Obviousness: Overcoming Obviousness Rejections by Attacking the Prima Facie Case

A Lexis Practice Advisor® Practice Note adapted from *Top Tips for Overcoming Section 103 Obviousness Rejections* by Tom Irving and Stacy Lewis, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

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This practice note teaches patent prosecutors how to overcome a patent examiner's obviousness rejection by attacking the examiner's prima facie case. Obviousness is one of the grounds for rejection of a patent application that is most frequently asserted by the U.S. Patent and Trademark Office (USPTO). Accordingly, knowing how to attack the examiner's prima facie case is an essential patent prosecution skill. If you successfully attack the prima facie case, rather than rebutting it, you may avoid amending the claims and the resultant possibility of prosecution history estoppel that may later limit your client's ability to rely on the doctrine of equivalents to prove infringement of its patent.

We discuss how to attack the prima facie case of obviousness in the context of the examination of patent application claims by a patent examiner. Note that the same principles apply in the context of inter partes patentability challenges before the USPTO's Patent Trial and Appeal Board (PTAB), because the claims do not have a presumption of validity before the PTAB. However, in PTAB proceedings, the initial burden of persuasion is on the petitioner, the rebuttal burden is on the patent owner, and PTAB operates as an adjudicator of the parties' arguments. For a discussion of obviousness in the context of federal court litigation, see Obviousness in Patent Litigation.

The Essential Law on Obviousness

Even though the prior art does not identically disclose or describe the invention, a patent cannot be granted on the invention if the differences between the invention and the prior art are such that the invention as a whole would have been obvious to the person of ordinary skill in the pertinent art at the pertinent time. 35 U.S.C. § 103. 35 U.S.C. § 102 defines the prior art that can be used to invalidate a patent for obviousness under Section 103.

The Leahy-Smith America Invents Act of 2011 (AIA) changed the definition of prior art for patents governed by the post-AIA version of the Patent Act. For a discussion of the changes to Section 102 made by the AIA, see America Invents Act Fundamentals — First-To-File. For a summary of the categories of prior art under the pre-AIA and post-AIA versions of 35 U.S.C. § 102, see Prior Art Checklist (Comparing Pre-AIA and Post-AIA Law).

For patents and patent applications governed by the pre-AIA version of the Patent Act, the relevant time period for evaluating whether the person skilled in the pertinent art would have considered the invention to have been obvious is just before the invention was made. For patents governed by the post-AIA version of the Patent Act, the relevant time period is just before the effective filing date of the claimed invention.

You will find the foundational Supreme Court guidance on how to conduct an obviousness analysis in Graham v. John Deere Co. of Kansas City, 383 U.S. 1 (1966) (setting forth the so-called *Graham* factors) and KSR International Co. v. Teleflex, Inc., 550 U.S. 398 (2007).

In crafting arguments of nonobviousness during prosecution, you should cite the Manual of Patent Examining Procedure (MPEP) (the examination handbook of the USPTO's examining corps). You should also cite the pertinent case law in footnotes. The case law will provide valuable support if the claims issue and are later challenged before the PTAB or the district courts. By having cited case law during prosecution, the case law will not appear to be an afterthought.

The Prima Facie Case of Obviousness – A Procedural Tool of Examination

The legal concept of prima facie obviousness represents a procedural tool to allocate the burden of going forward and the burden of persuasion as between the USPTO and the applicant. See In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992); In re Piasecki, 745 F.2d 1468, 1471 (Fed. Cir. 1984); In re Rinehart, 531 F.2d 1048, 1051-52 (CCPA 1976). The USPTO bears the initial burden of establishing the prima facie case. MPEP § 2142 ("The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness"). In satisfying this burden, the MPEP instructs the examiner to step back in time and into the shoes of the hypothetical person of ordinary skill in the art "when the invention was unknown and just before it was made." Under the post-AIA version of Section 103, the key time would be just before the effective filing date. MPEP § 2142.7.

If the examiner does not establish a prima facie case, you need not submit any evidence of nonobviousness in rebuttal. But if the examiner shows that the prior art suggests the invention in question, rendering it prima facie obvious, the burden shifts to the applicant to come forward with evidence or argument persuasive of the invention's nonobviousness. MPEP § 2142. If the applicant puts forth rebuttal evidence, the examiner must reconsider the question of obviousness de novo based on the totality of the evidence. MPEP § 2142.

The Examination Guidelines Update: Developments in the Obviousness Inquiry After KSR v. Teleflex, 75 Fed. Reg. 53643 and MPEP § 2143 provide valuable guidance for overcoming obviousness challenges at the USPTO. These Guidelines contain detailed reviews of several Federal Circuit cases and lessons from each. The Guidelines arrange the cases in the following groups of obviousness rationales:

> 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

See MPEP § 2143(I).

You may attack the examiner's prima facie case by challenging one or more of the following:

- Any unsupported conclusions or reliance on only common sense by the examiner (Argue that the examiner's rejection is conclusory and unsupported.)
- Any failure to consider the rebuttal evidence or failure to reconsider all the evidence (Do not accept simply the "knockdown" value of the rebuttal evidence—argue that the examiner failed to consider the totality of the evidence.)
- A faulty *Graham* analysis or any failure to undertake a full *Graham* analysis
- Any conclusion of obviousness based on the differences between the prior art and the invention rather than the obviousness of the claimed invention "as a whole."
- A finding of obviousness based on reference(s) that do not disclose one or more claim limitations (Argue that the examiner ignored a claim limitation.)
- Any assumption that there was a finite number of predictable solutions with anticipated success (Show that the number of predictable solutions for which success

could be anticipated was not finite, and show how many choices the inventor had to make and how uncertain the outcomes of each choice were.)

- Any finding that a person of ordinary skill in the art would have been reasonably motivated to combine or modify the prior art to arrive at the claimed invention (You might challenge the examiner's analysis on a variety of grounds, for example, the prior art taught away from the claimed invention, or the prior art failed to suggest the solution to the problem solved by the invention.)

- A finding that the claimed invention was obvious to try (Emphasize unpredictability and variables and, if possible, show unexpected results.)

The arguments that you can make in support of each challenge are discussed in detail below.

The Examiner's Rejection Is Conclusory and Unsupported

You should always challenge any unsupported conclusions or reliance on only common sense by the examiner, by arguing that the rejection is conclusory and unsupported.

An examiner must provide fully supported reasoning in an obviousness rejection. "The key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in KSR Int'l Co. v. Teleflex Inc., 550 U.S. 538, 418, (2007) noted that the analysis supporting a rejection under 35 U.S.C. § 103 should be made explicit." MPEP § 2143.

The Federal Circuit pulled no punches in its opinion in In re Lee, 277 F.3d 1338 (Fed. Cir. 2002), vacating the Board's obviousness rejection based only on "common sense" rather than scientific analysis. The Board did not explain the "common knowledge and common sense" on which it relied. The Federal Circuit cited extensive authority that reliance on common sense alone is insufficient. Instead, "the agency tribunal must present a full and reasoned explanation of its decision. The agency must set forth its findings and the grounds thereof, as supported by the agency record, and explain its application of the law to the found facts." 277 F.3d at 1342. The court went on to note as follows:

- The common knowledge and common sense on which the Board relied in rejecting the application are not the specialized knowledge and expertise contemplated by the Administrative Procedure Act. Conclusory statements do not fulfill the agency's obligation.

- Common knowledge and common sense, even if assumed to derive from the agency's expertise, do not substitute for authority when the law requires authority.

- The rationale that the agency relies on must be set forth.

277 F.3d at 1344–45.

See also, In re Zurko, 258 F.3d 1379 (Fed. Cir. 2001) (deficiencies of references cannot be saved by appeals to common sense and basic knowledge without any evidentiary support.); In re Nuvasive, Inc., 842 F.3d 1376, 1383 (Fed. Cir. 2016), ("'conclusory statements' alone are insufficient and, instead, the finding must be supported by a 'reasoned explanation'").

The Examiner Failed to Consider the Totality of the Evidence

Challenge any failure to consider the rebuttal evidence or failure to reconsider all the evidence—do not accept simply the "knockdown" value of the rebuttal evidence.

An examiner's decision to maintain or withdraw a rejection requires consideration of all the evidence of record. The totality of the evidence includes not only the facts derived from the *Graham* inquires but also any rebuttal evidence an applicant may have submitted. MPEP § 2141(V) and § 2145; see In re Eli Lilly & Co., 902 F.2d 943, 945 (Fed. Cir. 1990) ("Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself."). The Federal Circuit reemphasized the importance of basing obviousness determinations on the totality of the record in its review of the Board's decision in In re Chu, 66 F.3d 292 (Fed. Cir. 1995). The court held that the Board erred in requiring that the appellant's specification contain the evidence and arguments submitted in response to an obviousness rejection, particularly since "obviousness is determined by the totality of the record including, in some instances most significantly, the evidence and arguments proffered during the give-and-take of ex parte patent prosecution." 66 F.3d at 299.

The Examiner Failed to Undertake a Full Graham Analysis

You should challenge a faulty *Graham* analysis or any failure to undertake a full *Graham* analysis.

The legal conclusion that a claim is obvious depends on at least the following four underlying factual issues set forth in Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17 (1966):

- The scope and content of the prior art
- The differences between the prior art and the claims at issue
- The level of ordinary skill in the pertinent art
- An evaluation of any relevant secondary considerations

In April 2007, the Supreme Court affirmed the *Graham* analysis as the framework for determining obviousness. See KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1739 (2007). See MPEP § 2141. The four *Graham* factors are not alternatives; all four factors must be analyzed. Kinetic Concepts, Inc. v. Smith & Nephew, Inc., 688 F.3d 1342, 1360 (Fed. Cir. 2012).

As part of the first *Graham* inquiry (the scope and content of the prior art), you must make certain that any prior art reference that the examiner relies on constitutes analogous art. See In re Clay, 966 F.2d 656, 659 (Fed. Cir. 1992); see also In re Oetiker, 977 F.2d 1443, 1447 (Fed. Cir. 1992); In re Deminski, 796 F.2d 436, 442 (Fed. Cir. 1986); MPEP § 2141.01(a).

In addition, there may be other grounds for objecting to a reference's characterization as prior art or other relevant evidence. For example, you may assert that the reference does not enable what it discloses, it does not antedate the claim(s) due to a faulty priority date assertion, or it is not properly characterized as prior art based on the difference between pre-AIA and AIA prior art definitions.

The examiner must consider the prior art in its entirety. The prior art is good for everything it teaches, not just the invention that it describes or claims. "It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." In re Wesslau, 353 F.2d 238, 241 (CCPA 1965); see also Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 449 (Fed. Cir. 1986) (holding that the district court, by failing to consider a prior art reference in its entirety, ignored portions of the reference that led away from obviousness).

The Examiner Failed to Consider the Claimed Invention as a Whole

Challenge any conclusion of obviousness based on the differences between the prior art and the invention rather than the obviousness of the claimed invention as a whole.

In determining obviousness, both pre-AIA and post-AIA Section 103 expressly requires considering the claimed invention as a whole. Focusing the Section 103 inquiry on a particular aspect of the invention that differs from the prior art improperly disregards the "as a whole" statutory mandate. MPEP § 2141.02. See Jones v. Hardy, 727 F.2d 1524, 1530 (Fed. Cir. 1984); Ruiz v. A.B. Chance Co., 357 F.3d 1270, 1275 (Fed. Cir. 2004). ("The 'as a whole' instruction in title 35 prevents evaluation of the invention part by part. This form of hindsight reasoning, using the invention as a roadmap to find its prior art components, would discount the value of combining various existing features or principles in a new way to achieve a new result—often the very definition of invention."); Princeton Biochemicals, Inc. v. Coulter, Inc., 411 F.3d 1332, 1337 (Fed. Cir. 2005); Allergan, Inc. v. Apotex, Inc., 754 F.3d 952 (Fed. Cir. 2014).

Similarly, an obviousness analysis should consider not only the subject matter literally recited in the claims but also the inherent properties of the claimed invention. MPEP § 2141.02(V). See In re Antonie, 559 F.2d 618, 619 (CCPA 1977). The recognition by Antonie of the relationship between the result produced and the particular design parameters was the touchstone of nonobviousness in this case.

The Examiner Ignored a Claim Limitation

Challenge a finding of obviousness based on reference(s) that do not disclose one or more claim limitations, by arguing that the examiner improperly ignored one or more limitations.

All the claim limitations must be considered when assessing patentability. MPEP § 2143.03. If a claim limitation is not met by the prior art reference or other appropriate evidence, a rejection is inappropriate. Also, "[i]t is . . . entirely proper to consider the functions of an invention in seeking to determine the meaning of particular claim language." Medrad, Inc. v. MRI Devices Corp., 401 F.3d 1313, 1319 (Fed. Cir. 2005).

Even if the USPTO initially considers that a claim limitation does not comply with the requirements of 35 U.S.C. § 112 or constitutes new matter, it cannot disregard the limitation in evaluating the patentability of the claimed invention as a whole. See In re Grasselli, 231 U.S.P.Q. 393, 394 (Bd. Pat. App. 1983) ("All of these limitations of the claims must be considered regardless of whether or not they were supported by the specification as filed."), aff'd mem., 738 F.2d 453 (Fed. Cir. 1984); MPEP § 2143.03.

The Number of Predictable Solutions with Anticipated Success Was Not Finite

Challenge any conclusion that the invention was merely one of a finite number of predictable solutions. Demonstrate that the number of predictable solutions for which success could be anticipated was not finite. Show how many choices the inventor had to make and how uncertain the outcomes of each choice were.

Post-*KSR*, applicants can try to overcome an obviousness rejection by showing a wide range of possible outcomes. In contrast, a limited range of choices, or, in the words of the Supreme Court in *KSR*, "a finite number of identified, predictable solutions" may support a conclusion of obviousness. For example, in Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd., 533 F.3d 1353 (Fed. Cir. 2008), the Federal Circuit articulated the approach as requiring an examination of whether there are reasons for narrowing the prior art universe to a finite number of identified, predictable solutions. If so, a small and finite number of alternatives might support an inference of obviousness. 533 F.3d at 1359.

Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc., 520 F.3d 1358, 1363–64 (Fed. Cir. 2008) is also instructive. The defendant argued that there was a finite number of identified, predictable solutions. However, the Federal Circuit was not persuaded and laid out all the steps that a person of ordinary skill in the art would have to take and how each step involved unpredictability.

Cases such as *Eisai* and *Ortho-McNeil* suggest that practitioners have a better chance of surviving an obviousness rejection if they can establish that there is no finite number of predictable solutions with anticipated success—and the number can be rather small. In other words, a rather small number may not be finite, contrary to what one would expect from mathematics.

The Examiner Failed to Show a Reasonable Motivation to Combine or Modify the Prior Art

Consider asserting that the examiner failed to show that a person of ordinary skill in the art would have been reasonably motivated to combine or modify the cited prior art in such a way as to arrive at the claimed invention. Evaluate the following possible arguments, which are discussed in more detail below:

- The prior art or other appropriate evidence did not provide a basis for the modification.
- The examiner's proposed modification of the prior art renders the invention inoperable.
- The examiner relied on prior art that did not recognize the unsolved problem or the solution.
- The prior art teaches away from the invention.
- The prosecution history of the cited prior art rebuts a motivation to combine references.
- The examiner's position on the state of knowledge of those skilled in the art is incorrect.
- There was no reasonable expectation of success in combining or modifying the prior art.

The Prior Art or Other Appropriate Evidence Did Not Provide a Basis for the Modification

A conclusion of obviousness cannot derive from the applicant's specification. It is improper, in determining whether a person of ordinary skill would have been led to this combination of references, simply to use "that which the inventor taught against its teacher." In re Lee, 277 F.3d at 1343, citing W.L. Gore & Assocs. v. Garlock, Inc., 721 F.2d 1540, 1553 (Fed. Cir. 1983). See In re Dow Chem. Co., 837 F.2d 469, 473 (Fed. Cir. 1988) ("[t]here must be a reason or suggestion in the art for selecting the procedure used, other than the knowledge learned from the applicant's disclosure"); Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., 381 F.3d 1371 (Fed. Cir. 2004) ("the suggestion to combine references must not be derived by hindsight from knowledge of the invention itself").

Using an applicant's disclosure as a blueprint to reconstruct the claimed invention from isolated pieces of the prior art contravenes the statutory mandate of Section 103 which

requires judging obviousness at the point in time when the invention was made (or, for applications governed by the post-AIA version of Section 103, just before the filing date). See Grain Processing Corp. v. American Maize-Prods. Co., 840 F.2d 902, 907 (Fed. Cir. 1988). Calling the defendants' analysis a poster child for hindsight reasoning, the Federal Circuit affirmed the finding of nonobviousness in Otsuka Pharmaceutical Co., Ltd. v. Sandoz, Inc., 678 F.3d 1280, 1291–92 (Fed. Cir. 2012). The Federal Circuit used the following two-part inquiry typically called a "lead compound analysis" but applicable to any art field:

1. Determine whether a chemist of ordinary skill would have selected the asserted prior art compounds as lead compounds, or starting points, for further development efforts.
2. If so, then determine whether the prior art would have supplied one of ordinary skill in the art with a reason or motivation to modify a lead compound to make the claimed compound with a reasonable expectation of success.

The inventor's own path itself never leads to a conclusion of obviousness because that is hindsight. What matters is the path that the person of ordinary skill in the art would have followed, as evidenced by the pertinent prior art. See Otsuka, 678 F. 3d at 1296. You should always challenge any hindsight reasoning that relies on the applicant's specification.

The Examiner's Proposed Modification of the Prior Art Renders the Invention Inoperable

If a proposal for modifying the prior art in an effort to attain the claimed invention causes the art to become inoperable or destroys its intended function, then the requisite motivation to make the modification would not have existed. See In re Fritch, 972 F.2d 1260, 1265 n.12 ("A proposed modification [is] inappropriate for an obviousness inquiry when the modification render[s] the prior art reference inoperable for its intended purpose."); In re Ratti, 270 F.2d 810, 813 (CCPA 1959) (holding the suggested combination of references improper under § 103 because it "would require a substantial reconstruction and redesign of the elements shown in [a prior art reference] as well as a change in the basic principles under which [that reference's] construction was designed to operate"); In re Gordon, 733 F.2d 900, 902 (Fed. Cir. 1984) ("The question is not whether a patentable distinction is created by viewing a prior art apparatus from one direction and a claimed apparatus from another, but, rather, whether it would have been obvious from a fair reading of the prior art reference as a whole to turn the prior art apparatus upside down"). See MPEP § 2143.01(V) and (VI).

The Examiner Relied on Prior Art That Did Not Recognize the Unsolved Problem or the Solution

You should challenge any conclusion of obviousness that does not explain how the problem was known in the field or how the prior art or other relevant evidence suggested the solution. Be aware that even if the prior art clearly recognized the problem, it may not have suggested the solution.

Sometimes, particularly with the aid of hindsight, the art appears combinable or modifiable in a manner that will yield the claimed invention. That itself will not make the resultant modification obvious, however. In Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., 381 F.3d 1371 (Fed. Cir. 2004), the district court found the claimed implantable heart stimulator would have been obvious because each of the claimed elements was previously known. Specifically, "there was a known need to treat mixtures of arrhythmias, and that it would have been obvious to combine known methods of separate treatment." 381 F.3d at 1377. The Federal Circuit disagreed: "Recognition of a need does not render obvious the achievement that meets that need. There is an important distinction between the general motivation to cure an uncured disease . . . , and the motivation to create a particular cure . . . Recognition of an unsolved problem does not render the solution obvious." Id. In *Cardiac*, the Federal Circuit found the claims would not have been not obvious.

The Prior Art Teaches Away from the Invention

Try to show the prior art would have led one in ordinary skill in the art in a different direction than the claimed invention or would have meant that one of ordinary skill in the art would not have expected success to proceed on the path resulting in the claimed invention.

The state of the art at the time of the effective filing date of the invention may have pointed researchers in a different direction than that followed by the inventor. The Federal Circuit has repeatedly recognized that proceeding contrary to the accepted wisdom in the art represents "strong evidence of unobviousness." In re Hedges, 783 F.2d 1038, 1041 (Fed. Cir. 1986); W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1552 (Fed. Cir. 1983) (prior art teaching that conventional polypropylene should have reduced crystallinity before stretching and should undergo slow stretching led away from the claimed process of producing porous article by expanding highly crystalline PTFE by rapid stretching).

Practitioners are cautioned, however, that "teaching away" can be a high bar and is usually not met by mere disclosure

of alternatives or even a description as somewhat inferior. MPEP § 2143(E) and § 2143.01(I); In re Gurley, 27 F.3d 551 (Fed. Cir. 1994); In re Fulton, 391 F.3d 1195, 1201 (Fed. Cir. 2004); Galderma Labs. v. Tolmar, Inc., 737 F.3d 731, 738 (Fed. Cir. 2013).

Citing In re Gurley and In re Fulton, the Federal Circuit reiterated the proper standard for teaching away as follows: a reference will teach away when it suggests that the developments flowing from its disclosures are unlikely to produce the objective of the applicant's invention. A statement that a particular combination is not a preferred embodiment does not teach away absent clear discouragement of that combination. See Syntex (U.S.A.) LLC v. Apotex, Inc., 407 F.3d 1371, 1380 (Fed. Cir. 2005).

The Prosecution History of the Prior Art Rebuts a Motivation to Combine References

If an examiner rejects your claim based on patents or published patent applications, it may be worth having a close look at the prosecution history of the patent or application. You may be able to use it to rebut any asserted motivation to combine references.

In the prosecution of U.S. Patent No. 5,976,195, an obviousness rejection was overcome based on the prosecution history of the cited reference, as well as its specification. The applicant was able to argue that the prosecution history strongly counseled against making the combination that the examiner asserted was obvious. The claim at issue read as follows:

> An oxidation dye composition for keratin fibers, said composition comprising, in a medium which is suitable for dyeing, at least one oxidation dye precursor and at least one anionic amphiphilic polymer containing at least one hydrophilic unit and at least one allyl ether unit containing a fatty chain.

This claim was initially rejected as obvious over the prior art references Cohen in view of Holden. Cohen taught two-part aqueous hair dye compositions which form a gel upon mixing. Cohen's examples included two-part compositions wherein the first part comprises an alkalizing agent such as monoethanolamine, the oxidation base p-phenylenediamine, the coupler resorcinol, a cationic polymer, sodium sulfite, and water, and wherein the second part comprises hydrogen peroxide, an anionic ACULYN polymer (a copolymer of acrylic or methacrylic acid with their lower alkyl esters), and water.

The examiner relied on Holden as teaching the specifically claimed anionic amphiphilic polyacrylate thickeners (i.e., Salcare SC80 and Salcare SC90) for use in personal care products, including hair gels. The examiner also relied on Holden as teaching that these polymers are insoluble in free acid form, but dissolve in water by increasing the pH, thereby forming a gel.

According to the examiner, it would have been obvious to one of ordinary skill in the art at the time the invention was made to at least partially substitute the anionic polymers in the developer solutions of Cohen, which also contain the claimed hydrogen peroxide oxidants, with the Salcare associative polyacrylate thickeners as taught by Holden, because Cohen does not require any specific anionic polymers for addition to the patentee's compositions.

But based on the specification and the prosecution history of Cohen, the applicant was able to show that the unpredictability associated with the subject matter of Cohen was so high, there was no way one of ordinary skill in the art would have read Cohen to teach that any anionic polymer could be used.

Cohen heavily emphasized the unpredictability associated with oxidative hair dyes throughout his patent specification. For example, Cohen taught that oxidative dyes having a two-part system, as recited therein, involve a "delicate balance" designed to satisfy seven different conditions. Cohen utilized only ACULYN 33 in his examples and characterized the selection as "critical." Cohen emphasized, moreover, in the file history the noninterchangeability of anionic polymers in general with the specific water-insoluble anionic acrylic polymers he found useful. In a claim amendment, Cohen urged that prior art ACULYN 22 is "very different" from ACULYN 33, and filed an expert declaration testifying that ACULYN 22 is unacceptably much more volatile and sensitive to concentration changes than ACULYN 33.

Viewed in light of its prosecution history, the applicant showed that Cohen provided no rule or basis for selecting anionic polymers other than ACULYN 33. One skilled in the art would thus have had no motivation to substitute Salcare SC90 or SC80, and the rejection was overcome.

The Examiner's Position on the State of Knowledge of Those Skilled in the Art Is Incorrect

Consider challenging the examiner's position on the state of knowledge of a person of ordinary skill in the art skilled by filing a declaration as to the state of knowledge in the art at the pertinent time.

The point of disagreement with an examiner rejecting a claim for obviousness may be the state of the art at the time of the relevant time and what one of ordinary skill in the art

would have understood and reasonably been motivated to do. In the prosecution of U.S. Patent No. 5,527,814 to Louvel, the applicant was able to go to the author of the reference asserted by the examiner and get the author to retract statements made in the reference, leading to an allowance of the claims.

The claim read as follows:

> A method for treating a mammal with amyotrophic lateral sclerosis, comprising the step of administering to said mammal in need of said treatment an effective amount of 2-amino-6-(trifuoromethoxy)-benzothiazole [riluzole] a pharmaceutically acceptable salt thereof.

The examiner applied Munsat et al. in view of Girdlestone et al. and Mizoule et al. in an obviousness rejection, arguing that the Munsat article taught antiglutamate agents as a treatment for amyotrophic lateral sclerosis (ALS). The applicant spoke with Dr. Munsat, who agreed that at the time the article was written and published, it was reasonable to try using antiglutamates in treating ALS, but by the time of the invention, it was not reasonable to expect that any particular antiglutamate would statistically significantly prolong the lives of those patients suffering from this fatal disease. Also, by March 1992, the relevant time, there were several other hypotheses for etiology-based therapeutic approaches.

Dr. Munsat testified as follows:

> "[It is fair to say that at the time Dr. Louvel filed his French patent application in March 1992, one skilled in the art, notwithstanding the hypothesis proposed in my Therapie 1990 article, would have had no reasonable expectation that Riluzole would be successful in treating ALS . . . . Given the great uncertainty in treating ALS that existed in March 1992, one skilled in the art would have found the success in treating ALS of Dr. Louvel's invention utilizing Riluzole to be unexpected."

The applicant then argued that, based on the primary Munsat reference, that there was no reasonable expectation at the time of Louvel's priority date, that Riluzole would be successful in treating ALS. Therefore, when the totality of the evidence was considered, as of Dr. Louvel's priority date, March 6, 1992, Louvel's invention, as defined, for example, in amended claim 2, would not have been obvious to one of ordinary skill in the art. Certainly, there was no reasonable expectation that Riluzole would be successful in treating ALS.

The claims issued and survived a challenge in the district court, including the court's rejection of the theory that it would have been obvious to consider treating ALS with antiglutamates. See Impax Labs., Inc. v. Aventis Pharms., 333 F. Supp. 2d 265, 275 (D. Del. 2004), on appeal, 545 F.3d 1312 (Fed. Cir. 2008).

There Was No Reasonable Expectation of Success in Combining or Modifying the Prior Art

Analyze possible grounds for challenging the examiner's position that one of ordinary skill in the art would have had a reasonable expectation of success in combining or modifying the prior art references to arrive at the claimed invention.

Beyond looking to the prior art to determine if it suggests doing what the inventor has done, you must also examine whether the art or other appropriate evidence provides the required expectation of succeeding in that endeavor. See In re Dow Chem. Co., 837 F.2d at 473 ("Both the suggestion and the expectation of success must be founded in the prior art, not in applicant's disclosure."). "Obviousness does not require absolute predictability, but a reasonable expectation of success is necessary." In re Clinton, 527 F.2d 1226, 1228 (CCPA 1976).

Consider the following:

- **Look for any conflict in the teachings of the prior art references.** Sometimes one of the prior art references conflicts with the teachings of another reference. In those instances, an examiner must consider all of the prior art, taking into account the degree to which one reference might fairly discredit the other; selective conclusions are not allowed. See In re Young, 927 F.2d 588, 591 (Fed. Cir. 1991) ("When prior art contains apparently conflicting references, the [USPTO] must weigh each reference for its power to suggest solutions to an artisan of ordinary skill"); MPEP § 2143.01(II).

- **Submit evidence showing a lack of expectation of success.** An applicant may submit evidence, typically in the form of a declaration or affidavit, showing that the prior art does not provide a reasonable expectation of succeeding in doing what the applicant has done. See In re Rinehart, 531 F.2d 1048, 1051(CCPA 1976); Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1207–08 (Fed. Cir. 1991).

The Examiner Inappropriately Applied Obvious to Try

You may challenge the application of any "obvious to try" rejection by emphasizing unpredictability and variables with no guidance. If possible, show unexpected results.

Prior to *KSR*, it was well-established that "obvious to try" was not the standard for evaluating patentability under 35 U.S.C. § 103. See, e.g., Ecolochem, Inc. v. Southern California Edison Co., 227 F.3d 1361, 1374 (Fed. Cir. 2000) ("With hindsight, we could perhaps agree that the Houghton article seems like an obvious place to start . . . But, 'obvious to try' is not the standard."). Yet, the *KSR* court articulated the following scenarios in which "obvious to try" is enough to defeat patentability under 35 U.S.C. § 103:

> 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 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.

KSR, 550 U.S. at 420.

There is a line of post-*KSR* obviousness cases from the Federal Circuit in which claims have been found invalid because they were obvious to try. In Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348 (Fed. Cir. 2007), for example, the Federal Circuit invalidated claims to the besylate salt of amlodipine as obvious because the prior art provided "ample motivation to narrow the genus of 53 pharmaceutically-acceptable anions disclosed by Berge to a few, including benzene sulphonate." Pfizer, Inc., 480 F.3d at 1367.

In In re Kubin, 561 F.3d 1351(Fed. Cir. 2009), the Board held biotech claims to isolated nucleic acid molecule obvious. The Federal Circuit affirmed, repudiating its 1995 *Deuel* opinion in favor of its 1988 *O'Farrell* opinion and the Supreme Court's *KSR* opinion. In its analysis, however, the Federal Circuit pointed out that "obvious to try" is erroneously equated to obviousness in the following circumstances:

- The inventor is faced with numerous possible choices where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. –or–
- The prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.

See In re Kubin, 561 F.3d at 1359.

In Eisai Co. Ltd. V. Dr. Reddy's Labs., Ltd., 533 F.3d 1353, 1359 (Fed. Cir. 2008), the Federal Circuit articulated the post-*KSR* application of the obvious to try approach as follows:

- Determine if there are reasons for narrowing the prior art universe to a finite number of identified, predictable solutions.
- If so, the small and finite number of alternatives might support an inference of obviousness.

As noted in In re Kubin, 561 F.3d 1351, 1360 (Fed. Cir. 2009), the court cannot, in the face of *KSR*, cling to formalistic rules for obviousness, customize its legal tests for specific scientific fields in ways that deem entire classes of prior art teachings irrelevant, or discount the significant abilities of artisans of ordinary skill in an advanced area of art.

What is considered obvious to try then? According to the USPTO Guidelines, when a person of ordinary skill has good reason to pursue the known options within his or her technical grasp, and this leads to the anticipated success, the result is likely that 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. See MPEP § 2143(I)(E), citing KSR, 550 U.S. at 421.

Conclusion

Showing a lack of predictability or expectation of success may require you to submit the data or declarations earlier in prosecution rather than later. It may even be part of the disclosure in the specification. Such evidence may undermine the alleged prima facie case and remove the need to proceed with rebuttal evidence. But submission of this evidence during prosecution requires careful thought and planning. Evidence or a declaration thrown together in haste, or otherwise considered defective, may even be harmful rather than helpful. See, e.g., K-40 Electronics, LLC v. Escort, Inc., IPR2013-00203, Paper 6, at 6 (PTAB Aug. 29, 2013) (instituting an IPR based on a defective declaration submitted during prosecution). Additionally, the duty of candor (Rule 56) applies. Beware of the danger of inconsistent or non-disclosed data. Finally, bear in mind that declarations may create prosecution history estoppel.

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A significant portion of Tom's current practice is focused on AIA post-grant proceedings, including how to enhance the strength of patents in the pharmaceutical space to protect against post-grant challenges. He has served as lead counsel in numerous patent interferences, reissues, and reexaminations; as counsel in numerous AIA post-grant proceedings; and as an expert witness in patent litigation. Tom directed the preparation of two highly complex IPRs for possible use in settling litigation.

Tom has been extensively involved in counseling, due diligence, prosecution and prelitigation for matters involving major drugs such as Kalydeco®, Orkambi®, Aloxi®, Tecfidera®, Lorcaserin®, Pulmicort® Respules®, Taxotere®, Eloxatin®, Lantus®, Crestor®, Targretin®, Brilinta®, Halaven®, Allegra®, Apidra®, Epiduo Gel®, Rilutek®, Ramipril®, Jakafi®, Duexis®, Viracept®, and other drugs such as Rimonabant®, VX-661, and HMPL 0004®, in clinical trials prior to FDA approval. He successfully reissued the patent for the low molecular weight heparin drug, Lovenox®, a blockbuster product.

For more than 25 years, Tom has served as principal teacher of the Patent Resources Group (PRG) Chemical Patent Practice course, a comprehensive course on U.S. chemical patent law taught twice a year; he coauthors the multi-volume treatise used in the course. He originated PRG's Orange Book and Due Diligence courses, which help prepare patent owners, through effective application drafting and prosecution, to withstand the rigors of AIA's inter partes review (IPR) and post-grant review (PGR). He presents analyses of U.S. Court of Appeals for the Federal Circuit patent decisions for many state bar association groups and has spoken at numerous national trade and bar association meetings such as the Intellectual Property Owners Association, American Intellectual Property Law Association (AIPLA), and American Bar Association. Tom has lectured at many law schools in both the United States and China, and at the Patent Office of the State Intellectual Property Office (SIPO) of the People's Republic of China. He has participated in multiple Strafford Webinars on patent law topics, including several that deal with AIA post-grant proceedings.

Over the years, Tom has been recognized by *Intellectual Asset Management* as a leading patent prosecutor in the D.C. area, and nationally for post-grant procedures. The *Legal 500 U.S.* recognized him for patent portfolio management and licensing. Tom was inducted into the *LMG Life Sciences* Hall of Fame and recognized as the Patent Strategy & Management Attorney of the Year: District of Columbia.

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