B, Filling in the Blanks with Art-Skilled Knowledge.*

Prior to *KSR* there was a relatively rigid condition that to establish obviousness of a combination invention, it was *necessary* to establish a teaching, suggestion or motivation to combine the several elements. Now, under *KSR* the teaching, suggestion or motivation is but one of the indicia used to determine obviousness under a more flexible review. *See § V, Teaching-Suggestion-Motivation Lives On.*

One of the more important points of *KSR* is the discussion of “problems” faced by the inventor and those skilled in the art. *See § VI, The “Problem” Solved by the Invention.* Patent applicants all too often – and unnecessarily – create sophisticated “problems” that are identified in the specification that are faced by workers skilled in the art which are solved by the invention. Yet, given the “ordinary creativity” of the post-*KSR* worker in the art, perhaps the problem is then one that can be solved, making the invention obvious. *See § VI-A, The “Known Problem” as Fatal to Patent Validity.*

Often, the applicant cleverly develops a problem that *he* faced that is *different* from any problem suggested by the prior art. Yet, the Court crafts an objective test of obviousness that minimizes the value of the applicant’s subjective problem. *See § VI-B, The Applicant’s Subjective Problem is not Controlling.*

The patent applicant attempts to portray the worker skilled in the art as being without imagination, so that every gap between what is shown in the prior art and the claimed invention should, per applicant, result in a finding of nonobviousness. Yet, *KSR* credits the worker skilled in the art with the ability to use the common knowledge in the art to fill in such gaps. See § VII, *Knowledge of a Worker Skilled in the Art*.

Unlike the Federal Circuit that anticipated the reversal in *KSR* for the more than two years of pendency after the petition was filed – and adjusted its case law to accommodate where it saw the law as heading, the PTO essentially followed the pre-*KSR* law up until the decision itself. Thus, whereas the Federal Circuit law has dramatically evolved in this two year interval, the PTO is only now starting on the road to restructuring its practice to accommodate *KSR*. See § VIII, *An Evolving PTO Practice*. The PTO, of course, does not operate in a vacuum, but must be reactive to how the Federal Circuit interprets *KSR*. In this regard, the 2006 Federal Circuit precedent *prior* to the grant of *certiorari* – but after the petition was filed – is instructive as a starting point. See § VIII-A, *Kahn as a Useful Starting Point*. Already, there has been interim guidance from the Deputy Commissioner, with the expectation that Solicitor Stephen Walsh will complement this early guidance as part of more formal guidelines that the PTO will issue in the relatively near term. See § VIII-B, *PTO Policy Pronouncements*. Complementing the existing case law from 2006, the Federal Circuit will surely issue a series of panel opinions in the near term that will help flesh out the contours of *KSR*. See § VIII-C, *A Series of Federal Circuit Panel Opinions*.

While guidance from the PTO policy-makers and from the Federal Circuit will be more authoritative, at the same time there are several points that are clearly worth mentioning at this early stage. See § IX, *Special Considerations for Ex Parte Practice*. First, the post-*KSR* worker in the art is armed with “ordinary creativity” and can benefit from the knowledge of workers skilled in the art. Great care must be taken to *avoid* any detailed “Background” section or recitation of “objects”, which, if they are “given” as knowledge of a worker skilled in the art, may very well make the solution to problems obvious. See § IX-A, *Avoiding Prosecution Characterizations of the Invention*. Declarations may very well prove necessary to establish nonobviousness of a combination of prior art references or to fill in gaps of knowledge. See § IX-B, *A Declaration-based State of “Common Knowledge”*. Precisely what *is* the state of “common knowledge” available to a

worker skilled in the art – and which can be used to find an invention obvious. Here, it may be necessary to establish the state of knowledge through declarations. See § IX-B-1, *Establishing the Extent of “Common Sense.”* Any expert declaration should be supported by research and preferably include citations to works that establish the declarant’s position. See § IX-B-2, *Providing Reasons to Support an Expert Opinion.* To be sure, any third party attacking a declaration-based patent will cry, “fraud”. The plague of inequitable conduct charges is incessant. Therefore, any declaration obviously is prepared with a prospective eye on this later challenge and will include adequate review by a patent expert familiar with post-patenting consequences. See § IX-B-3, *Prospective Expert Review to Avoid Inequitable Conduct.* While patent litigators routinely say, “don’t file a declaration”, without a declaration a plausible opinion of an Examiner against patentability may carry the day on appeal under the “substantial evidence” rule. See § IX-B-4, *The “Substantial Evidence” Rule.*

A weird quirk of *KSR* is the reliance by the Court upon an irrelevant chemical “structural obviousness” case as the seminal CCPA case establishing the “suggestion” test for combination of prior art references to render a combination invention obvious. See § X, *An Odd Reliance on Chemical Case Law.* Indeed, a bread and butter key focal point for *ex parte* procurement in the organic chemistry arts is the question of whether a unique, new structure is “structurally” or prima facie obvious; this is based upon the closest prior art structure under a doctrine that has CCPA roots dating back to 1944. See § X-A, *The Unique World of Chemical “Structural” Obviousness.* It is therefore an oddity of *KSR* that the Court cites as seminal a 1961 CCPA case that has absolutely nothing to do with putting together a combination of references to render a combination invention obvious, when that case is but one of numerous in a line of cases dealing with “structural” obviousness dating back to 1944. See § X-B, *The Odd Citation of the Bergel Case.* Instead, there *is* a line of CCPA case law dealing with the requirement for a “suggestion” to combine prior art to render a mechanical invention obvious that has many cases that date back to 1937. See § X-C, *The Mechanical “Suggestion” Lineage.*

While the *KSR* case should have only indirect impact on chemical practice, clearly some of the more extreme biotechnology cases from the 1990’s will be under intense scrutiny, including one case that had created a virtually *per se* patentability rule for new biotechnology entities. See § X-D, *Deuel, the Biotechnology Victim of KSR.*

II. SUCCESSIVE SHOCK WAVES AT THE COURT AND THE PTO

*KSR*² represents the most important Supreme Court obviousness case in the more than forty years since *Graham*.³ With a more than two year interval between the *certiorari* petition and the decision, the changes in practice have or are taking place in waves. First, a major course correction was *already made* at the Federal Circuit in early 2006 even before the grant of *certiorari*. Second, the changes at the PTO are only now emerging, and will continue to develop over the coming months and next few years.

A. The 2006 Change in Federal Circuit practice

Without a doubt, the practice at the Federal Circuit today is markedly changed from two years ago when the *certiorari* petition was filed in early 2005, more than two full years before the decision itself. Yet, whatever course correction the Federal Circuit was required to make was *already* signaled even before grant of *certiorari* in *Kahn*⁴ which, thanks to the Supreme Court's imprimatur through its favorable citation and quotation from *Kahn*, represents the leading Federal Circuit case on obviousness today. In the wake of the grant of *certiorari* and up until the decision itself, opinions of the Chief Judge may have been an *overreaction* to such grant, including an argument eve majority opinion⁵ and a bizarre chemical obviousness precedent squarely in conflict with pre- and post-*Graham* precedent.⁶

Because of the *Kahn* course correction, the expected successor Chief Judge of the court was able to state that the *KSR* opinion has made no "great change" in

²*KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007)(Kennedy, J.).

³ *Graham v. John Deere & Co.*, 383 U.S. 1 (1966)(Clark, J.). Since *Graham*, obviousness has been reviewed in *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57 (1969); *Dann v. Johnston*, 425 U.S. 219 (1976); *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273 (1976); see also *Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809 (1986)(per curiam grant, vacate and remand to consider FRCP 52(a) standard of deference to underlying factual issues of obviousness determination).

⁴ *In re Kahn*, 441 F.3d 977 (Fed. Cir. 2006)(Linn, J.).

⁵ *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356 (Fed. Cir. 2006)(Michel, C.J.).

⁶ *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 (2007)(Michel, C.J.), *subsequent proceedings*, ___ F.3d ___ (2007)(en banc)(order).

practice at his court and that the first post-*KSR* opinion of his court “did not require one iota of change.”⁷

B. Evolving Changes at the PTO

There was little noticeable change in practice at the PTO in the more than two year period between the 2005 *certiorari* petition in *KSR* and the recent decision itself. It may be expected that there will be wildly different views taken by individual examiners amongst the 4000-plus corps now that a decision from the Court has been issued. Over time, the practice will stabilize.⁸

III. THE *KSR* REDRAFT OF *GRAHAM* OBVIOUSNESS STANDARDS

The Court in *KSR* “begin[s] by rejecting the rigid approach of the [Federal Circuit]. Throughout this Court's engagement with the question of obviousness, our cases have set forth an expansive and flexible approach inconsistent with the way the Court of Appeals applied its TSM test here. To be sure, *Graham* [*v. John Deere & Co.*, 383 U.S. 1 (1966),] recognized the need for ‘uniformity and definiteness.’ 383 U.S., at 18. Yet the principles laid down in *Graham* reaffirmed the ‘functional approach’ of *Hotchkiss* [*v. Greenwood*, 52 U.S. (11 How.) 248 (1851)]. See 383 U.S., at 12. To this end, *Graham* set forth a broad inquiry and invited courts, where appropriate, to look at any secondary considerations that would prove instructive. *Id.*, at 17.”⁹

A. Unpredictable Results to Establish Nonobviousness

It is important to establish that a combination of references yields *unpredictable* results: “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”¹⁰

⁷Joff Wild, *IAM Magazine*, May 21, 2007 (quoting Hon. Randall R. Rader’s remarks that day to the CIP Forum, Gothenburg, Sweden).

⁸See § IX, *Special Considerations for Ex Parte Practice*.

⁹*KSR*, 127 S.Ct. at 1739.

¹⁰ *KSR*, 127 S.Ct. at 1739. More completely, the Court states that “[n]either the enactment of [35 USC] § 103 nor the analysis in *Graham* disturbed this Court's earlier instructions concerning the need for caution in granting a patent based on the combination of elements found in the prior art. For over a half century, the Court has held that a ‘patent for a combination which only unites old elements with no

As an example of a nonobvious combination, the Court referred to the *Adams Battery* case.¹¹ There, the combination of known elements was found to be nonobvious where the result was unpredictable:

“The Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result. 383 U.S., at 50-51. It nevertheless rejected the Government's claim that Adams's battery was obvious. The Court relied upon the corollary principle that when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious. *Id.*, at 51-52. When Adams designed his battery, the prior art warned that risks were involved in using the types of electrodes he employed. *The fact that the elements worked together in an unexpected and fruitful manner supported the conclusion that Adams's design was not obvious to those skilled in the art.*”¹²

B. Restated Law of Combination Invention Obviousness

The Court summarizes the three most recent combination obviousness cases: “The principles underlying [*Adams Battery*, *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57 (1969), and *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273 (1976)] are instructive when the question is whether a patent claiming the combination of elements of prior art is obvious.”¹³

It then provides two lessons instructive to the obviousness inquiry:

1. “Design incentives and... market forces”

change in their respective functions ... obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men. *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152 (1950). This is a principal reason for declining to allow patents for what is obvious. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *Id.*

¹¹ *KSR*, 127 S.Ct. at 1739-40, discussing *United States v. Adams*, 383 U.S. 39 (1966)).

¹² *KSR*, 127 S.Ct. at 1740; emphasis added.

¹³ *KSR*, 127 S.Ct. at 1740.

Based upon the three cases, the court concludes that “[w]hen a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.”¹⁴

2. Improvement of “Similar Devices”

The second lesson drawn from the three combination cases is that “[f]or the same reason [concerning design incentive and other market forces], if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *Sakraida* and *Anderson's-Black Rock* are illustrative – a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.”¹⁵

3. Obviousness Involving More Complex Arts

The Court acknowledges that “[f]ollowing these principles [from *Adams Battery*, *Anderson's-Black Rock* and *Sakraida*] 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 another or the mere application of a known technique to a piece of prior art ready for the improvement. Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.”¹⁶

¹⁴ *KSR*, 127 S.Ct. at 1740.

¹⁵ *KSR*, 127 S.Ct. at 1740.

¹⁶ *KSR* 127 S.Ct. at 1740-41.

IV. AN EXPLICIT EVIDENTIARY FRAMEWORK

A. An “Explicit” Analysis

One of the more positive aspects of the *KSR* opinion from the standpoint of traversing an obviousness rejection is the Court’s demand that the challenge have an *explicit* analysis demonstrating the obviousness of the invention. After discussion of the obviousness of a combination invention, the Court demands that “[t]o facilitate review, this analysis should be made explicit.”¹⁷

In this regard, the Court quotes with approval from the recent opinion of the Federal Circuit in the *Kahn* case:

“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”¹⁸

B. Filling in the Blanks with Art-Skilled Knowledge

At the same time, “[a]s our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.”¹⁹

V. TEACHING-SUGGESTION-MOTIVATION LIVES ON

The teaching, suggestion or motivation – or TSM – test continues but not as an exclusive test, and not as part of any rigid framework:

“When it first established the requirement of demonstrating a teaching, suggestion, or motivation to combine known elements in order to show that the combination is obvious, the Court of Customs and Patent Appeals captured a helpful insight. See *[In re] Bergel*, 292 F.2d 955, 956-957 (CCPA 1961). As is clear from cases such as *Adams*, a patent composed of several elements is not

¹⁷ *KSR* 127 S.Ct. at 1741.

¹⁸ *KSR* 127 S.Ct. at 1741 (quoting *In re Kahn*, 441 F.3d 977, 988 (C.A.Fed.2006)(Linn, J.).

¹⁹ *KSR* 127 S.Ct. at 1741.

proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

“Helpful insights, however, need not become rigid and mandatory formulas; and when it is so applied, the TSM test is incompatible with our precedents. The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way. In many *fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design trends.* Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility.”²⁰

VI. THE “PROBLEM” SOLVED BY THE INVENTION

All too often, patent applicants needlessly include detailed “Background” sections, create “objects” and, particularly, set up “problems” in the prior art to be solved. *None of this verbiage is necessary* to meet statutory requirements of patentability.

A. The “Known Problem” as Fatal to Patent Validity

Setting up a strawman, a “problem”, in the “Background” may now prove fatal to patentability; it is irrelevant what purpose the applicant intends to solve:

²⁰ *KSR*, 127 S.Ct. at 1741; emphasis added.

“In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103. One of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims.”²¹

B. The *Applicant's* Subjective Problem is not Controlling

Long prior to *KSR*, the Federal Circuit in *en banc* precedent had *overruled* panel precedent that limited consideration of the problem solved to the *applicant's* problem. This subjective standard was set forth in the notorious panel opinions in the *Wright* and *Dillon* cases, and repudiated *en banc* by the court in a reversal of the latter *Dillon* case.

Without citation of *Wright* or either *Dillon* case, the Supreme Court in *KSR* followed the same logic:

“The first error of the Court of Appeals in this case was to foreclose this reasoning by holding that courts and patent examiners should look only to the problem the patentee was trying to solve. 119 Fed.Appx., at 288. The Court of Appeals failed to recognize that the problem motivating the patentee may be only one of many addressed by the patent's subject matter. *The question is not whether the combination was obvious to the patentee but whether the combination was obvious to a person with ordinary skill in the art.* Under the correct analysis, 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.”²²

VII. KNOWLEDGE OF A WORKER SKILLED IN THE ART

Following the same rationale as the *en banc* court in *Dillon*, the Supreme Court in *KSR* criticized the panel's exclusion of consideration of prior art unrelated to the *applicant's* problem: “The second error of the Court of Appeals lay in its

²¹ *KSR*, 127 S.Ct. at 1741-42; emphasis added.

²² *KSR*, 127 S.Ct. at 1742; emphasis added.

assumption that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem.”²³

Explaining the error of the panel, “[c]ommon sense teaches... that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle. Regardless of [the cited prior art reference]’s primary purpose, the design provided an obvious example of an adjustable pedal with a fixed pivot point [which is the novel feature of the invention]; and the prior art was replete with patents indicating that a fixed pivot point was an ideal mount for a sensor. The idea that a designer hoping to make an adjustable electronic pedal would ignore Asano because Asano was designed to solve [a different] problem makes little sense. *A person of ordinary skill is also a person of ordinary creativity, not an automaton.*”²⁴

VIII. AN EVOLVING PTO PRACTICE

A. *Kahn* as a Useful Starting Point

Already, the Supreme Court has blessed the *Kahn* case with its imprimatur, so that *Kahn* as a decision from an appeal from the PTO, will in any event hold special significance for the examining corps. As months and years go by, it will be seen how closely the PTO and the Federal Circuit follow or seek to modify *Kahn*.

B. PTO Policy Pronouncements

It is expected that in the near term the PTO, working particularly through Acting Solicitor Stephen Walsh, will provide a detailed set of guidelines interpreting *KSR*. Such guidance should be forthcoming within a few months.

²³ *KSR*, 127 S.Ct. at 1742, citing 119 Fed.Appx., at 288..

²⁴ *KSR*, 127 S.Ct. at 1742; emphasis added.

In the meantime, the Deputy Commissioner for Patent Operations has provided guidance to the corps.²⁵ She first underscores the continued vitality of *Graham*, summarizing “four factual inquiries”:

- “(a) determining the scope and contents of the prior art;
- “(b) ascertaining the differences between the prior art and the claims in issue;
- “(c) resolving the level of ordinary skill in the pertinent art; and
- “(d) evaluating evidence of secondary consideration.”²⁶

She noted the continued vitality of the teaching-suggestion-motivation test which “[t]he Court did not totally reject” because the teaching-suggestion-motivation test “could provide a helpful insight in determining whether the claimed subject matter is obvious under 35 U.S.C. § 103(a).”²⁷

The guidance includes a mandate that “in formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed.”²⁸

The guidance quotes from *KSR*:

“[It is] ‘important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements’ in the manner claimed.” She also quotes with approval the statement in *KSR* that “[o]ften, it will be necessary . . . to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an *apparent*

²⁵ Memorandum captioned *Supreme Court decision on KSR Int'l. Co., v. Teleflex, Inc.*, May 3, 2007, to Technology Center Directors from Margaret A. Focarino, Deputy Commissioner for Patent Operations.

²⁶ *Id.* (citing *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966)).

²⁷ *Id.*, point (2). She also noted as point (3) that the Court rejected a “rigid” application of this test.

²⁸ *Id.*; concluding paragraph of Memorandum.

reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis *should be made explicit*.”²⁹

C. A Series of Federal Circuit Panel Opinions

An ongoing stream of Federal Circuit panel opinions will help flesh out the contours of *KSR* for the foreseeable future. It is unlikely that there will be any *en banc* consideration of obviousness for some time, if the denial of *en banc* consideration in the *Pfizer* case is any guide for the future.

Some issues of obviousness are unique to PTO practice. For these areas, PTO practice will more fully stabilize when significant Board decisions are issued and Federal Circuit review of such decisions occurs. Numerous obviousness decisions will be forthcoming almost immediately. Certainly dozens if not hundreds of relevant decisions will be issued during calendar year 2007. Thus, it will not be necessary to await decisions from cases now at the examining corps because the *existing* pipeline of appeals now being heard or awaiting decision will be decided continually as they exit the pipeline.

To the extent that a decision *reverses* an Examiner, it will have very little overall impact on the policy of the PTO because almost all of the decisions of the Board are designated as nonprecedential. Even if precedential, without the imprimatur of a Federal Circuit review, the decision will have relatively minimal impact.

Of the hundreds of obviousness *affirmances* that will be forthcoming this year, it will be up to individual applicants to select appropriate cases for appeal. Many if not most appeals from the PTO to the Federal Circuit are not presented in an artful manner worthy of review. This is manifested by the roughly ninety (90) percent affirmance rate of Board decisions at the Federal Circuit, and the very high percentage of affirmances that are simply *per curiam* decisions without even the benefit of an opinion.

²⁹ *Id.*, point (4)(quoting *KSR*)(emphasis added by the PTO).

IX. SPECIAL CONSIDERATIONS OR *EX PARTE* PRACTICE

A. Avoiding Prosecution Characterizations of the Invention

Clearly, the invention must be disclosed in an enabling manner, and the best known prior art must be *cited* to the examiner to meet the duty of disclosure. Yet, there is no duty to *characterize* the invention. In particular, there is no need to identify a problem that is faced or solved nor is it necessary to include “objects” of the invention.

In the wake of *KSR*, it may well be the best policy to simply *disclose* the invention *without* any discussion of the “Background...”, “objects” or “problems” faced by workers in the art. To the extent that the patent applicant overstates any “problems”, the patent applicant may be digging a grave for the invention:

Perhaps, *given* a problem identified in the specification as one facing workings in the art, the next step in logic could well be that the invention is an “to advance[] that would occur in the ordinary course without real innovation [that, if a patent is granted, would] retard[] progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility.”³⁰ The advance may well be within the “ordinary skill is also a person of ordinary creativity [who is] not an automaton.”³¹

B. A Declaration-based State of “Common Knowledge”

1. Establishing the Extent of “Common Sense”

A patent applicant may very well face an Examiner’s rejection of claims where the Examiner presents a seemingly plausible argument that the applicant’s solution is the result of a common sense approach to solve a known problem. The Examiner has basis for such a rejection in *KSR*: “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 anticipated

³⁰ *KSR*, 127 S.Ct. at 1741; emphasis added.

³¹ *KSR*, 127 S.Ct. at 1742; emphasis added.

success, it is likely the product not of innovation but of *ordinary skill and common sense*. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.”³²

2. Providing Reasons to Support an Expert Opinion

Here, it is essential that the applicant present compelling fact-based reasons *why* the worker skilled in the art would not be led to the claimed invention, preferably through a fact-based expert opinion that is rich in details as to an explanation for this position.

3. Prospective Expert Review to Avoid Inequitable Conduct

To be sure, any declaration must be very carefully scrutinized before filing and should benefit from the critical analysis of a senior patent expert who has a practice focused upon patent opinions and litigation, to make sure that all facts are fairly laid out and that a one-sided picture is not presented. Certainly, any declaration-based patent will be challenged on the basis of the universally raised charge of inequitable conduct: Avoiding a finding of inequitable conduct is best served by having the independent counsel of a patent expert involved to second guess the proceedings on a *prospective* basis before the declaration is filed.

4. The “Substantial Evidence” Rule

Without declaration evidence, a plausible rejection will likely be affirmed by the Board and will surely be affirmed by the Federal Circuit under the substantial evidence test.

As explained in the affirmance of the obviousness rejection in *Kahn*, “[b]ecause the factual findings underlying the Board's analysis, including the findings on motivation to combine, are supported by substantial evidence, we conclude that the Board did not err in rejecting claims 1-20 as *prima facie* obvious.

³² *KSR*, 127 S.Ct. at 1742; emphasis added.

[The Board’s decision is therefore affirmed b]ecause Khan did not rebut the Board's *prima facie* case...”³³

As explained in *Harris*, the Federal Circuit “reviews the Board's legal conclusion of obviousness de novo and its underlying factual determinations for substantial evidence.”³⁴ Establishing unexpected results and considering whether prior art teaches away from an invention represent heavily fact-based inquiries:

Whether an invention has produced unexpected results and whether a reference teaches away from a claimed invention are questions of fact.”³⁵ Where the patent applicant has failed to provide evidence to demonstrate that the Examiner’s position is not one which “a reasonable mind *might* accept”, the Federal Circuit should affirm the PTO and deny patentability: “Under the substantial evidence standard, this court affirms the Board's factual determinations if they are based upon “such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.”³⁶

X. AN ODD RELIANCE ON CHEMICAL CASE LAW

A. The Unique World of Chemical “Structural” Obviousness

There is an entirely separate world of patent practice for brand new entities in biotechnology and organic chemistry. The relevant question here is not whether a combination of old elements can or should be recombined into a new arrangement of old elements like the old “gas pedal” and the old electronic engine as in *KSR*. Rather, the usual question instead is whether a *brand new entity* is suggested by an old, prior art compound having a somewhat similar structure.

³³ *Kahn*, 441 F.3d at 991.

³⁴ *In re Harris*, 409 F.3d 1339, 1341 (Fed. Cir. 2005)(Rader, J.)(citing *In re Gartside*, 203 F.3d 1305, 1316 (Fed.Cir.2000)).

³⁵ *Id.*, citing *In re Mayne*, 104 F.3d 1339, 1343 (Fed.Cir.1997) (unexpected results); *Para-Ordnance Mfg. v. SGS Importers Int'l*, 73 F.3d 1085, 1088 (Fed.Cir.1995) (teaching away).

³⁶ *Id.*, citing *Gartside*, 203 F.3d at 1312 (quoting *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 217 (1938)).

In determining obviousness of a new chemical compound, there is a two stage inquiry. *First*, is the claimed compound “structurally obvious” or “prima facie” obvious under the *Haas-Henze* doctrine: “The question of ‘structural similarity’ in chemical patent cases has generated a body of patent law unto itself.”³⁷ *Second*, even if there is structural or prima facie obviousness, has the patent applicant presented rebuttal evidence to demonstrate that the compound *as a whole* is nonobvious under the *Papesch* test?³⁸

The question of structural obviousness more often than not boils down to whether there is a specific disclosure in the prior art of a closely related compound. Beyond questions of close similarity of compounds, there is also the question of a generic anticipation, where a claimed compound is nowhere suggested in the prior art but merely caught within the web of a very broad generic disclosure – as was the situation in the *Jones* case: Merely because the prior art has a very broad, sweeping generic disclosure – a “haystack” – does not render each species – the “needles” – obvious. As in *Baird*, “[a] disclosure [in a generic formula] of millions of compounds does not render obvious a claim to three compounds, particularly when that disclosure indicates a preference leading away from the claimed compounds.”³⁹

B. The Odd Citation of the *Bergel* Case

Bergel is prominently quoted in *KSR* as the seminal CCPA case that there must be a “suggestion” test for a combination of prior art references to render a combination of old elements obvious. Yet, *Bergel* was neither seminal nor did it have anything whatsoever to do with the obviousness of a combination of old elements. Rather, *Bergel* was simply one in a very long line of cases dating back to the earliest *Haas-Henze* cases with the issue of motivation to modify a prior art

³⁷*In re Jones*, 958 F.2d 347, 349 (Fed. Cir. 1992)(Rich, J.), citing Helmuth A. Wegner, *Prima Facie Obviousness of Chemical Compounds*, 6 Am.Pat.L.Assoc.Q.J. 271 (1978)(discussing the evolution of *In re Hass*, 141 F.2d 122, 127, 130 (CCPA 1944); *In re Henze*, 181 F.2d 196 (CCPA 1950)).

³⁸*In re Mayne*, 104 F.3d 1339, 1342 (Fed. Cir. 1997)(Rader, J.)(citing *In re Papesch*, 315 F.2d 381, 391 (CCPA 1963)) (“[U]nexpected properties can show that a claimed compound that appear[s] to be obvious on structural grounds [is] not obvious when looked at as a whole.”).

³⁹*In re Baird*, 16 F.3d 380, 383 (Fed. Cir. 1994).

structure by substituting a chloro group (-Cl) for hydrogen (-H) on each of two ethyl groups of that prior art compound.⁴⁰ With very close structural deviations in a known pattern, there is implicit motivation to modify a useful, known product and hence “structural” obviousness where the prior art compound has a known utility.⁴¹

C. The Mechanical “Suggestion” Lineage

The *Bergel* lineage is substantially from a different line of case law than the older consideration of mechanical obviousness case law: While the *Bergel* provenance stems from the 1944 series of *Haas* cases, CCPA case law concerning a requirement for a suggestion for a combination invention dates back to the 1937 *Huntzicker* case *Huntzicker* case where the Patent Office was reversed because of the absence of a *suggestion* in the prior art to combine the known elements: “We find nothing in the references to *suggest* that appellant's new, useful, and commercially successful device might be constructed by combining some of their elements.”⁴² *Huntzicker*, however, stood alone as an aberration in the early case law as the CCPA paid lip service to this rationale in *dicta* in its *affirmance* of the Patent Office in 1943 in *Fridolph*,⁴³ *Goepfrich*⁴⁴ and *Gillett*⁴⁵ and the following

⁴⁰The issue in *Bergel* was simply whether a particular ethyl derivative in the prior art renders a chloro-ethyl derivative *prima facie* obvious: The claimed compound in *Bergel* is p-bis-(2-chloroethyl)-aminophenylalanine, which differs from the closest prior art compound, p-diethylamino-phenylalanine, in that each of the ethyl groups in the prior art compound instead has a chloro group, i.e., each -CH₂CH₃ in the prior art compound instead has -CH₂CH₂Cl instead. The issue boils down as to whether the substitution of a chloro group (-Cl) for one hydrogen (H) in each ethyl group is obvious. This is a classic “structural obviousness” issue.

⁴¹ Cf. *In re Lalu*, 747 F.2d 703, 705 (Fed. Cir. 1984)(quoting *In re Stemniski*, 444 F.2d 581, 586 (CCPA 1971)(“How can there be obviousness of structure, or particularly of the subject matter as a whole, when no apparent purpose or result is to be achieved, no reason or motivation to be satisfied, upon modifying the reference compounds' structure? Where the prior art reference neither discloses nor suggests a utility for certain described compounds, why should it be said that a reference makes obvious to one of ordinary skill in the art an isomer, homolog or analog of related structure, when that mythical, but intensely practical, person knows of no ‘practical’ reason to make the reference compounds, much less any structurally related compounds?”).

⁴²*In re Huntzicker*, 90 F.2d 366, 368-69 (CCPA 1937).

⁴³*In re Fridolph*, 134 F.2d 414 (CCPA 1943). See also Chisum, Chisum on Patents, § 5.04[1][e][i] (2007)(calling *Fridolph* “the germinal decision”).

year in *Stover*.⁴⁶ Slightly later came *Merkle*⁴⁷ and *Dalzell*⁴⁸ followed by the 1949 *Udy* case: “In considering more than one reference, or a reference alleged not to be in the art involved, the question always is: does such art suggest doing the thing which the applicant has done?”⁴⁹ Recent scholarship also identifies *Grushkin*,⁵⁰ *Shaffer*⁵¹ and *Hortman*,⁵² all in the five year period prior to *Bergel*.

D. *Deuel*, the Biotechnology Victim of KSR

A virtually *per se* rule of patentability for new biotechnology entites is set in the 1995 *Deuel* case.⁵³ *Deuel* has been the subject of heavy criticism from the scholarly community and is cynically discussed in a dissent in the *Fisher* case.⁵⁴

⁴⁴ *In re Goepfrich*, 136 F.2d 918, 920 (CCPA 1943).

⁴⁵ *In re Gillett*, 133 F.2d 910, 912 (CCPA 1943).

⁴⁶ *In re Stover*, 146 F.2d 299, 301 (CCPA 1944)(quoting *Fridolph*) See also Chisum, Chisum on Patents, § 5.04[1][e][i] (2007)(quoting *In re Milne*, 140 F.2d 1003, 1005 (CCPA 1944)(repudiating *Ex parte Gee*, 261 O.G. 800; C.D. 1919, p. 49 (Comm’r dec. 1919))

⁴⁷ *In re Merkle*, 150 F.2d 445, 448 (CCPA 1945).

⁴⁸ *In re Dalzell*, 152 F.2d 1013, 1014 (CCPA 1946)(citing *Fridolph*)(emphasis added).

⁴⁹ *In re Udy*, 173 F.2d 230, 233 (CCPA 1949)(dictum)(quoting *In re Fridolph*, 134 F.2d 414, 416 (CCPA 1943)).

⁵⁰ S. Jafar Ali, *You Suggest What? How KSR Returned Bite to Nonobviousness*, 16 Fed. Circuit B.J. 247, 257 n.79 (2006)(quoting *In re Gruskin*, 234 F.2d 493, 498 (C.C.P.A. 1956) (“[W]hen references are combined, it should be considered whether the references suggest doing the thing which an applicant has done.”).

⁵¹ John S. Goetz, *An “Obvious” Misunderstanding: Zurko, Lee and the Death of Official Notice (Part II)*, 86 J. Pat. & Trademark Off. Soc’y 183, 193 n.133 (2004)(quoting *In re Hortman*, 264 F.2d 911, 913 (CCPA 1959) as “holding that ‘references may not be combined where ‘there is no suggestion in either of the references that they can be combined’”; *In re Shaffer*, 229 F.2d 476, 479 (CCPA 1956), as “holding that references ‘may not be combined indiscriminately, and to determine whether the combination of references is proper, the following criterion is often used: namely, whether *the prior art suggests* doing what an applicant has done.’”).

⁵² *Id.* (quoting *In re Hortman*, 264 F.2d 911, 913 (CCPA 1959) as “holding that ‘references may not be combined where ‘there is no suggestion in either of the references that they can be combined’[.]”).

⁵³ *In re Deuel*, 51 F.3d 1552 (Fed.Cir.1995).

It may be expected that in the wake of *KSR* there will be a renewed challenge to the viability of *Deuel*.

XI. CONCLUSION

With over 4,000 patent examiners, each with their own take on what *KSR* means, the practice before the PTO at the examiner level will have *some* changes but changes that will not be predictable across the board. Yet, for cases that *do* reach the Board of Patent Appeals and Interferences – or go even further to the Federal Circuit – there will be a marked stiffening of practice. Special care must be taken to streamline patent prosecution without harmful statements in a “Background...” section. And, above all, careful consideration must be given to establishing an evidentiary basis to demonstrate the “common sense” level of the worker skilled in the art.

⁵⁴ *In re Fisher*, 421 F.3d 1365, 1381-82 (Fed. Cir. 2005)(Rader, J., dissenting) (“The Office needs some tool to reject inventions that may advance the ‘useful arts’ but not sufficiently to warrant the valuable exclusive right of a patent. ... The proper tool for assessing sufficient contribution to the useful arts is the obviousness requirement of 35 U.S.C. § 103. Unfortunately this court has deprived the Patent Office of the obviousness requirement for genomic inventions. See *In re Deuel*, 51 F.3d 1552 (Fed.Cir.1995); Martin J. Adelman et al., *Patent Law*, 517 (West Group 1998) (commenting that scholars have been critical of *Deuel*, which ‘overly favored patent applicants in biotech by adopting an overly lax nonobviousness standard.’ (citing Anita Varma & David Abraham, *DNA Is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market*, 9 Harv. J.L. & Tech. 53 (1996))); Philippe Ducor, *The Federal Circuit and In re Deuel: Does § 103 apply to Naturally Occurring DNA?*, 77 J. Pat. & Trademark Off. Soc’y 871, 883 (Nov.1995) (‘The Court of Appeals for the Federal Circuit could have formulated its opinion in only one sentence: ‘ 35 U.S.C. § 103 does not apply to newly retrieved natural DNA sequences.’); Philippe Ducor, *Recombinant Products and Nonobviousness: A Typology*, 13 Santa Clara Computer and High Tech. L.J. 1, 44-45 (Feb.1997) (‘This amounts to a practical elimination of the requirement for nonobviousness for these products, even when all the information necessary to discover them is previously available.’); see also over fifty additional articles critical of *Deuel* in the ‘Citing References’ tab for *Deuel* on Westlaw. Nonetheless, rather than distort the utility test, the Patent Office should seek ways to apply the correct test, the test used world wide for such assessments (other than in the United States), namely inventive step or obviousness.”).