Top Tips for Overcoming
Section 103 Obviousness Rejections

by

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I. INTRODUCTION

Assuming novelty, the USPTO, PTAB, or a court must establish that the claimed invention would have been obvious over the prior art. In other words, even though the prior art does not identically disclose or describe the invention, one may not obtain a patent 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.[3] 35 U.S.C. §102 (both pre-AIA §102 and AIA §102) defines the prior art that can be used to invalidate a patent for obviousness under §103. AIA §102, and its definitions of prior art, went into effect March 16, 2013.

Pre-AIA, the relevant time period for evaluating what the person skilled in the pertinent art would have considered to have been obvious is just prior to when the invention was made.[4] Under AIA 35 U.S.C. §103, effective March 16, 2013, the relevant time period is "before the effective filing date of the claimed invention."[5]

In crafting arguments of nonobviousness during prosecution, it is useful to cite both the MPEP, the examination handbook of the examining corps, as well as the case law. The case law will provide valuable support if the claims issue and are then challenged before the Patent Trial and Appeal Board (PTAB) or the district courts. By having footnoted the case law during prosecution, the case law will not appear to be an afterthought.

We now proceed to give you our top 20 tips.

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[3] AIA SEC. 3(c), 125 STAT. 287, amended 35 U.S.C. §103 to remove all the subparagraphs. As of March 16, 2013, 35 U.S.C. §103 reads: "A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious **before the effective filing date of the claimed invention** to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made." (Emphasis added)

[4] Pre-AIA 35 U.S.C. §103(a) provides:

> A patent may not be obtained through the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been **obvious at the time the invention was made** to a person having ordinary skill in the art to which said subject matter pertains. (Emphasis added).

[5] AIA SEC. 3(c), 125 STAT. 287.

Tip 1: Before the USPTO cite the MPEP and footnote the case law; before PTAB, cite the case law.

II. THE *PRIMA FACIE* CASE OF OBVIOUSNESS: A PROCEDURAL TOOL OF EXAMINATION[6]

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 AIA §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, the applicant 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.

Valuable guidance for overcoming obviousness challenges at the USPTO can be

[6] This article discusses the prima facie case of obviousness in the context of examination of patent application claims by a USPTO examiner. The principles apply in the context of IPRs and PGRs, because the claims do not have a presumption of validity. But because the AIA post-grant proceedings are inter partes, the initial burden of persuasion is on the petitioner. The rebuttal burden is on the patentee. PTAB operates as an adjudicator of the parties' arguments.

[7] MPEP §2141 and §2143 were both revised in 2017 and include the following: "[Editor Note: This MPEP section is applicable to applications subject to the first inventor to file (FITF) provisions of the AIA except that the relevant date is the 'effective filing date' of the claimed invention instead of the 'time of the invention,' which is only applicable to applications subject to pre-AIA 35 U.S.C. 102. See 35 U.S.C. 100 (note) and MPEP § 2150 et seq.]." MPEP §2142 is dated 2015, and does not include the revision, but the shift in time for the analysis applies to AIA §103.

found in the “Examination Guidelines Update: Developments in the Obviousness Inquiry After KSR v.Teleflex”[8] and MPEP §2143. These Guidelines provide detailed reviews of several Federal Circuit cases and lessons from each.

The Guidelines arrange the cases in 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.[9]

III. ATTACKING THE PRIMA FACIE CASE; AN EXCELLENT WAY TO WIN

Tip 2: Attacking the prima facie case rather than rebutting may help to avoid amending claims and the resultant possibility of prosecution history estoppel.

A. Examiner’s 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.

[8] https://www.uspto.gov/patent/laws-and-regulations/examination-policy/examination-guidelines-training-materials-view-ksr
[9] MPEP §2143(I).

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 tribunal 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." *Id*. at 1342. The court went on:

> The "common knowledge and common sense" on which the Board relied in rejecting Lee's application are not the specialized knowledge and expertise contemplated by the Administrative Procedure Act. Conclusory statements such as those here provided 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 board … must set forth the rationale on which it relies.

Id. at 1344-1345. *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.'").

Tip 3: Challenge any unsupported conclusions or reliance on only common sense by the examiner.

B. Examiner Failed to Consider the Totality of the 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." *Id.* at 299.

Tip 4: Challenge any failure to consider rebuttal evidence and/or failure to reconsider all evidence, do not accept simply the "knockdown" value of the rebuttal evidence.

C. Examiner Failed to Undertake a Full *Graham* Analysis

The legal conclusion that a claim is obvious depends on at least four underlying factual issues set forth in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966): (1) the scope and content of the prior art; (2) differences between the prior art and the claims at issue; (3) the level of ordinary skill in the pertinent art; and (4) evaluation of any relevant secondary considerations. In April 2007, the Supreme Court affirmed the *Graham* analysis as the framework for determining obviousness. *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).

Consider, with respect to the first inquiry, "scope and content of the prior art." For purposes of evaluating the obviousness of claimed subject matter, one must make certain that a particular reference relied upon constitutes "analogous art." *In re Clay*, 966 F.2d 656, 659-59 (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 grounds for objecting to a reference's characterization as prior art or other relevant evidence, either because it 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 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, 449-49 (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).

Tip 5: Challenge any failure to undertake a full *Graham* analysis or a faulty *Graham* analysis.

D. Failure to Consider the Claimed Invention as a Whole

In determining obviousness, both pre-AIA and AIA §103 expressly require considering the claimed invention "as a whole." Focusing the §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, one must 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.

Tip 6: Challenge conclusion of obviousness based on differences between the prior art and the invention rather than the obviousness of the claimed invention "as a whole."

E. Examiner Ignored a Claim Limitation

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.

Tip 7: Challenge finding of obviousness based on reference(s) that do not disclose a claim limitation.

F. No Finite Number Of Predictable Solutions With Anticipated Success

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 *KSR*, "a finite number of identified, predictable solutions" may support a conclusion of obviousness. For example, *Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353 (Fed. Cir. 2008), the Federal Circuit articulated the approach as:

> determine if there are "reasons for narrowing the prior art universe to a 'finite number of identified, predictable solutions'[.]" If so, "this 'easily traversed, small and finite number of alternatives . . . might support an inference of obviousness.'"

Id. at 1359.

Ortho-McNeil Pharms. Inc. v. Mylan Labs., Inc., (Fed. Cir. 2008), provides an example where although the defendant argued there was a "finite number of identified, predictable solutions," the Federal Circuit was not persuaded and laid out all the steps a person of ordinary skill in the art would have to take and how each step involved unpredictability:

> the record shows that a person of ordinary skill would not even be likely to start with 2,3:4,5 di-isopropylidene fructose (DPF), .. Beyond that step, however, the ordinarily skilled artisan would have had to have some reason to select (among several unpredictable alternatives) the exact route that produced topiramate as an intermediate. Even beyond that, the ordinary artisan in this field would have had to (at the time of invention without any clue of potential utility of topiramate) stop at that intermediate and test it for properties far afield from the purpose for the development in the first place (epilepsy rather than diabetes).
>
> …this clearly is not the easily traversed, small and finite number of alternatives that KSR suggested might support an inference of obviousness.
>
> …Mylan's expert… simply retraced the path of the inventor with hindsight, discounted the number and complexity of the alternatives, and concluded that the invention of topiramate was obvious. Of course, this reasoning is always inappropriate for an obviousness test"

Id. at 1364.

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 that finite number can be rather small. In other words, a rather small number may not be finite, contrary to what one would expect from mathematics.

Tip 8: Show that there is no finite number of predictable solutions

with anticipated success. Show how many choices the inventor had to make and how uncertain the outcomes of each choice were.

G. The Examiner Failed to Show A Reasonable Motivation to Combine/Modify the Reference(s)

1. The Prior Art or Appropriate Evidence Must Provide a Basis for the Modification; Conclusion of Obviousness Cannot Derive from 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 §103 which requires judging obviousness at the point in time when the invention was made. *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 (Fed. Cir. 2012). The Federal Circuit used a 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. ("analysis is guided by evidence of the compound's pertinent properties.… Absent a reason or motivation based on such prior art evidence, mere structural similarity between a prior art compound and the claimed compound does not inform the lead compound

selection." *Otsuka*, 678 F.3d at 1292.

> 2. Would the prior art 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?

Id. at 1291-92.

> Even assuming that one would have selected OPC4392 as a lead compound, the district court found that the Defendants failed to prove that the prior art would have directed one to make the various modifications necessary to convert OPC–4392 into aripiprazole. …On appeal, the Defendants rely in large part on the inventors' and Otsuka's own development efforts in an attempt to prove that aripiprazole would have been obvious. … The inventor's own path itself never leads to a conclusion of obviousness; 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.

Id.

> **Tip 9: Challenge hindsight reasoning relying on the applicant's specification.**

2. Modification Makes 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).

Tip 10. Show how proposed modification renders invention inoperable.

3. Examiner Relied Upon Recognition of Problem Rather than Recognition of 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." *Id.* 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.

Tip 11: Challenge conclusion of obviousness that does not explain how the problem was known in the field and how prior art or other relevant evidence suggested the solution.

4. Prior Art Teaches Away

The state of the art at the time of the effective filing date of the invention in question may have pointed researchers in a different direction than the inventor proceeded. 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 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 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:

> 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.

Syntex (U.S.A.) LLC v. Apotex, Inc., 407 F.3d 1371, 1380 (Fed. Cir. 2005).

> **Tip 12: Show how the prior art would have led one in ordinary skill in the art in a different direction than the claimed invention and/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.**

5. Using the Prosecution History of the Cited Prior Art to Rebut Motivation to Combine References

If an examiner rejects your claim based on an issued patent or published patent application, it may be worth having a close look at the prosecution history of the patent/application. In the prosecution of U.S. Pat. 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 counselled against making the combination the examiner asserted was obvious.

The claim at issue read:

> 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 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.

Holden was relied upon as set forth above 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. Holden was also relied upon above 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**.**

Tip 13: Use the cited prior art to rebut motivation to combine references.

6. Use of Prior Art Reference, an Interview, and the Statement of Reasons for Allowance to Attack *Prima Facie* Case of Obviousness

U.S. Patent Number 6,013,662, provides another example of using the prosecution history of the applied reference to overcome an obviousness rejection.

The rejected claim was to a complex organic compound with possible substituents listed at 6 locations. Each of the six substitutions had options and sometimes several options. But the applicant was able to show that in the prior art

reference, of all the combinations attempted, none attempted the substitution at the precise position used by the inventor.

After this was shown to the examiner in an interview, the claims were allowed: “The compounds disclosed in the examples of [the prior art reference] contain multiple points of alkyl substitution. However, none of the Ref. A compounds are alkyl substituted in the Ar position. Hence, [the prior art reference], taken as a whole, teaches away from the applicants' claimed compounds. There is insufficient motivation to make the applicants' claimed compounds from those of [the prior art reference].” Excerpt from Reasons for Allowance.

Tip 14: Interview the case to show the examiner how the cited reference does not show one of ordinary skill in the art to modify/combine the prior art or provide a reasonable expectation of success to arrive at the claimed invention.

7. Establishing Knowledge of Those Skilled in the Art by a Declaration From the Author of the Prior Art

The point of disagreement with an examiner rejecting a claim for obviousness may be the state of the art at the time of the invention 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, 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:

> 1. A method for treating a mammal with amyotrophic lateral sclerosis[10], 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).

[10] Lou Gehrig’s disease

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: "… 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."

Applicant then argued that, based on the primary Munsat reference, there was no reasonable expectation at the time of Dr. Louvel's priority date, that Riluzole would be successful in treating ALS. Therefore, when the totality of the evidence was considered, one concludes that as of Dr. Louvel's priority date, March 6, 1992, Dr. 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, therewas no reasonable expectation that Riluzole would be successful in treating ALS.

The claims issued and survived 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. "Although riluzole was known to be an antiglutamate, the effectiveness of its antiglutamic properties in treating ALS was not established. Accordingly, the Court finds that the theory that an antiglutamate could treat ALS was known but unconfirmed as of the priority date of the '814 patent." The Federal Circuit reversed the novelty holding, and remanded the case.[11]

Tip 15: Challenge the examiner's position on the state of knowledge of those skilled in the art.

[11] *Impax Labs., Inc. v. Aventis Pharmaceuticals, Inc*., 333 F.Supp.2d 265 (D. Del., August 30, 2004), *on appeal*, 545 F.3d 1312 (Fed. Cir. 2008).

8. No Reasonable Expectation of Success

a. Conflict in Teachings of the Prior Art References

Beyond looking to the prior art to determine if it suggests doing what the inventor has done, one must also consider if 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).

Situations may arise where 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).

Tip 16: Point out how conflicting teachings in the prior art would have meant no reasonable expectation of success.

b. 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 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).

Tip 17: Challenge the examiner’s position that one of ordinary skill in the art would have had a reasonable expectation of success in combining/modifying the prior art references to arrive at the claimed

invention.

H. Examiner Inappropriately Applied Obvious to Try

Prior to KSR, it was well-established that "obvious to try" was not the standard for evaluating patentability under 35 U.S.C. § 103. *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 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, 127 S.Ct. at 1742, 550 U.S. at 420.

There is a line of post-*KSR* obviousness cases from the Federal Circuit wherein 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." *Id.* 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 if:

(1) 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
>
> (2) "the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it."

Id. at 1359.

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

> determine if there are "reasons for narrowing the prior art universe to a 'finite number of identified, predictable solutions[.]' [citation to KSR and Ortho-McNeil omitted] If so, "this 'easily traversed, small and finite number of alternatives . . . might support an inference of obviousness.'"

Id. at 1359.

As noted in *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009):

> This 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.

Id. at 1360.

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, it is likely that product [was] 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." [citing *KSR*] MPEP §2143(I)(E).

> **Tip 18: Challenge application of obvious to try by emphasizing unpredictability and variables with no guidance; if possible, show unexpected results.**

IV. REBUTTING THE PRIMA FACIE CASE

Only if an examiner establishes a *prima facie* case of obviousness does the burden of going forward shift to the applicant. *See In re Dillon*, 919 F.2d 688, 692 (Fed. Cir. 1990); *In re Giannelli,* 739 F.3d 1375, 1379 (Fed. Cir. 2014).[12] To rebut the examiner's *prima facie* case, the applicant may produce evidence of nonobviousness. As mentioned above, when rebuttal evidence is submitted in response to a prima facie case of obviousness during prosecution, the examiner must then consider all of the evidence anew, irrespective of the strength of the *prima facie* case. *See In re De Blauwe,* 736 F.2d 699, 706 (Fed. Cir. 1984); *In re Rinehart*, 531 F.2d 1048, 1052 (CCPA 1976). If present, objective evidence cannot be disregarded. *See* MPEP §716.01(a); §716.01(d); §2142; MPEP §2145; *Apple Inc. v. International Trade Com'n,* 725 F.3d 1356, 1365 (Fed. Cir. 2013); *TriMed v. Stryker*, 608 F.3d 1333, 1343 (Fed. Cir. 2010). If the examiner finds the evidence insufficient, a full explanation must be provided to the applicant; general statements do not meet this requirement. MPEP §716.01.

A. The Examiner Failed to Consider Objective Indicia of Unobviousness

Objective indicia of nonobviousness provide an indication of the economic and motivational issues and tend to shed light on whether the skilled artisan would have found the modification obvious to do. This evidence can include a showing of unexpected superiority over the prior art as well as other objective indicia of nonobviousness, such as commercial success or a long-felt need. Often, evidence of multiple objective indicia will be submitted at the same time. The type of indicia typically presented in the specification of the application when filed or in the form of an affidavit or declaration during prosecution are:

(1) showing the criticality or unexpected results of the invention;

[12] Similarly in an inter partes proceeding, “once a challenger has presented a prima facie case of invalidity, the patentee has the burden of going forward with rebuttal evidence.” *Prometheus Laboratories, Inc. v. Roxane Laboratories, Inc.*, 805 F.3d 1092, 1101 (Fed. Cir. 2015).

(2) resolution of a long-felt need;

(3) failure of others to find a solution to the problem plaguing the art;

(4) commercial success;

(5) industry's acquiescence in the invention's merit through licensing it;

(6) copying of the invention by others;

(7) disbelief and acclaim by experts in the art of the invention's success;

(8) admissions of nonobviousness by an adversary; and

(9) near simultaneous invention by others.

Evaluating the obviousness of the subject matter as a whole also requires considering the objective evidence of nonobviousness along with the other *Graham* factual inquiries.

For an examiner, PTAB, or a court to credit such objective evidence, the applicant must establish a nexus between the evidence and the merits of the claimed invention. MPEP §716.01(b). This “nexus” between the evidence and the claimed invention “is a legally and factually sufficient connection.” *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988). The objective evidence must also be commensurate in scope with the claims. MPEP §716; *Allergan, Inc. v. Apotex Inc.,* 754 F.3d 952, 965 (Fed. Cir. 2014). If the court finds no nexus to the claimed invention, or that the evidence is not commensurate in scope with the claims, or that, on balance, the objective evidence does not outweigh the showing of obviousness, the objective evidence will fail to rebut a prima facie case of obviousness.

To be persuasive, objective evidence must be supported by actual proof, not simply argument. *See* MPEP §716.01(c).

Tip 19: Submit objective evidence of nonobviousness with supported explanation of nexus and how is commensurate in scope with claimed invention.

B. Objective Proof Of Nonobviousness: Unexpected Results

An applicant can rebut a *prima facie* case of obviousness by presenting comparative test data showing that the claimed invention possesses unexpectedly improved properties or properties that the prior art does not have. If a person of ordinary skill in the art would have been surprised by applicant's results, then the invention could not have been obvious.

An applicant could include support for the unexpected results in the specification. Specifically, an applicant should describe in the application the property or properties alleged to exhibit unexpected results. *See In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997); *In re Davies*, 475 F.2d 667, 671 (CCPA 1973); *In re Stewart*, 222 F.2d 747, 754 (CCPA 1955); *see also Ex parte Engelhardt*, 208 U.S.P.Q. 343, 352 (Bd. Pat. App. 1980) (finding prima facie case of obviousness unrebutted and noting that application did not teach any special or unusual properties for the claimed compound).

In addition to the requirements on all objective evidence outlined above (nexus, commensurate in scope with the claims, fully supportive evidence), courts, examiners, and the PTAB require that the results actually be unexpected. *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1306 (Fed. Cir. 2015)("We also conclude that the district court did not clearly err in finding that the claimed formulation exhibited 'unexpected results,' which differed in kind, not just in degree, from the prior art."). In other words, the unexpectedness must be sufficient "to secure the validity of the claims in suit." *Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1381 (Fed. Cir. 2005).

The most common and effective way applicants establish unexpected results is by performing comparative testing. In addition to the requirements on all objective evidence outlined above (nexus, commensurate in scope with the claims, fully supportive evidence), the courts, examiners, and the PTAB have further requirements on such evidence:

- An applicant must compare his invention to the closest prior art. Further, within the closest prior art reference, the applicant must test against the closest disclosure from that reference. *See* MPEP §716.02(e). If presenting rebuttal evidence such as test results, interview the examiner and try to agree on what kind of testing will

be persuasive before the tests are initiated.

- While an applicant must show that the unexpected results are commensurate in scope with the claims. It is possible that testing one species could be sufficient if there is some sort of supporting evidence, such as proof that equivalence of the other species would be obvious to one skilled in the art. *See* MPEP §716.02(d).

- The results are actually unexpected. *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1306 (Fed. Cir. 2015)("We also conclude that the district court did not clearly err in finding that the claimed formulation exhibited 'unexpected results,' which differed in kind, not just in degree, from the prior art."). In other words, the unexpectedness must be sufficient "to secure the validity of the claims in suit." *Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1381 (Fed. Cir. 2005). *See* MPEP §716.02

Tip 20: Agree on scope of comparative testing with the examiner and submit evidence of unexpected results to show nonobviousness.

V. CONCLUSION

Showing a lack of predictability or expectation of success may require submitting data and/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.

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.[13] Additionally, the duty of candor (Rule 56) applies. A possible danger is inconsistent and/or non-disclosed data. Finally, declarations may create prosecution history estoppel.

[13] *See, e.g.*, K-*40 Electronics, LLC v. Escort, Inc*., IPR2013-00203, Paper 6, at 6 (P.T.A.B. Aug. 29, 2013) (instituting IPR based on defective declaration submitted during prosecution).