

From: James Crowne [redacted]
Sent: Thursday, February 17, 2011 2:28 PM
To: KSR_Guidance
Subject: FW: Comments on KSR Guidelines

Dear Ms. Fonda, may I ask that the attached document be substituted for the previously sent document, which was inadvertently sent without a signature.

With apologies for any inconvenience,

Jim Crowne

From: James Crowne
Sent: Friday, February 11, 2011 4:17 PM
To: 'KSR_Guidance@uspto.gov'
Subject:

Kathleen Kahler Fonda
Legal Advisors
Office of Patent Legal Administration
Office of the Associate Commissioner for Patent Examination Policy

Dear Ms. Fonda, please accept the attached comments of the American Intellectual Property Law Association on the 2010 KSR Guidelines Update, published in the September 1, 2010 issue of the Federal Register, 75 Fed. Reg. 53643. We appreciate the opportunity to contribute our thoughts on the important update for examiners on obviousness determinations. We would appreciate confirmation of the receipt of these comments. If I can be of any assistance in this connection, please don't hesitate to contact me at the telephone number or email address below.

Best regards,

JIM CROWNE
Director of Legal Affairs

AIPLA

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11 February, 2011

The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

**Response to Request for Comments on “Examination Guidelines Update:
Developments in the Obviousness Inquiry after KSR v. Teleflex”
75 Federal Register 53643 (September 1, 2010)**

Dear Under Secretary Kappos:

The American Intellectual Property Law Association (AIPLA) appreciates the opportunity to offer comments on the Federal Register notice entitled “Request for Comments on Examination Guidelines Update: Developments in the Obviousness Inquiry After KSR v. Teleflex,” 75 Fed. Reg. 53643 (“the Notice”). AIPLA is a national bar association whose approximately 16,000 members are primarily lawyers and other patent practitioners in private and corporate practice, in government service, and in the academic community. AIPLA represents a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property.

AIPLA commends the U.S. Patent and Trademark Office (“PTO”) for updating the previously published “KSR Guidelines” on obviousness through this Notice to reflect developments since the Supreme Court’s decision *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). AIPLA suggests that the Office continue to provide such updates as the courts further develop the law of obviousness. The use of “Teaching Points” in the guideline examples is a welcome approach, as is the inclusion of examples showing both obviousness and non-obviousness determinations.

While the Office acknowledges in the Notice that “every question of obviousness must be decided on its own facts” (see col. 1, p.53644, last sentence), we believe it is particularly important to emphasize this point in providing guidance to Office personnel. That is, while case law provides guidance for analyzing and resolving obviousness inquiries, when examining a particular invention, it is important to avoid over generalization of case law and to analyze the facts at hand as they would have been appreciated by one of skill in the art *at the time the invention was made*.

There are several additional points that we also believe should be emphasized or re-emphasized, as the case may be, in providing guidance and training to Office personnel:

- (1) Even after *KSR*, the application of 35 U.S.C. §103 is controlled by the factual analysis set forth in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966). The following passage from *Graham* is quoted by the *KSR* opinion :

“[T]he scope and content of the prior art are . . . determined; differences between the prior art and the claims at issue are . . . ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.”

Examiners should understand, as stated in *KSR*, that the *Graham* factors continue to define the controlling inquiry, even if the sequence of considering those factors might be reordered in any particular case.

(2) Obviousness rejections cannot be based solely on the mere presence of a claim element somewhere in the prior art without some legal rationale supporting the inclusion of the particular prior art element in a rejection. There must be some articulated reason as to why one skilled in the art would have selected particular teachings from the prior art or the general knowledge of one skilled in the relevant art and combined them into the claimed invention. In other words, while the motivation for combining teachings might not be explicit in the prior art, it must still be articulated, present, or apparent to such a degree that one reviewing the legal conclusion can analyze the rejection and, where appropriate, rebut the underlying rationale, whether by argument, evidence, or both.

(3) Obviousness rejections need to identify the underlying factual evidence, especially when it is based on common sense or other reasoning outside of that explicitly presented in the reference(s). In particular, if a rejection notes a specifically cited section of a reference, but the examiner brings up another section in response to an applicant’s rebuttal, that is tantamount to a “new rejection.” Thus, where new sections of a reference or new rationales or implicit arguments are introduced during prosecution, the ensuing Office Action should be Non-Final. One of the dangers of using *KSR* theories is that rebuttable rationales are not clearly articulated. Training should emphasize that the object of the examination exercise is to arrive at a clear and reviewable record.

(4) Impermissible hindsight is not a substitute for logical reasoning. When explaining a motivation to combine and/or modify the art that is not explicit in the prior art, care should be taken to provide a substantive explanation of the rejection in the context of the invention and the knowledge of one skilled in the art at the time the invention was made; it should not be based on impermissible hindsight. For example, in more crowded arts general motivations may not be sufficient to support conclusions of obviousness without specific blaze marks. Further, in relying on “predictability” in the art as part of the reasoning for an obviousness rejection, care should be taken not to construe the invention using impermissible hindsight, which can misleadingly suggest the presence of a motivation to combine elements of an invention in a nonobvious way. Office personnel should not use hindsight to find motivation to combine and then use that misguided finding to conclude that the operation of the device would have been predictable to one of ordinary skill in the art once the invention was pieced together. This type of rejection is virtually impossible to discuss since it does not come from objective, rebuttable reasoning.

(5) When relying on common sense, the underlying reasoning for the “common sense” needs to be clearly articulated so that it is clear from the ultimate record what implicit

evidence was used and how it was addressed. The explanation of the “common sense” relied upon should be in the context of the invention and based on the knowledge of one skilled in the art *at the time the invention was made* rather than on the impermissible hindsight.

(6) Office personnel should be cautioned against relying on “common sense” in evaluating evidence, especially obviousness evidence that is based on a “common sense” view of elements recited in the claims themselves. This contrasts with providing motivation in constructing an obviousness rejection, as discussed in the *KSR* case. While that decision provides for the use of common sense in specific instances, reliance on common sense should be treated similarly to “official notice.” If a “common sense” obviousness refusal is challenged, the burden should shift to the Office to provide evidence that this “common sense” applied at the time the invention was made.

(7) When a response to an Office action is received, the entirety of the basis of the rejection must be reconsidered in light of any evidence and argument presented by applicant. For example, if allegations of unexpected or synergistic results are presented, such evidence should be weighed against other evidence that may establish a conclusion of obviousness.

We have grouped exemplary cases according to obviousness concepts and rationales to provide Office personnel with clear examples of the obviousness analysis. These cases generally fall under the broader concepts of: (a) combining prior art elements; (b) substituting one known element for another; and (c) the obviousness to try rationale.

(a) Combining Prior Art Elements

The phrasing of the Teaching Point for **Example 4.1** may be interpreted as suggesting that a problem-solution approach to obviousness is appropriate under U.S. law. The Teaching Point should be revised to clarify that the standard for obviousness under U.S. law remains as set forth in *Graham v. Deere*, which includes a requirement that a finding of obviousness include reasons and a rationale for making a particular combination.

With regard to **Example 4.2**, the Teaching Point does not fully track *Crocs, Inc. v. U.S. International Trade Commission*, 598 F.3d 1294 (Fed. Cir. 2010). This Teaching Point states that “A claimed combination of prior art elements may be nonobvious where the prior art teaches away from the claimed combination *and* the combination yields more than predictable results” (emphasis added). More specifically, AIPLA is concerned that this Teaching Point stands for the proposition that the court’s finding of nonobviousness was conditioned upon both a teaching away *and* an unpredictable result.

In *Crocs*, the court based its nonobviousness conclusion upon three separate and independent grounds: (1) the prior art taught away from the claimed combination; (2) the claimed combination yielded more than predictable results; and (3) there was no reason to make the claimed combination of the prior art elements. On the latter, the Court expressly stated that “One of ordinary skill would have no reason to use foam straps in combination with a foam base portion. *Thus*, the new combination *would not have been obvious* at the time of the invention of the ’858 patent.” *Id.* at 1309 (emphasis added).

With regard to the unpredictable results of the claimed combination, the court remarked that “Even if the ‘858 patent were a combination of known elements according to their established functions—which it is not as foam straps were not in the prior art—it yields more than predictable results; thus it is non-obvious.” *Id.* at 1309. The court also stated that “Because this claimed feature of the invention yielded more than predictable results, the ‘858 patent for this reason also would not have been obvious at the time of the invention.” *Id.* at 1310.

The court also stated that “The prior art, in fact, taught away from the passive restraint system. Because this claimed feature of the invention yielded more than predictable results, the ‘858 patent *for this reason also* would not have been obvious at the time of the invention.” *Id.* at 1310 (emphasis added). The Court’s use of the phrase “for this reason also” demonstrates that the teaching away finding was one independent and sufficient ground for nonobviousness and that an unpredictable result finding was another.

For at least these reasons, AIPLA suggests that the current Teaching Point be rewritten as follows: “A claimed combination of prior art elements may be nonobvious where the prior art teaches away from the claimed combination, **the claimed combination yields more than predictable results, or there would be no reason to make the claimed combination of prior art elements.**”

While the Teaching Point for **Example 4.3** is framed as an example of what may be obvious, the overall teaching of the prior art needs to be considered. For example, in evaluating a combination of known prior art elements reasonably expected to maintain a desired property or function after the combination, an undesired effect on another property or function could result from the combination. The prior art may teach that adding ribs to a surface will improve stability, a desirable property, but the addition of the ribs might also introduce undesired stress points, especially if covering materials are used that are not resistant to stress. Thus, while the Teaching Point may be true *for the facts at issue in Example 4.3*, the application of this type of combination should be comparable to the *facts at issue in the application* under consideration at the time and based upon the invention as articulated in the claims being examined.

With regard to **Example 4.4**, the need for Office personnel to provide a record of the reasons for combining the references is not sufficiently emphasized in the Teaching Point. As a preliminary point AIPLA notes that, although the *KSR* approach is flexible as to the line of reasoning to be applied, any rejection under 35 U.S.C. § 103 must include a clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. § 103 should be explicit. The Court, quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), stated that “[R]ejections on obviousness 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.” *KSR*, 550 U.S. at 409 (2007).

The discussion of Example 4.4 cites *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335 (Fed. Cir. 2009), for the following proposition: an examiner may articulate an apparent reason to combine known elements to establish *prima facie* obviousness by showing that a skilled artisan would have recognized an apparent reason to combine those elements and would have known how to do so. *Ecolab*, however, demonstrates that any showing of obviousness requires explicit and articulated reasoning. In that case, *Ecolab*’s claims to combining high pressure with other limitations in found in *FMC*’s patent were found to be obvious because (1) the second reference taught “using high pressure to improve the effectiveness of an antimicrobial solution when sprayed onto meat, and (2)

an artisan of ordinary skill would have recognized the reasons for applying the claimed antimicrobial solution using high pressure and would have known how to do so. 569 F.3d at 1350. Such explicit and articulated reasoning is required for any showing of obviousness under 35 U.S.C. § 103.

Accordingly, AIPLA recommends changing the Teaching Point to, “A combination of known elements would have been *prima facie* obvious if an ordinary skilled artisan would have recognized an apparent reason to combine those elements and would have known how to do so for reasons and in situations as set forth in the as-claimed invention under consideration. **Such reason and knowledge must be supported by articulated reasoning based on facts specific to the invention.**”

With regard to **Example 4.5**, AIPLA believes that the Teaching Point identified for *Wyers v. Master Lock*, 616 F.3d 1231 (2010), is overly broad. The Guidelines state the following: “The scope of analogous art is to be construed broadly and includes references that are reasonably pertinent to the problem that the inventor was trying to solve.” This implies that *Wyers* teaches that the scope of analogous art may extend beyond references that are reasonably pertinent to the problem that the inventor was trying to solve. AIPLA does not believe that *Wyers* supports this conclusion.

Citing *Comaper Corp. v. Antect, Inc.*, 596 F.3d 1343, 1351 (Fed. Cir. 2010), the *Wyers* court stated:

Two criteria are relevant in determining whether prior art is analogous: “(1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor’s endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.”

Additionally, the court stated:

The Supreme Court’s decision in *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 127 S. Ct. 1727, 167 L. Ed. 2d 705 (2007), directs us to construe the scope of analogous art broadly, stating that “*familiar items may have obvious uses beyond their primary purposes*, and a person of ordinary skill often will be able to fit the teachings of multiple patents together like pieces of a puzzle.” *Id.* at 402 (emphasis added). Here, the prior art padlocks were clearly directed toward the sample problem the inventor was trying to solve Thus, as a matter of law [the prior art references] were pertinent prior art

Although the Supreme Court has indicated that the scope of analogous art is to be construed broadly, the above passages suggest that the Federal Circuit has restricted analogous art outside the inventor’s field of endeavor to that which is reasonably pertinent to the problem the inventor is trying to solve, a position that is consistent with existing law.

AIPLA is also concerned with the statement in the Teaching Point that “common sense may be used to support a legal conclusion of obviousness as long as it is explained with sufficient reasoning.” This Teaching Point provides Office personnel with little guidance as to what constitutes “sufficient reasoning.” The text of the Guidelines found in the paragraph of the Federal

Register notice that bridges pages 53648 and 53649 provides better language which AIPLA recommends be included in the Teaching Point.

Thus, AIPLA recommends that the Teaching Point in the Guidelines for *Wyers* be changed to recite “The scope of analogous art is to be construed broadly. **References outside of the field of endeavor, however, are limited to those that would have been recognized by the skilled artisan as reasonably pertinent to, or directed to solving, the same problem confronted by the applicant.** Such references are limited to those used to decide the scope of the “problem”, addressed by the invention, *as articulated in the claims themselves*. These references should serve as guidance as to the breadth of art from which analogous art may be appropriately drawn. Common sense may be used to support a legal conclusion of obviousness **as long as it is presented with a reasoned explanation of why a skilled artisan, at the time of the invention and in view of the facts relevant to the case would have found the claimed invention to be obvious.**”

(b) Substituting One Known Element for Another

In regard to **Example 4.7**, the Guidelines should emphasize the need for an obviousness determination to include a clear statement as to why one skilled in the art would be motivated to use solutions from non-analogous art. The question is whether or not the fields of endeavor from which teachings are taken are appropriate to one in the inventor’s art “*at the time the invention was made.*” In particular, a solution taken from non-analogous teachings may in fact indicate a point of patentability where an inventor has drawn beyond that normally considered by the ordinary artisan. Thus, it is urged that, where non-analogous art is used, an additional motivation statement be included that articulates why, at the time of the invention, one would have ranged beyond the technology being addressed.

With regard to Teaching Points on analogous art in **Examples 4.8**, AIPLA also has concerns about the characterization of *Agrizap, Inc. v. Woodstream Corp.*, 520 F.3d 1337 (Fed. Cir. 2010). This case is presented as teaching that analogous art includes not only references in the applicant’s field of endeavor, but also references “*useful* for the applicant’s purpose” (emphasis added). AIPLA is concerned that the use of the term “useful” takes an overly expansive view of analogous art that goes beyond the scope of the holding in *Agrizap*. Specifically, the *Agrizap* court concluded that a prior art combination rendered the asserted claims obvious, in part, because “[the prior art patents] are directed to solving *the same problem* as [the asserted claims]” *Id.* at 1344 (emphasis added).

While *Agrizap* cites no authority for this approach, it comports with *In re Clay* and the two-part test for analogous art enunciated therein. 966 F.2d 656 (Fed. Cir. 1992). *In re Clay* held that analogous art includes art in the applicant’s field of endeavor as well as references “reasonable pertinent” to the problem confronted by the inventor. *Id.* at 659-60. In this regard, “[a] reference is reasonably pertinent if, even though it may be in a different field from that of the inventor’s endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor’s attention in considering his problem.” *Id.* Consequently, AIPLA recommends amending this Teaching Point to include the limiting language of *Agrizap* as informed by the holding of *In re Clay*, namely, that “analogous art is not limited to references in the field of endeavor of the invention.

AIPLA suggests that an additional Teaching Point be included in the Guidelines based on *Aventis Pharma Deutschland v. Lupin Ltd.*, 499 F.3d 1293 (Fed. Cir. 2007) and *Eisai Co. Ltd. V. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353 (Fed. Cir. 2008). Both of these cases concern the use of a starting compound in an obviousness rejection.

According to *Aventis*, a prior art compound which is structurally similar to the claimed compound may, under certain circumstances, provide a basis for combining prior art references. That is, structural similarity, combined with “articulated reasoning with some rational underpinning” will “support the legal conclusion of obviousness[.]” *Aventis* at 1301 (quoting *KSR*, 550 U.S. at 419). The requisite “articulated reasoning” need not rise to the level of an explicitly stated teaching, suggestion, or motivation; rather, it is sufficient to show “a sufficiently close relationship [between the claimed and prior art compounds] to create an expectation, in view of the totality of the prior art, that the new compound will have similar properties to the old.” *Id.* (internal quotations and citations omitted).

The court in *Aventis* based its conclusion of obviousness upon the structural similarity between the claimed stereoisomer of the drug ramipril and a predecessor drug, enalapril. *Id.* at 1302-03. The claims at issue in *Aventis* were directed to the SSSSS, or “5(S),” stereoisomer of ramipril, to wit, the configuration of ramipril where all five stereocenters are in the “S” configuration. *Id.* at 1293. The 5(S) stereoisomer demonstrated significantly enhanced efficacy in comparison to a prior art mixture containing the SSSSS and SSSSR stereoisomers of ramipril. *Id.* at 1301-02. Enalapril, a predecessor drug of ramipril, contained 3 of ramipril’s 5 stereocenters. *Id.* at 1297. Additionally, a prior art study disclosed that the “all-S (SSS) stereoisomer of enalapril was found to have 700 times the potency of the SSR stereoisomer.” *Id.*

The *Aventis* court concluded that the purified 5(S) stereoisomer of ramipril was rendered obvious by the mixture of ramipril stereoisomers in view of the structural similarity between ramipril and enalapril and the teaching that SSS enalapril is therapeutically superior to its SSR stereoisomer. *Id.* at 1302. In reaching this conclusion, the court noted that “[t]he close structural analogy between 5(S) and SSSSR ramipril and SSS and SSR enalapril would have led a person of ordinary skill to expect 5(S) and SSSSR ramipril to differ similarly in potency.” *Id.* Also important to the court’s decision was evidence in the record that the purification process required to obtain the 5(S) stereoisomer of ramipril was within the capabilities of one skilled in the art. *Id.*

While structural similarity provides a starting point for combining prior art references, Office personnel must bear in mind that a *prima facie* case of obviousness requires more. In addition to structural similarity, it is necessary to show “some motivation that would have led one of ordinary skill in the art to select and then modify a known compound (*i.e.*, a lead compound) in a particular way to achieve the claimed compound.” *Eisai Co. Ltd. V. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353, 1357 (Fed. Cir. 2008) (internal quotations and citations omitted). It follows that, where the record not only fails to reflect such a motivation, but also demonstrates that the proposed modification would instead destroy an advantageous property of the prior art compound, a conclusion of obviousness is unsupported. *Id.* at 1358.

Consequently, AIPLA recommends adding the following Teaching Point based on these two cases: **“In the chemical arts, structural similarity can provide a starting point for combining references. Structural similarity alone, however, is insufficient for combination where there is no reason to modify the references or where the modification would destroy advantageous properties of one of the compounds.”**

In regard to the Teaching Point for **Example 4.9**, a caution should be added in the explanation that there needs to be a sufficient reason to choose the appropriate search terms, and that the statement of rejection should include, where not immediately obvious, reasons for the selection of terms, especially when they are not found in the application under examination. This standard would provide a safeguard against the use of impermissible hindsight, especially in an age where search engines themselves provide results that are only useful *when recognized as such by an inventor*. While it is possible to cast a broad net in searching on the internet, one skilled in the art needs reasons for selecting the search terms that would have been applicable to find the necessary teachings at the time the invention was made.

The Teaching Point in **Example 4.10** notes that a chemical compound may have been obvious over a mixture containing the compound where the method and the selection of the method was routine in the art. However, when considering the patentability of the compound, one should be careful to ascertain whether it would have been obvious to select the method for isolating the compound from the mixture with a reasonable expectation of success.

With regard to the Teaching Point for **Example 4.11**, unless there is a rationale such as a blaze mark or apparent property for selection of a lead compound, the selection itself may be the evidence for a legal conclusion of nonobviousness. In addition, it is important to consider the size of the group from which a lead compound is drawn as well as the uses and variations that such a group has been used.

With regard to **Example 4.13**, AIPLA questions the use of *Altana Pharma AG v. Teva Pharmaceuticals USA, Inc.*, 566 F.3d 999 (Fed. Cir. 2009), as the basis for a Teaching Point. Because the issue in the case was the denial of a preliminary injunction, the case was decided on a different standard of review than the other cases in the Guidelines. The *Altana* decision did not affirm a finding of invalidity but only affirmed the finding that a substantial question of validity had been raised. In addition, if there were an error in the District Court's analysis, it could only be reversed by the Federal Circuit if there were an abuse of discretion. *Id.* at 1005. Although the Guidelines make it clear that these findings are "preliminary," we are concerned that this distinction may not be appreciated by the Office personnel.

Essentially, the analysis presented in the Guidelines is that of the District Court, with minimal attention given to the substantive review by the Federal Circuit. Germane to the Teaching Point, the appellant contended that a larger number of possible compounds should have been considered in addition to the eighteen compounds in Altana's prior patent. AIPLA notes that the court, bound by its limited standard of review, merely accepted the opinion of the expert as ratified by the court rather than analyze whether this contention was correct.. *Id.* at 1008.

In addition, AIPLA is concerned that a reference, relied upon to find a substantial question of validity, in fact taught away from the reasoning used to modify the lead compound to reach the patented product. In particular, the District Court relied on the Sachs article as teaching that the product should have a pK_a of 4 or less, and then relied on the Bryson article as teaching how to obtaining that pK_a . The Federal Circuit noted that Bryson article taught that the proposed modification would produce a much higher pK_a , one that would not have been suitable in view of the Sachs article. *Id.* at 1009.

Again, because the Federal Circuit’s review of the evidence was limited to a finding of an abuse of discretion, this error in the District Court’s decision was ignored. Consequently, AIPLA recommends removing this Teaching Point from the Guidelines.

(c) The Obvious To Try Rationale

In regard to the “obvious to try” **Examples 4.14-4.19**, it is important to consider the field of the invention because conclusions of obviousness may be attenuated or altered depending on the nature of the technology and field of endeavor. For example, biotechnology, pharmaceutical, and many electrical inventions arise in uncrowded arts where many things remain to be done. One might articulate many reasons for finding something obvious, but such articulation must also account for the field of endeavor.

Consider, for example, *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005). While this was a case addressing utility, the issue was whether or not general teachings were sufficient to perform an endeavor and provide a useful result. What is obvious today may not have been obvious a decade prior when an application was filed. Office personnel are cautioned that impermissible hindsight is an inevitable problem particularly when dealing with cutting edge technology. Where evidence, rationales, or motivations are not specifically articulated in a timely published reference, it is imperative that a rejection carefully explain why a line of reasoning would have applied *at the time the invention was made*.

Further with regard to **Example 4.16** (and any situation in which one is selecting from among candidate pools), it is important to consider the reasonable expectation of success at the time the invention was made, as well as to articulate appropriate reasoning commensurate with the technology at hand. In the biotechnology arts, it may be routine to screen for thousands of monoclonal antibodies, but the reason for screening in a particular instance may well reflect on a reasonable expectation of success or a useful result. The same considerations would apply for an electrical invention where one would need to explain why a particular component was selected if the rationale is not apparent from the applicable prior art.

In regard to the Teaching Point of **Example 4.18**, when discussing chemical mixtures, including isomers, it is important to consider any unexpected results or other secondary consideration in light of the relevant technology.

Further, with regard to **Example 4.19** and *Rolls-Royce, PLC v. United Technologies Corp.*, 603 F.3d 1325 (Fed. Cir. 2010), AIPLA recommends amending the Teaching Point to clarify what findings of fact are needed to support an “obvious to try” rationale.

In *Rolls-Royce*, in addition to the Teaching Point described in the *KSR* Guidelines, the court also discussed other factors that should be taken into account when asserting that a modification of a reference would be obvious to try. The invention in that case related to an outer region of a fan casing for a ducted gas turbine engine in which the outer region was translated forward relative to a leading edge. In the prior art, this outer region previously had only been swept backward.

The appellate court reviewed the record and determined that it did not show that one of ordinary skill in the art would have had any reason to try a forward sweep in the outer region at all. Citing *KSR*, the court stated:

A particular course or selection is not obvious to try unless some design need or market pressure or other motivation would suggest to one of ordinary skill to pursue the claimed course or selection. ... In other words, one of ordinary skill must have good reason to pursue the known options within his or her technical grasp.

Id. at 1339 (internal citations and quotations omitted).

Accordingly, AIPLA recommends amending the Teaching Point to read: “An obvious to try rationale may be proper when the possible options for solving a problem were known and finite. However, if the possible options were not known or finite, then an obvious to try rationale cannot be used to support a conclusion of obviousness. **Even if the options are known and finite, a particular course or selection is not obvious to try unless some design method need, market pressure, or other motivation would suggest the claimed course or selection to one of ordinary skill.**”

In regard to the “sufficient reasoning” sentence of the Teaching Point in **Example 20**, AIPLA suggests that, if reasoning is not explicit from the art, the reasoning needs to be explained so the reader can understand both the validity of the rejection and what is needed for an attempt to rebut the rejection (*i.e.*, where logical gaps might exist).

AIPLA recommends that the MPEP be revised to clarify that a showing of obviousness or non-obviousness must be based on the combination of teachings or knowledge rather than on individual teachings or knowledge. More specifically, the MPEP discussions of *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981) and *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986), should be revised to indicate that obviousness is a conclusion of law based on a fact finding involving the totality of the teachings or knowledge, rather than on individual teachings or knowledge.

AIPLA further recommends that future updates to the obviousness guidelines include a discussion of examples of evidence that may be considered in evaluating rejections and rebuttals thereto, and of the way such evidence is to be considered by Office personnel. Finally, appropriate MPEP Sections need to be revised to be consistent with the final guidelines.

We appreciate the opportunity to provide these comments on the Notice regarding the “Request for Comments on Examination Guidelines Update: Developments in the Obviousness Inquiry After *KSR v. Teleflex*.” We would be pleased to answer any questions our comments may raise, and we look forward to participation in the continuing development of rules applicable to PTO patent practice.

Sincerely,



Q. Todd Dickinson
Executive Director