

716-Affidavits or Declarations Under 37 CFR 1.132 and Other Evidence Traversing Rejections

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716 Affidavits or Declarations Under 37 CFR 1.132 and Other Evidence Traversing Rejections [R-07.2022]

37 CFR 1.132 Affidavits or declarations traversing rejections or objections.

When any claim of an application or a patent under reexamination is rejected or objected to, any evidence submitted to traverse the rejection or objection on a basis not otherwise provided for must be by way of an oath or declaration under this section.

It is the responsibility of the primary examiner to personally review and decide whether affidavits or declarations under [37 CFR 1.132](#) and other evidence submitted for the purpose of traversing grounds of rejection are responsive to the rejection and present sufficient facts to overcome the rejection. Publications may be evidence of the facts at issue and should be considered to the extent that they are probative and properly submitted. See [MPEP § 716.01](#) *et seq.*

This rule sets forth the general policy of the Office consistently followed for a long period of time of receiving affidavit evidence traversing rejections or objections. All affidavits or declarations presented which do not fall within or under other specific rules are to be treated or considered as falling under this rule.

An affidavit is a statement in writing made under oath before a notary public, magistrate, or officer authorized to administer oaths. See [MPEP § 602](#) *et seq.* for additional information regarding formal requirements of affidavits.

[37 CFR 1.68](#) permits a declaration to be used instead of an affidavit. The declaration must include an acknowledgment by the declarant that willful false statements and the like are punishable by fine or imprisonment, or both ([18 U.S.C. 1001](#)) and may jeopardize the validity of the application or any patent issuing thereon. The declarant must set forth in the body of the declaration that all statements made of the declarant's own knowledge are true and that all statements made on information and belief are believed to be true.

Form paragraph [7.65](#) or [7.66](#) and any of form paragraphs [7.66.01](#) through [7.66.05](#), as appropriate, should be used to comment on a [37 CFR 1.132](#) affidavit or declaration.

¶ 7.65 Affidavit or Declaration Under 37 CFR 1.132: Effective To Withdraw Rejection

The [1] under [37 CFR 1.132](#) filed [2] is sufficient to overcome the rejection of claim [3] based upon [4].

Examiner Note:

- 1. In bracket 1, insert either --affidavit-- or --declaration--.
- 2. In bracket 2, insert the filing date of the affidavit or declaration.
- 3. In bracket 3, insert the affected claim or claims.
- 4. In bracket 4, indicate the rejection that has been overcome, including the statutory grounds, e.g.: insufficiency of disclosure under [35 U.S.C. 112\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), first paragraph; lack of utility under [35 U.S.C. 101](#); inoperativeness under [35 U.S.C. 101](#); a specific reference applied under [35 U.S.C. 103](#); etc. See [MPEP § 716](#).

¶ 7.66 Affidavit or Declaration Under 37 CFR 1.132: Insufficient

The [1] under [37 CFR 1.132](#) filed [2] is insufficient to overcome the rejection of claim [3] based upon [4] as set forth in the last Office action because:

Examiner Note:

- 1. In bracket 1, insert either --affidavit-- or --declaration--.
- 2. In bracket 2, insert the filing date of the affidavit or declaration.
- 3. In bracket 3, insert the claim or claims affected.
- 4. In bracket 4, indicate the rejection that has not been overcome, including the statutory grounds, i.e.: insufficiency of disclosure under [35 U.S.C. 112\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), first paragraph; lack of utility and/or inoperativeness under [35 U.S.C. 101](#); a specific reference applied under [35 U.S.C. 103](#); etc. See [MPEP § 716](#).
- 5. Following this form paragraph, set forth the reasons for the insufficiency; e.g., categories include: --untimely--; --fails to set forth facts--; --facts presented are not germane to the rejection at issue--; --showing is not commensurate in scope with the claims--; etc. See [MPEP § 716](#). Also include a detailed explanation of the reasons why the affidavit or declaration is insufficient. Any of form paragraphs [7.66.01](#) - [7.66.05](#) may be used, as appropriate.

¶ 7.66.01 Reason Why Affidavit or Declaration Under 37 CFR 1.132 Is Insufficient: Affiant Has Never Seen Invention Before

It includes statements which amount to an affirmation that the affiant has never seen the claimed subject matter before. This is not relevant to the issue of nonobviousness of the claimed subject matter and provides no objective evidence thereof. See [MPEP § 716](#).

Examiner Note:

- 1. This form paragraph must be preceded by form paragraph [7.66](#).
- 2. A full explanation must be provided, if appropriate.

¶ 7.66.02 Reason Why Affidavit or Declaration Under 37 CFR 1.132 Is Insufficient: Invention Works as Intended

It includes statements which amount to an affirmation that the claimed subject matter functions as it was intended to function. This is not relevant to the issue of nonobviousness of the claimed subject matter and provides no objective evidence thereof. See [MPEP § 716](#).

Examiner Note:

- 1. This form paragraph must be preceded by form paragraph [7.66](#).
- 2. A full explanation must be provided, if appropriate.

¶ 7.66.03 Reason Why Affidavit or Declaration Under 37 CFR 1.132 Is Insufficient: Refers Only to Invention, Not to Claims

It refers only to the system described in the above referenced application and not to the individual claims of the application. As such the declaration does not show that the objective evidence of nonobviousness is commensurate in scope with the claims. See [MPEP § 716](#).

Examiner Note:

- 1. This form paragraph must be preceded by form paragraph [7.66](#).
- 2. A full explanation must be provided, if appropriate.

¶ 7.66.04 Reason Why Affidavit or Declaration Under 37 CFR 1.132 Is Insufficient: No Evidence of Long-Felt Need

It states that the claimed subject matter solved a problem that was long standing in the art. However, there is no showing that others of ordinary skill in the art were working on the

problem and if so, for how long. In addition, there is no evidence that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references, they would still be unable to solve the problem. See [MPEP § 716.04](#).

Examiner Note:

- 1. This form paragraph must be preceded by form paragraph [7.66](#).
- 2. A full explanation must be provided, if appropriate.

¶ 7.66.05 Reason Why Affidavit or Declaration Under 37 CFR 1.132 Is Insufficient: Conclusion

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Examiner Note:

This form paragraph should be presented as a conclusion to your explanation of why the affidavit or declaration under [37 CFR 1.132](#) is insufficient, and it must be preceded by form paragraph [7.66](#).

716.01 Generally Applicable Criteria [R-08.2012]

The following criteria are applicable to all evidence traversing rejections submitted by applicants, including affidavits or declarations submitted under [37 CFR 1.132](#):

- (A) *Timeliness*.
 - Evidence traversing rejections must be timely or seasonably filed to be entered and entitled to consideration. *In re Rothermel*, 276 F.2d 393, 125 USPQ 328 (CCPA 1960).
 - Affidavits and declarations submitted under [37 CFR 1.132](#) and other evidence traversing rejections are considered timely if submitted:
 - (1) prior to a final rejection,
 - (2) before appeal in an application not having a final rejection,
 - (3) after final rejection, but before or on the same date of filing an appeal, upon a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented in compliance with [37 CFR 1.116\(e\)](#); or
 - (4) after the prosecution is closed (e.g., after a final rejection, after appeal, or after allowance) if applicant files the affidavit or other evidence with a request for continued examination (RCE) under [37 CFR 1.114](#) in a utility or plant application filed on or after June 8, 1995; or a continued prosecution application (CPA) under [37 CFR 1.53\(d\)](#) in a design application.

For affidavits or declarations under [37 CFR 1.132](#) filed after appeal, see [37 CFR 41.33\(d\)](#) and [MPEP § 1206](#) and [§ 1211.03](#).

- (B) *Consideration of evidence*.

Evidence traversing rejections, when timely presented, must be considered by the examiner whenever present. All entered affidavits, declarations, and other evidence traversing rejections are acknowledged and commented upon by the examiner in the next succeeding action. The extent of the commentary depends on the action taken by the examiner. Where an examiner holds that the evidence is sufficient to overcome the *prima facie* case, the comments should be consistent with the guidelines for statements of reasons for allowance. See [MPEP § 1302.14](#). Where the evidence is insufficient to overcome the rejection, the examiner must specifically explain why the evidence is insufficient. General statements such as “the declaration lacks technical validity” or “the evidence is not commensurate with the scope of the claims” without an explanation supporting such findings are insufficient.

716.01(a) Objective Evidence of Nonobviousness [R-08.2017]

OBJECTIVE EVIDENCE MUST BE CONSIDERED WHEN TIMELY PRESENT

Affidavits or declarations, when timely presented, containing evidence of criticality or unexpected results, commercial success, long-felt but unsolved needs, failure of others, skepticism of experts, etc., must be considered by the examiner in determining the issue of obviousness of claims for patentability under [35 U.S.C. 103](#). The Court of Appeals for the

Federal Circuit stated in *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538, 218 USPQ 871, 879 (Fed. Cir. 1983) that “evidence rising out of the so-called ‘secondary considerations’ must always when present be considered en route to a determination of obviousness.” Such evidence might give light to circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or unobviousness, such evidence may have relevancy. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966); *In re Palmer*, 451 F.2d 1100, 172 USPQ 126 (CCPA 1971); *In re Fielder*, 471 F.2d 640, 176 USPQ 300 (CCPA 1973). The *Graham v. John Deere* pronouncements on the relevance of commercial success, etc. to a determination of obviousness were not negated in *Sakraida v. Ag Pro*, 425 U.S. 273, 189 USPQ 449 (1976) or *Anderson’s-Black Rock Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 163 USPQ 673 (1969), where reliance was placed upon *A&P Tea Co. v. Supermarket Corp.*, 340 U.S. 147, 87 USPQ 303 (1950). See *Dann v. Johnston*, 425 U.S. 219, 226 n.4, 189 USPQ 257, 261 n. 4 (1976).

Examiners must consider comparative data in the specification which is intended to illustrate the claimed invention in reaching a conclusion with regard to the obviousness of the claims. *In re Margolis*, 785 F.2d 1029, 228 USPQ 940 (Fed. Cir. 1986). The lack of objective evidence of nonobviousness does not weigh in favor of obviousness. *Miles Labs. Inc. v. Shandon Inc.*, 997 F.2d 870, 878, 27 USPQ2d 1123, 1129 (Fed. Cir. 1993), *cert. denied*, 127 L. Ed. 232 (1994). However, where a *prima facie* case of obviousness is established, the failure to provide rebuttal evidence is dispositive.

716.01(b) Nexus Requirement and Evidence of Nonobviousness [R-01.2024]

TO BE OF PROBATIVE VALUE, ANY SECONDARY EVIDENCE MUST BE RELATED TO THE CLAIMED INVENTION (NEXUS REQUIRED)

The weight attached to evidence of secondary considerations by the examiner will depend upon its relevance to the issue of obviousness and the amount and nature of the evidence. Note the great reliance apparently placed on this type of evidence by the Supreme Court in upholding the patent in *United States v. Adams*, 383 U.S. 39, 148 USPQ 479 (1966).

If the evidence is to be given substantial weight in the determination of obviousness or nonobviousness, evidence of secondary considerations must be relevant to the subject matter as claimed, and therefore the examiner must determine whether there is a nexus between the merits of the claimed invention and the evidence of secondary considerations. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 305 n.42, 227 USPQ 657, 673-674 n. 42 (Fed. Cir. 1985), *cert. denied*, 475 U.S. 1017 (1986). The term “nexus” designates a factually and legally sufficient connection between the objective evidence of nonobviousness and the claimed invention so that the evidence is of probative value in the determination of

nonobviousness. *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 7 USPQ2d 1222 (Fed. Cir.), *cert. denied*, 488 U.S. 956 (1988). See also *Yita LLC v. MacNeil IP LLC*, 69 F.4th 1356, 1363, 2023 USPQ2d 667 (Fed. Cir. 2023).

Applicant or patent owner bears the burden of establishing a nexus between the objective evidence of nonobviousness and the claimed invention. See *In re Huang*, 100 F.3d 135, 140, 40 USPQ 1685, 1689 (Fed. Cir. 1996). Nexus is presumed when the applicant or patent owner shows that the asserted objective evidence of record is tied to a certain product and that product includes the claimed features, and is coextensive with them. See *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373, 2019 USPQ2d 483355 (Fed. Cir. 2019), *cert. denied*, 141 S.Ct. 373 (2020). “[T]he purpose of the coextensiveness requirement is to ensure that nexus is only presumed when the product tied to the evidence of secondary considerations ‘is the invention disclosed and claimed.’” *Id.* at 1374 (quoting *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392, 7 USPQ2d 1222, 1226 (Fed. Cir. 1988)). “[T]he degree of correspondence between a product and the patent claim falls along a spectrum. At one end of the spectrum lies perfect or near perfect correspondence. At the other end lies no or very little correspondence.” *Id.* “A patent claim is not coextensive with a product that includes a ‘critical’ unclaimed feature that is claimed by a different patent and that materially impacts the product’s functionality.” *Id.* at 1375.

Even if there is no presumption of nexus, the consideration of the rebuttal evidence does not end. “To the contrary, the patent owner is still afforded an opportunity to prove nexus by showing that the evidence of secondary considerations is the ‘direct result of the unique characteristics of the claimed invention.’” *Id.* at 1373-74 (quoting *In re Huang*, 100 F.3d 135, 140, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996)). See also *Volvo Penta of the Americas, LLC v. Brunswick Corp.*, 81 F.4th 1202, 1211, 2023 USPQ2d 1000 (Fed. Cir. 2023) (A nexus, independent of the presumption, was demonstrated between the claims and objective indicia of nonobviousness through evidence of commercial success and copying due to the unique features of the claimed invention). “Where the offered secondary consideration actually results from something other than what is both claimed and novel in the claim, there is no nexus to the merits of the claimed invention,” meaning that “there must be a nexus to some aspect of the claim not already in the prior art.” *In re Kao*, 639 F.3d 1057, 1068-69, 98 USPQ2d 1799, 1808 (Fed. Cir. 2011) (emphasis in original). On the other hand, there is no requirement that “objective evidence must be tied exclusively to claim elements that are not disclosed in a particular prior art reference in order for that evidence to carry substantial weight.” *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1331, 119 USPQ2d 1301, 1308 (Fed. Cir. 2016). A patent owner may show, for example, “that it is the claimed combination as a whole that serves as a nexus for the objective evidence; proof of nexus is not limited to only when objective evidence is tied to the supposedly ‘new’ feature(s).” 639 F.3d at 1330. Ultimately, the

fact finder must weigh the secondary considerations evidence presented in the context of whether the claimed invention as a whole would have been obvious to a skilled artisan. 639 F.3d at 1331-32. *Fox Factory, Inc. v. SRAM, LLC*, 813 Fed. Appx. 539, 542-43, 2020 USPQ2d 10546 (Fed. Cir. 2020) (the record has substantial evidence to support nexus and nonobviousness based on secondary considerations regarding industry skepticism and subsequent praise and long-felt need because it was shown that the underlying product's success was attributed to the allegedly obvious claim feature). *Campbell Soup Co. v. Gamon Plus, Inc.*, 10 F.4th 1268, 1279, 2021 USPQ2d 875 (Fed. Cir. 2021) (internal quotation marks omitted) (“[T]he obviousness analysis involves determining whether ‘the claimed invention as a whole would have been obvious[]’ (quoting [35 U.S.C. 103](#))[]”, and yet we still require a link to the claimed invention's unique characteristics in that context. We therefore hold that, as in the utility patent context, objective indicia must be linked to a design patent claim's unique characteristics.”). See also *Teva Pharms. Int'l GmbH v. Eli Lilly & Co.*, 8 F.4th 1349, 2021 USPQ2d 866 (Fed. Cir. 2021).

“Where the offered secondary consideration actually results from something other than what is both claimed and novel in the claim, there is no nexus to the merits of the claimed invention.” *In re Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011); see also *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1369 (Fed. Cir. 2011) (“If commercial success is due to an element in the prior art, no nexus exists.”); *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (2006) (“[I]f the feature that creates the commercial success was known in the prior art, the success is not pertinent.”). In evaluating whether the requisite nexus exists, the identified objective indicia must be directed to what was not known in the prior art, including patents and publications, which may well be the novel combination or arrangement of known individual elements. See *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418–19 (2007); *Veritas Techs. LLC v. Veeam Software Corp.*, 835 F.3d 1406, 1414-15 (Fed. Cir. 2016).

716.01(c) Probative Value of Objective Evidence [R-01.2024]

I. TO BE OF PROBATIVE VALUE, ANY OBJECTIVE EVIDENCE SHOULD BE SUPPORTED BY ACTUAL PROOF

Objective evidence which must be factually supported by an appropriate affidavit or declaration to be of probative value includes evidence of unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the inventor or at least one joint inventor. See, for example, *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984) (“It is well settled that unexpected results must be established by factual evidence.” “[A]ppellants have not presented any experimental data showing that prior heat-shrinkable articles split. Due to the absence of tests comparing

appellant's heat shrinkable articles with those of the closest prior art, we conclude that appellant's assertions of unexpected results constitute mere argument.”). See also *In re Lindner*, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972); *Ex parte George*, 21 USPQ2d 1058 (Bd. Pat. App. & Inter. 1991).

II. ARGUMENTS BY APPLICANT CANNOT TAKE THE PLACE OF EVIDENCE

Arguments presented by the applicant cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965) and *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984). Examples of statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the inventor or at least one joint inventor.

See [MPEP § 2145](#) generally for case law pertinent to the consideration of applicant's rebuttal arguments.

III. OPINION EVIDENCE

Although factual evidence is preferable to opinion testimony, such testimony is entitled to consideration and some weight so long as the opinion is not on the ultimate legal conclusion at issue. While an opinion as to a legal conclusion is not entitled to any weight, the underlying basis for the opinion may be persuasive. *In re Chilowsky*, 306 F.2d 908, 134 USPQ 515 (CCPA 1962) (expert opinion that an application meets the requirements of [35 U.S.C. 112](#) is not entitled to any weight; however, facts supporting a basis for deciding that the specification complies with [35 U.S.C. 112](#) are entitled to some weight); *In re Lindell*, 385 F.2d 453, 155 USPQ 521 (CCPA 1967) (Although an affiant's or declarant's opinion on the ultimate legal issue is not evidence in the case, “some weight ought to be given to a persuasively supported statement of one skilled in the art on what was not obvious to him.” 385 F.2d at 456, 155 USPQ at 524 (emphasis in original)).

In assessing the probative value of an expert opinion, the examiner must consider the nature of the matter sought to be established, the strength of any opposing evidence, the interest of the expert in the outcome of the case, and the presence or absence of factual support for the expert's opinion. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 227 USPQ 657 (Fed. Cir. 1985), *cert. denied*, 475 U.S. 1017 (1986). See also *In re Oelrich*, 579 F.2d 86, 198 USPQ 210 (CCPA 1978) (factually based expert opinions on the level of ordinary skill in the art were sufficient to rebut the *prima facie* case of obviousness); *Ex parte Gray*, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989) (statement in publication dismissing the “preliminary identification of a human b-NGF-like molecule” in the prior art, even if considered

to be an expert opinion, was inadequate to overcome the rejection based on that prior art because there was no factual evidence supporting the statement); *In re Carroll*, 601 F.2d 1184, 202 USPQ 571 (CCPA 1979) (expert opinion on what the prior art taught, supported by documentary evidence and formulated prior to the making of the claimed invention, received considerable deference); *In re Beattie*, 974 F.2d 1309, 24 USPQ2d 1040 (Fed. Cir. 1992) (declarations of seven persons skilled in the art offering opinion evidence praising the merits of the claimed invention were found to have little value because of a lack of factual support); *Ex parte George*, 21 USPQ2d 1058 (Bd. Pat. App. & Inter. 1991) (conclusory statements that results were “unexpected,” unsupported by objective factual evidence, were considered but were not found to be of substantial evidentiary value).

Although an affidavit or declaration which states only conclusions may have some probative value, such an affidavit or declaration may have little weight when considered in light of all the evidence of record in the application. *In re Brandstadter*, 484 F.2d 1395, 179 USPQ 286 (CCPA 1973).

An affidavit of an applicant as to the advantages of their claimed invention, while less persuasive than that of a disinterested person, cannot be disregarded for this reason alone. *Ex parte Keyes*, 214 USPQ 579 (Bd. App. 1982); *In re McKenna*, 203 F.2d 717, 97 USPQ 348 (CCPA 1953).

IV. PROBATIVE VALUE OF COMMERCIAL SUCCESS OR LONG FELT NEED EVIDENCE

Objective evidence of commercial success or long felt need and failure of others may be given less weight if the record shows that the applicant or patent owner has a strong market power or blocking patent depending on the facts of record. “A patent has been called a ‘blocking patent’ where practice of a later invention would infringe the earlier patent. The existence of such a blocking patent may deter non-owners and non-licensees from investing the resources needed to make, develop, and market such a later, ‘blocked’ invention, because of the risk of infringement liability and associated monetary or injunctive remedies. If the later invention is eventually patented by an owner or licensee of the blocking patent, that potential deterrent effect is relevant to understanding why others had not made, developed, or marketed that ‘blocked’ invention and, hence, to evaluating objective indicia of the obviousness of the later patent.” *Acorda Therapeutics, Inc. v. Roxane Lab., Inc.*, 903 F.3d 1310, 1337, 128 USPQ2d 1001, 1021 (Fed. Cir. 2018). “Such a blocking patent therefore can be evidence that can discount the significance of evidence that nobody but the blocking patent’s owners or licensees arrived at, developed, and marketed the invention covered by the later patent at issue in litigation. But the magnitude of the diminution in incentive in any context—in particular, whether it was great enough to have actually deterred activity that otherwise would have occurred—is ‘a fact-specific inquiry.’” *Id.* at 1339, 128 USPQ2d at 1022. While having record evidence of such a blocking patent may not be common, examiners

should be aware of its potential impact in evaluating secondary evidence of nonobviousness. In any Office action, examiners should articulate why there is any discounting of the weight of the secondary consideration evidence when addressing the evidence.

716.01(d) Weighing Objective Evidence [R-01.2024]

IN MAKING A FINAL DETERMINATION OF PATENTABILITY, EVIDENCE SUPPORTING PATENTABILITY MUST BE WEIGHED AGAINST EVIDENCE SUPPORTING *PRIMA FACIE* CASE

When an applicant timely submits evidence traversing a rejection, the examiner must reconsider the patentability of the claimed invention. The ultimate determination of patentability must be based on consideration of the entire record, by a preponderance of evidence, with due consideration to the persuasiveness of any arguments and any secondary evidence. *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). The submission of objective evidence of patentability does not mandate a conclusion of patentability in and of itself. *In re Chupp*, 816 F.2d 643, 2 USPQ2d 1437 (Fed. Cir. 1987). Facts established by rebuttal evidence must be evaluated along with the facts on which the conclusion of a *prima facie* case was reached, not against the conclusion itself. *In re Eli Lilly*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990). In other words, each piece of rebuttal evidence should not be evaluated for its ability to knockdown the *prima facie* case. All of the competent rebuttal evidence taken as a whole should be weighed against the evidence supporting the *prima facie* case. *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984). Although the record may establish evidence of secondary considerations which are indicia of nonobviousness, the record may also establish such a strong case of obviousness that the objective evidence of nonobviousness is not sufficient to outweigh the evidence of obviousness. *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 769, 9 USPQ2d 1417, 1427 (Fed. Cir. 1988), *cert. denied*, 493 U.S. 814 (1989); *Richardson-Vicks, Inc., v. The Upjohn Co.*, 122 F.3d 1476, 1484, 44 USPQ2d 1181, 1187 (Fed. Cir. 1997) (showing of unexpected results and commercial success of claimed ibuprofen and pseudoephedrine combination in single tablet form, while supported by substantial evidence, held not to overcome strong *prima facie* case of obviousness). See *In re Piasecki*, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984) for a detailed discussion of the proper roles of the examiner's *prima facie* case and applicant's rebuttal evidence in the final determination of obviousness.

If, after evaluating the evidence, the examiner is still not convinced that the claimed invention is patentable, the next Office action should include a statement to that effect and identify the reason(s) (e.g., evidence of commercial success not convincing, the commercial success not related to the technology, etc.). See *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 7 USPQ2d 1222 (Fed. Cir.), *cert. denied*, 488 U.S. 956 (1988). See also [MPEP](#)

[§ 716.01](#). Any conclusion of whether the evidence of obviousness outweighs the objective evidence, along with any individual weights assigned to different objective indicia, should be explained. *Volvo Penta of the Americas, LLC v. Brunswick Corp.*, 81 F.4th 1202, 1215, 2023 USPQ2d 1000 (Fed. Cir. 2023) (The court found the assignment of weight to different considerations was overly vague and ambiguous because, despite evidence of copying, commercial success, and industry praise, the Board assigned all of these factors only “some weight,” “did not explain why it gave these three factors the same weight, or even whether or not that constituted precisely the same weight,” and regarding the weight of all six factors “[did] not discuss the summation of the factors at all other than to say, without explanation, that they collectively ‘weigh[] somewhat in favor of nonobviousness’”). See [MPEP § 2145](#) for guidance in determining whether rebuttal evidence is sufficient to overcome a *prima facie* case of obviousness.

716.02 Allegations of Unexpected Results [R-01.2024]

Any differences between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected. *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (differences in sedative and anticholinergic effects between prior art and claimed antidepressants were not unexpected). In *In re Waymouth*, 499 F.2d 1273, 1276, 182 USPQ 290, 293 (CCPA 1974), the court held that unexpected results for a claimed range as compared with the range disclosed in the prior art had been shown by a demonstration of “a marked improvement, over the results achieved under other ratios, as to be classified as a difference in kind, rather than one of degree.” Compare *In re Wagner*, 371 F.2d 877, 884, 152 USPQ 552, 560 (CCPA 1967) (differences in properties cannot be disregarded on the ground they are differences in degree rather than in kind); *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992) (“we generally consider a discussion of results in terms of ‘differences in degree’ as compared to ‘differences in kind’ . . . to have very little meaning in a relevant legal sense”). See also *UCB, Inc. v. Actavis Labs, UT, Inc.*, 65 F.4th 679, 693, 2023 USPQ2d 448 (Fed. Cir. 2023) (“A difference of degree is not as persuasive as a difference in kind – i.e., if the range produces “a new property dissimilar to the known property,” rather than producing a predictable result but to an unexpected extent.”).

716.02(a) Evidence Must Show Unexpected Results [R-07.2022]

I. GREATER THAN EXPECTED RESULTS ARE EVIDENCE OF NONOBVIOUSNESS

“A greater than expected result is an evidentiary factor pertinent to the legal conclusion of obviousness ... of the claims at issue.” *In re Corkill*, 771 F.2d 1496, 226 USPQ 1005 (Fed. Cir. 1985). In *Corkhill*, the claimed combination showed an additive result when a diminished

result would have been expected. This result was persuasive of nonobviousness even though the result was equal to that of one component alone. Evidence of a greater than expected result may also be shown by demonstrating an effect which is greater than the sum of each of the effects taken separately (i.e., demonstrating “synergism”). *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989). However, a greater than additive effect is not necessarily sufficient to overcome a *prima facie* case of obviousness because such an effect can either be expected or unexpected. Applicants must further show that the results were greater than those which would have been expected from the prior art to an unobvious extent, and that the results are of a significant, practical advantage. *Ex parte The NutraSweet Co.*, 19 USPQ2d 1586 (Bd. Pat. App. & Inter. 1991) (Evidence showing greater than additive sweetness resulting from the claimed mixture of saccharin and L-aspartyl-L-phenylalanine was not sufficient to outweigh the evidence of obviousness because the teachings of the prior art lead to a general expectation of greater than additive sweetening effects when using mixtures of synthetic sweeteners.).

II. SUPERIORITY OF A PROPERTY SHARED WITH THE PRIOR ART IS EVIDENCE OF NONOBVIOUSNESS

Evidence of unobvious or unexpected advantageous properties, such as superiority in a property the claimed compound shares with the prior art, can rebut *prima facie* obviousness. “Evidence that a compound is unexpectedly superior in one of a spectrum of common properties . . . can be enough to rebut a *prima facie* case of obviousness.” No set number of examples of superiority is required. *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987) (Evidence showing that the claimed herbicidal compound was more effective than the closest prior art compound in controlling quackgrass and yellow nutsedge weeds in corn and soybean crops was sufficient to overcome the rejection under [35 U.S.C. 103](#), even though the specification indicated the claimed compound was an average performer on crops other than corn and soybean.). See also *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990) (unexpected superior therapeutic activity of claimed compound against anaerobic bacteria was sufficient to rebut *prima facie* obviousness even though there was no evidence that the compound was effective against all bacteria).

III. PRESENCE OF AN UNEXPECTED PROPERTY IS EVIDENCE OF NONOBVIOUSNESS

Presence of a property not possessed by the prior art is evidence of nonobviousness. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) (rejection of claims to compound structurally similar to the prior art compound was reversed because claimed compound unexpectedly possessed anti-inflammatory properties not possessed by the prior art compound); *Ex parte Thumm*, 132 USPQ 66 (Bd. App. 1961) (Appellant showed that the claimed range of ethylene diamine was effective for the purpose of producing “regenerated

cellulose consisting substantially entirely of skin” whereas the prior art warned “this compound has ‘practically no effect.’ ”). The submission of evidence that a new product possesses unexpected properties does not necessarily require a conclusion that the claimed invention is nonobvious. *In re Payne*, 606 F.2d 303, 203 USPQ 245 (CCPA 1979). See the discussion of latent properties and additional advantages in [MPEP § 2145](#).

IV. ABSENCE OF AN EXPECTED PROPERTY IS EVIDENCE OF NONOBVIOUSNESS

Absence of property which a claimed invention would have been expected to possess based on the teachings of the prior art is evidence of unobviousness. *Ex parte Mead Johnson & Co.*, 227 USPQ 78 (Bd. Pat. App. & Inter. 1985) (Based on prior art disclosures, claimed compounds would have been expected to possess beta-andrenergic blocking activity; the fact that claimed compounds did not possess such activity was an unexpected result sufficient to establish unobviousness within the meaning of [35 U.S.C. 103](#)).

716.02(b) Burden on Applicant [R-08.2012]

I. BURDEN ON APPLICANT TO ESTABLISH RESULTS ARE UNEXPECTED AND SIGNIFICANT

The evidence relied upon should establish “that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance.” *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992) (Mere conclusions in appellants’ brief that the claimed polymer had an unexpectedly increased impact strength “are not entitled to the weight of conclusions accompanying the evidence, either in the specification or in a declaration.”); *Ex parte C*, 27 USPQ2d 1492 (Bd. Pat. App. & Inter. 1992) (Applicant alleged unexpected results with regard to the claimed soybean plant, however there was no basis for judging the practical significance of data with regard to maturity date, flowering date, flower color, or height of the plant.). See also *In re Nolan*, 553 F.2d 1261, 1267, 193 USPQ 641, 645 (CCPA 1977) and *In re Eli Lilly*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) as discussed in [MPEP § 716.02\(c\)](#).

II. APPLICANTS HAVE BURDEN OF EXPLAINING PROFFERED DATA

“[A]ppellants have the burden of explaining the data in any declaration they proffer as evidence of non-obviousness.” *Ex parte Ishizaka*, 24 USPQ2d 1621, 1624 (Bd. Pat. App. & Inter. 1992).

III. DIRECT AND INDIRECT COMPARATIVE TESTS ARE PROBATIVE OF NONOBVIOUSNESS

Evidence of unexpected properties may be in the form of a direct or indirect comparison of the claimed invention with the closest prior art which is commensurate in scope with the claims. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) and [MPEP § 716.02\(d\)](#) - §

[716.02\(e\)](#). See *In re Blondel*, 499 F.2d 1311, 1317, 182 USPQ 294, 298 (CCPA 1974) and *In re Fouche*, 439 F.2d 1237, 1241-42, 169 USPQ 429, 433 (CCPA 1971) for examples of cases where indirect comparative testing was found sufficient to rebut a *prima facie* case of obviousness.

The patentability of an intermediate may be established by unexpected properties of an end product “when one of ordinary skill in the art would reasonably ascribe to a claimed intermediate the ‘contributing cause’ for such an unexpectedly superior activity or property.” *In re Magerlein*, 602 F.2d 366, 373, 202 USPQ 473, 479 (CCPA 1979). “In order to establish that the claimed intermediate is a ‘contributing cause’ of the unexpectedly superior activity or property of an end product, an applicant must identify the cause of the unexpectedly superior activity or property (compared to the prior art) in the end product and establish a nexus for that cause between the intermediate and the end product.” *Id.* at 479.

716.02(c) Weighing Evidence of Expected and Unexpected Results [R-08.2012]

I. EVIDENCE OF UNEXPECTED AND EXPECTED PROPERTIES MUST BE WEIGHED

Evidence of unexpected results must be weighed against evidence supporting *prima facie* obviousness in making a final determination of the obviousness of the claimed invention. *In re May*, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978) (Claims directed to a method of effecting analgesia without producing physical dependence by administering the levo isomer of a compound having a certain chemical structure were rejected as obvious over the prior art. Evidence that the compound was unexpectedly nonaddictive was sufficient to overcome the obviousness rejection. Although the compound also had the expected result of potent analgesia, there was evidence of record showing that the goal of research in this area was to produce an analgesic compound which was nonaddictive, enhancing the evidentiary value of the showing of nonaddictiveness as an indicium of nonobviousness.). See [MPEP § 716.01\(d\)](#) for guidance on weighing evidence submitted to traverse a rejection.

Where the unexpected properties of a claimed invention are not shown to have a significance equal to or greater than the expected properties, the evidence of unexpected properties may not be sufficient to rebut the evidence of obviousness. *In re Nolan*, 553 F.2d 1261, 1267, 193 USPQ 641, 645 (CCPA 1977) (Claims were directed to a display/memory device which was *prima facie* obvious over the prior art. The court found that a higher memory margin and lower operating voltage would have been expected properties of the claimed device, and that a higher memory margin appears to be the most significant improvement for a memory device. Although applicant presented evidence of unexpected properties with regard to lower peak discharge current and higher luminous efficiency, these properties were not shown to have a significance equal to or greater than that of the expected higher memory margin and lower

operating voltage. The court held the evidence of nonobviousness was not sufficient to rebut the evidence of obviousness.); *In re Eli Lilly*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) (Evidence of improved feed efficiency in steers was not sufficient to rebut *prima facie* case of obviousness based on prior art which specifically taught the use of compound X537A to enhance weight gain in animals because the evidence did not show that a significant aspect of the claimed invention would have been unexpected.).

II. EXPECTED BENEFICIAL RESULTS ARE EVIDENCE OF OBVIOUSNESS

“Expected beneficial results are evidence of obviousness of a claimed invention, just as unexpected results are evidence of unobviousness thereof.” *In re Gershon*, 372 F.2d 535, 538, 152 USPQ 602, 604 (CCPA 1967) (resultant decrease of dental enamel solubility accomplished by adding an acidic buffering agent to a fluoride containing dentifrice was expected based on the teaching of the prior art); *Ex parte Blanc*, 13 USPQ2d 1383 (Bd. Pat. App. & Inter. 1989) (Claims at issue were directed to a process of sterilizing a polyolefinic composition which contains an antioxidant with high-energy radiation. Although evidence was presented in appellant’s specification showing that particular antioxidants are effective, the Board concluded that these beneficial results would have been expected because one of the references taught a claimed antioxidant is very efficient and provides better results compared with other prior art antioxidants.).

716.02(d) Unexpected Results Commensurate in Scope With Claimed Invention [R-08.2012]

Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the “objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support.” In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980) (Claims were directed to a process for removing corrosion at “elevated temperatures” using a certain ion exchange resin (with the exception of claim 8 which recited a temperature in excess of 100°C). Appellant demonstrated unexpected results via comparative tests with the prior art ion exchange resin at 110°C and 130°C. The court affirmed the rejection of claims 1-7 and 9-10 because the term “elevated temperatures” encompassed temperatures as low as 60°C where the prior art ion exchange resin was known to perform well. The rejection of claim 8, directed to a temperature in excess of 100°C, was reversed.). See also *In re Peterson*, 315 F.3d 1325, 1329-31, 65 USPQ2d 1379, 1382-85 (Fed. Cir. 2003) (data showing improved alloy strength with the addition of 2% rhenium did not evidence unexpected results for the entire claimed range of about 1-3% rhenium); *In re Grasselli*, 713 F.2d 731, 741, 218 USPQ 769, 777 (Fed. Cir. 1983) (Claims were directed to certain catalysts containing an alkali metal. Evidence

presented to rebut an obviousness rejection compared catalysts containing sodium with the prior art. The court held this evidence insufficient to rebut the *prima facie* case because experiments limited to sodium were not commensurate in scope with the claims.).

I. NONOBVIOUSNESS OF A GENUS OR CLAIMED RANGE MAY BE SUPPORTED BY DATA SHOWING UNEXPECTED RESULTS OF A SPECIES OR NARROWER RANGE UNDER CERTAIN CIRCUMSTANCES

The nonobviousness of a broader claimed range can be supported by evidence based on unexpected results from testing a narrower range if one of ordinary skill in the art would be able to determine a trend in the exemplified data which would allow the artisan to reasonably extend the probative value thereof. *In re Kollman*, 595 F.2d 48, 201 USPQ 193 (CCPA 1979) (Claims directed to mixtures of an herbicide known as “FENAC” with a diphenyl ether herbicide in certain relative proportions were rejected as *prima facie* obvious. Applicant presented evidence alleging unexpected results testing three species of diphenyl ether herbicides over limited relative proportion ranges. The court held that the limited number of species exemplified did not provide an adequate basis for concluding that similar results would be obtained for the other diphenyl ether herbicides within the scope of the generic claims. Claims 6-8 recited a FENAC:diphenyl ether ratio of 1:1 to 4:1 for the three specific ethers tested. For two of the claimed ethers, unexpected results were demonstrated over a ratio of 16:1 to 2:1, and the effectiveness increased as the ratio approached the untested region of the claimed range. The court held these tests were commensurate in scope with the claims and supported the nonobviousness thereof. However, for a third ether, data was only provided over the range of 1:1 to 2:1 where the effectiveness decreased to the “expected level” as it approached the untested region. This evidence was not sufficient to overcome the obviousness rejection.); *In re Lindner*, 457 F.2d 506, 509, 173 USPQ 356, 359 (CCPA 1972) (Evidence of nonobviousness consisted of comparing a single composition within the broad scope of the claims with the prior art. The court did not find the evidence sufficient to rebut the *prima facie* case of obviousness because there was “no adequate basis for reasonably concluding that the great number and variety of compositions included in the claims would behave in the same manner as the tested composition.”).

II. DEMONSTRATING CRITICALITY OF A CLAIMED RANGE

To establish unexpected results over a claimed range, applicants should compare a sufficient number of tests both inside and outside the claimed range to show the criticality of the claimed range. *In re Hill*, 284 F.2d 955, 128 USPQ 197 (CCPA 1960).

716.02(e) Comparison With Closest Prior Art [R-08.2012]

An affidavit or declaration under [37 CFR 1.132](#) must compare the claimed subject matter with the closest prior art to be effective to rebut a *prima facie* case of obviousness. *In re Burckel*,

592 F.2d 1175, 201 USPQ 67 (CCPA 1979). “A comparison of the *claimed* invention with the disclosure of each cited reference to determine the number of claim limitations in common with each reference, bearing in mind the relative importance of particular limitations, will usually yield the closest single prior art reference.” *In re Merchant*, 575 F.2d 865, 868, 197 USPQ 785, 787 (CCPA 1978) (emphasis in original). Where the comparison is not identical with the reference disclosure, deviations therefrom should be explained, *In re Finley*, 174 F.2d 130, 81 USPQ 383 (CCPA 1949), and if not explained should be noted and evaluated, and if significant, explanation should be required. *In re Armstrong*, 280 F.2d 132, 126 USPQ 281 (CCPA 1960) (deviations from example were inconsequential).

I. THE CLAIMED INVENTION MAY BE COMPARED WITH PRIOR ART THAT IS CLOSER THAN THAT APPLIED BY THE EXAMINER

Applicants may compare the claimed invention with prior art that is more closely related to the invention than the prior art relied upon by the examiner. *In re Holladay*, 584 F.2d 384, 199 USPQ 516 (CCPA 1978); *Ex parte Humber*, 217 USPQ 265 (Bd. App. 1961) (Claims to a 13-chloro substituted compound were rejected as obvious over nonchlorinated analogs of the claimed compound. Evidence showing unexpected results for the claimed compound as compared with the 9-, 12-, and 14- chloro derivatives of the compound rebutted the *prima facie* case of obviousness because the compounds compared against were closer to the claimed invention than the prior art relied upon.).

II. COMPARISONS WHEN THERE ARE TWO EQUALLY CLOSE PRIOR ART REFERENCES

Showing unexpected results over one of two equally close prior art references will not rebut *prima facie* obviousness unless the teachings of the prior art references are sufficiently similar to each other that the testing of one showing unexpected results would provide the same information as to the other. *In re Johnson*, 747 F.2d 1456, 1461, 223 USPQ 1260, 1264 (Fed. Cir. 1984) (Claimed compounds differed from the prior art either by the presence of a trifluoromethyl group instead of a chloride radical, or by the presence of an unsaturated ester group instead of a saturated ester group. Although applicant compared the claimed invention with the prior art compound containing a chloride radical, the court found this evidence insufficient to rebut the *prima facie* case of obviousness because the evidence did not show relative effectiveness over all compounds of the closest prior art. An applicant does not have to test all the compounds taught by each reference, “[h]owever, where an applicant tests less than all cited compounds, *the test must be sufficient to permit a conclusion respecting the relative effectiveness of applicant’s claimed compounds and the compounds of the closest prior art.*” *Id.* (quoting *In re Payne*, 606 F.2d 303, 316, 203 USPQ 245, 256 (CCPA 1979)) (emphasis in original).).

III.THE CLAIMED INVENTION MAY BE COMPARED WITH THE CLOSEST SUBJECT MATTER THAT EXISTS IN THE PRIOR ART

Although evidence of unexpected results must compare the claimed invention with the closest prior art, applicant is not required to compare the claimed invention with subject matter that does not exist in the prior art. *In re Geiger*, 815 F.2d 686, 689, 2 USPQ2d 1276, 1279 (Fed. Cir. 1987) (Newman, J., concurring) (Evidence rebutted *prima facie* case by comparing claimed invention with the most relevant prior art. Note that the majority held the Office failed to establish a *prima facie* case of obviousness.); *In re Chapman*, 357 F.2d 418, 148 USPQ 711 (CCPA 1966) (Requiring applicant to compare claimed invention with polymer suggested by the combination of references relied upon in the rejection of the claimed invention under [35 U.S.C. 103](#) “would be requiring comparison of the results of the invention with the results of the invention.” 357 F.2d at 422, 148 USPQ at 714.).

716.02(f) Advantages Disclosed or Inherent [R-08.2012]

The totality of the record must be considered when determining whether a claimed invention would have been obvious to one of ordinary skill in the art at the time the invention was made. Therefore, evidence and arguments directed to advantages not disclosed in the specification cannot be disregarded. *In re Chu*, 66 F.3d 292, 298-99, 36 USPQ2d 1089, 1094-95 (Fed. Cir. 1995) (Although the purported advantage of placement of a selective catalytic reduction catalyst in the bag retainer of an apparatus for controlling emissions was not disclosed in the specification, evidence and arguments rebutting the conclusion that such placement was a matter of “design choice” should have been considered as part of the totality of the record. “We have found no cases supporting the position that a patent applicant’s evidence or arguments traversing a § 103 rejection must be contained within the specification. There is no logical support for such a proposition as well, given that 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, 36 USPQ2d at 1095.). See also *In re Zenitz*, 333 F.2d 924, 928, 142 USPQ 158, 161 (CCPA 1964) (evidence that claimed compound minimized side effects of hypotensive activity must be considered because this undisclosed property would inherently flow from disclosed use as tranquilizer); *Ex parte Sasajima*, 212 USPQ 103, 104 - 05 (Bd. App. 1981) (evidence relating to initially undisclosed relative toxicity of claimed pharmaceutical compound must be considered).

The specification need not disclose proportions or values as critical for applicants to present evidence showing the proportions or values to be critical. *In re Saunders*, 444 F.2d 599, 607, 170 USPQ 213, 220 (CCPA 1971).

716.02(g) [Reserved]

[Editor Note: Information pertaining to declaration or affidavit form has been moved to [MPEP § 716.](#)]

716.03 Commercial Success [R-01.2024]

I. BURDEN OF PRODUCTION FOR EVIDENCE OF COMMERCIAL SUCCESS AND NEXUS

An applicant who is asserting commercial success to support its contention of nonobviousness bears the burden of proof in establishing commercial success.

The Federal Circuit has acknowledged that applicant bears the burden of production for evidence of commercial success, stating:

In the *ex parte* process of examining a patent application, however, the PTO lacks the means or resources to gather evidence which supports or refutes the applicant's assertion that the sale constitute commercial success. *C.f. Ex parte Remark*, 15 USPQ2d 1498, 1503 (Bd. Pat. App. & Int. 1990)(evidentiary routine of shifting burdens in civil proceedings inappropriate in *ex parte* prosecution proceedings because examiner has no available means for adducing evidence). Consequently, the PTO must rely upon the applicant to provide hard evidence of commercial success.

In re Huang, 100 F.3d 135, 139-40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996). See also *In re GPAC*, 57 F.3d 1573, 1580, 35 USPQ2d 1116, 1121 (Fed. Cir. 1995); *In re Paulsen*, 30 F.3d 1475, 1482, 31 USPQ2d 1671, 1676 (Fed. Cir. 1994) (Evidence of commercial success of articles not covered by the claims subject to the [35 U.S.C. 103](#) rejection was not probative of nonobviousness).

The term “nexus” designates a factually and legally sufficient connection between the evidence of commercial success and the claimed invention so that the evidence is of probative value in the determination of nonobviousness. *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 7 USPQ2d 1222 (Fed. Cir. 1988). See [MPEP §§ 716.01\(b\)](#) and [2145](#) for guidance on determining if the nexus requirement is met.

II. COMMERCIAL SUCCESS ABROAD IS RELEVANT

Commercial success abroad, as well as in the United States, is relevant in resolving the issue of nonobviousness. *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984).

716.03(a) Commercial Success Commensurate in Scope With Claimed Invention [R-07.2022]

I. EVIDENCE OF COMMERCIAL SUCCESS MUST BE COMMENSURATE IN SCOPE WITH THE CLAIMS

Objective evidence of nonobviousness including commercial success must be commensurate in scope with the claims. *In re Tiffin*, 448 F.2d 791, 171 USPQ 294 (CCPA 1971) (evidence showing commercial success of thermoplastic foam “cups” used in vending machines was not commensurate in scope with claims directed to thermoplastic foam “containers” broadly). In order to be commensurate in scope with the claims, the commercial success must be due to claimed features, and not due to unclaimed features. *Joy Technologies Inc. v. Manbeck*, 751 F. Supp. 225, 229, 17 USPQ2d 1257, 1260 (D.D.C. 1990), *aff’d*, 959 F.2d 226, 228, 22 USPQ2d 1153, 1156 (Fed. Cir. 1992) (Features responsible for commercial success were recited only in allowed dependent claims, and therefore the evidence of commercial success was not commensurate in scope with the broad claims at issue.). See also [MPEP §§ 716.01\(b\)](#) and [2145](#) for more guidance on determining if the nexus requirement is met.

An affidavit or declaration attributing commercial success to a product or process “constructed according to the disclosure and claims of [the] patent application” or other equivalent language does not establish a nexus between the claimed invention and the commercial success because there is no evidence that the product or process which has been sold corresponds to the claimed invention, or that whatever commercial success may have occurred is attributable to the product or process defined by the claims. *Ex parte Standish*, 10 USPQ2d 1454, 1458 (Bd. Pat. App. & Inter. 1988).

II. REQUIREMENTS WHEN CLAIMED INVENTION IS NOT COEXTENSIVE WITH COMMERCIAL PRODUCT OR PROCESS

If a particular range is claimed, applicant does not need to show commercial success at every point in the range. “Where, as here, the claims are directed to a combination of ranges and procedures not shown by the prior art, and where substantial commercial success is achieved at an apparently typical point within those ranges, and the affidavits definitely indicate that operation throughout the claimed ranges approximates that at the particular points involved in the commercial operation, we think the evidence as to commercial success is persuasive.” *In re Hollingsworth*, 253 F.2d 238, 240, 117 USPQ 182, 184 (CCPA 1958). See also *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 7 USPQ2d 1222 (Fed. Cir. 1988) (where the commercially successful product or process is not coextensive with the claimed invention, applicant must show a legally sufficient relationship between the claimed feature and the commercial product or process).

716.03(b) Commercial Success Derived From Claimed Invention [R-01.2024]

I. COMMERCIAL SUCCESS MUST BE ATTRIBUTABLE TO THE CLAIMED INVENTION

In considering evidence of commercial success, care should be taken to determine that the commercial success alleged is a result of the invention claimed, in a marketplace where the consumer is free to choose on the basis of objective principles, and that such success is not the result of heavy promotion or advertising, shift in advertising, consumption by purchasers normally tied to applicant or assignee, or other business events extraneous to the merits of the claimed invention, etc. *In re Mageli*, 470 F.2d 1380, 176 USPQ 305 (CCPA 1973) (conclusory statements or opinions that increased sales were due to the merits of the invention are entitled to little weight); *In re Noznick*, 478 F.2d 1260, 178 USPQ 43 (CCPA 1973). See also *UCB, Inc. v. Actavis Labs. UT, Inc.*, 65 F.4th 679, 696, 2023 USPQ2d 448 (Fed. Cir. 2023)(where market entry by others was precluded due to blocking patents, the inference of non-obviousness of the asserted claims from evidence of commercial success may be weak).

In *ex parte* proceedings before the Patent and Trademark Office, an applicant must show that the claimed features were responsible for the commercial success of an article if the evidence of nonobviousness is to be given any weight. See *In re Huang*, 100 F.3d 135, 140, 40 USPQ2d 1685, 1690 (Fed. Cir. 1996) (Inventor's opinion as to the purchaser's reason for buying the product is insufficient to demonstrate a nexus between the sales and the claimed invention.). Merely showing that there was commercial success of an article which embodied the invention is not sufficient. *Ex parte Remark*, 15 USPQ2d 1498, 1502-02 (Bd. Pat. App. & Inter. 1990). Compare *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 7 USPQ2d 1222 (Fed. Cir. 1988) (In civil litigation, a patentee does not have to prove that the commercial success is not due to other factors. "A requirement for proof of the negative of all imaginable contributing factors would be unfairly burdensome, and contrary to the ordinary rules of evidence.").

See also *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 227 USPQ 766 (Fed. Cir. 1985) (commercial success may have been attributable to extensive advertising and position as a market leader before the introduction of the patented product); *In re Fielder*, 471 F.2d 690, 176 USPQ 300 (CCPA 1973) (success of invention could be due to recent changes in related technology or consumer demand; here success of claimed voting ballot could be due to the contemporary drive toward greater use of automated data processing techniques); *EWP Corp. v. Reliance Universal, Inc.*, 755 F.2d 898, 225 USPQ 20 (Fed. Cir. 1985) (evidence of licensing is a secondary consideration which must be carefully appraised as to its evidentiary value because licensing programs may succeed for reasons unrelated to the unobviousness of the product or process, e.g., license is mutually beneficial or less expensive

than defending infringement suits); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986) (Evidence of commercial success supported a conclusion of nonobviousness of claims to an immunometric “sandwich” assay with monoclonal antibodies. Patentee’s assays became a market leader with 25% of the market within a few years. Evidence of advertising did not show absence of a nexus between commercial success and the merits of the claimed invention because spending 25-35% of sales on marketing was not inordinate (mature companies spent 17-32% of sales in this market), and advertising served primarily to make industry aware of the product because this is not kind of merchandise that can be sold by advertising hyperbole.).

II. COMMERCIAL SUCCESS MUST FLOW FROM THE FUNCTIONS AND ADVANTAGES DISCLOSED OR INHERENT IN THE SPECIFICATION DESCRIPTION

To be pertinent to the issue of nonobviousness, the commercial success of devices falling within the claims of the patent must flow from the functions and advantages disclosed or inherent in the description in the specification. Furthermore, the success of an embodiment within the claims may not be attributable to improvements or modifications made by others. *In re Vamco Machine & Tool, Inc.*, 752 F.2d 1564, 224 USPQ 617 (Fed. Cir. 1985). See also *Merck & Cie v. Gnosis S.P.A.*, 808 F.3d 829, 833, 117 USPQ2d 1393, 1399 (Fed. Cir. 2015), *cert. denied*, 137 S. Ct. 297 (2016) (commercial success resulted from a “unique combination” of ingredients, a synergistic interaction of components, or a specific combination of specific forms of B-vitamins and other active ingredients, rather than from the claimed method of “using L-5-MTHF and ‘at least one B-vitamin’”).

III. IN DESIGN CASES, ESTABLISHMENT OF NEXUS IS ESPECIALLY DIFFICULT

Establishing a nexus between commercial success and the claimed invention is especially difficult in design cases. Evidence of commercial success must be clearly attributable to the design to be of probative value, and not to brand name recognition, improved performance, or some other factor. *Litton Systems, Inc. v. Whirlpool Corp.*, 728 F.2d 1423, 221 USPQ 97 (Fed. Cir. 1984) (showing of commercial success was not accompanied by evidence attributing commercial success of Litton microwave oven to the design thereof).

IV. SALES FIGURES MUST BE ADEQUATELY DEFINED

Gross sales figures do not show commercial success absent evidence as to market share, *Cable Electric Products, Inc. v. Genmark, Inc.*, 770 F.2d 1015, 226 USPQ 881 (Fed. Cir. 1985) (overruled on other grounds by *Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 50 USPQ2d 1672 (Fed. Cir. 1999)), or as to the time period during which the product was sold, or as to what sales would normally be expected in the market, *Ex parte Standish*, 10 USPQ2d 1454 (Bd. Pat. App. & Inter. 1988).

716.04 Long-Felt Need and Failure of Others [R-07.2022]

I. THE CLAIMED INVENTION MUST SATISFY A LONG-FELT NEED WHICH WAS RECOGNIZED, PERSISTENT, AND NOT SOLVED BY OTHERS

Establishing long-felt need requires objective evidence that an art recognized problem existed in the art for a long period of time without solution. The relevance of long-felt need and the failure of others to the issue of obviousness depends on several factors. First, the need must have been a persistent one that was recognized by those of ordinary skill in the art. *In re Gershon*, 372 F.2d 535, 539, 152 USPQ 602, 605 (CCPA 1967) (“Since the alleged problem in this case was first recognized by appellants, and others apparently have not yet become aware of its existence, it goes without saying that there could not possibly be any evidence of either a long felt need in the . . . art for a solution to a problem of dubious existence or failure of others skilled in the art who unsuccessfully attempted to solve a problem of which they were not aware.”); *Orthopedic Equipment Co., Inc. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 217 USPQ 1281 (Fed. Cir. 1983) (Although the claimed invention achieved the desirable result of reducing inventories, there was no evidence of any prior unsuccessful attempts to do so.).

Second, the long-felt need must not have been satisfied by another before the invention by the inventor. *Newell Companies v. Kenney Mfg. Co.*, 864 F.2d 757, 768, 9 USPQ2d 1417, 1426 (Fed. Cir. 1988) (Although at one time there was a long-felt need for a “do-it-yourself” window shade material which was adjustable without the use of tools, a prior art product fulfilled the need by using a scored plastic material which could be torn. “[O]nce another supplied the key element, there was no long-felt need or, indeed, a problem to be solved”).)

Third, the invention must in fact satisfy the long-felt need. *In re Cavanagh*, 436 F.2d 491, 168 USPQ 466 (CCPA 1971).

See *Ex parte Thompson*, Appeal 2011-011620 (March 21, 2014) (informative) for the board’s analysis of the above-mentioned three factors in reversing an obviousness rejection due to evidence of long felt need.

II. LONG-FELT NEED IS MEASURED FROM THE DATE A PROBLEM IS IDENTIFIED AND EFFORTS ARE MADE TO SOLVE IT

Long-felt need is analyzed as of the date the problem is identified and articulated, and there is evidence of efforts to solve that problem, not as of the date of the most pertinent prior art references. *Texas Instruments Inc. v. Int’l Trade Comm’n*, 988 F.2d 1165, 1179, 26 USPQ2d 1018, 1029 (Fed. Cir. 1993).

III. OTHER FACTORS CONTRIBUTING TO THE PRESENCE OF A LONG-FELT NEED MUST BE CONSIDERED

The failure to solve a long-felt need may be due to factors such as lack of interest or lack of appreciation of an invention's potential or marketability rather than want of technical know-how. *Scully Signal Co. v. Electronics Corp. of America*, 570 F.2d 355, 196 USPQ 657 (1st. Cir. 1977).

See also *Environmental Designs, Ltd. v. Union Oil Co. of Cal.*, 713 F.2d 693, 698, 218 USPQ 865, 869 (Fed. Cir. 1983) (presence of legislative regulations for controlling sulfur dioxide emissions did not militate against existence of long-felt need to reduce the sulfur content in the air); *In re Tiffin*, 443 F.2d 394, 170 USPQ 88 (CCPA 1971) (fact that affidavit supporting contention of fulfillment of a long-felt need was sworn by a licensee adds to the weight to be accorded the affidavit, as long as there is a *bona fide* licensing agreement entered into at arm's length).

716.05 Skepticism of Experts [R-08.2012]

"Expressions of disbelief by experts constitute strong evidence of nonobviousness."

Environmental Designs, Ltd. v. Union Oil Co. of Cal., 713 F.2d 693, 698, 218 USPQ 865, 869 (Fed. Cir. 1983) (citing *United States v. Adams*, 383 U.S. 39, 52, 148 USPQ 479, 483-484 (1966)) (The patented process converted all the sulfur compounds in a certain effluent gas stream to hydrogen sulfide, and thereafter treated the resulting effluent for removal of hydrogen sulfide. Before learning of the patented process, chemical experts, aware of earlier failed efforts to reduce the sulfur content of effluent gas streams, were of the opinion that reducing sulfur compounds to hydrogen sulfide would not adequately solve the problem.).

"The skepticism of an expert, expressed before these inventors proved him wrong, is entitled to fair evidentiary weight, . . . as are the five to six years of research that preceded the claimed invention." *In re Dow Chemical Co.*, 837 F.2d 469, 5 USPQ2d 1529 (Fed. Cir. 1988); *Burlington Industries Inc. v. Quigg*, 822 F.2d 1581, 3 USPQ2d 1436 (Fed. Cir. 1987) (testimony that the invention met with initial incredulity and skepticism of experts was sufficient to rebut the *prima facie* case of obviousness based on the prior art).

716.06 Copying [R-07.2022]

Another form of secondary evidence which may be presented by applicants during prosecution of an application, but which is more often presented during litigation, is evidence that competitors in the marketplace are copying the invention instead of using the prior art. *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1325, 73 USPQ2d 1225, 1230 (Fed. Cir. 2004) ("Our cases do establish that copying by a competitor may be a relevant consideration in the secondary factor analysis"). As indicated by the Federal Circuit in *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246, 95 USPQ2d 1525, 1537 (Fed. Cir. 2010), copying

“... requires evidence of efforts to replicate a specific product, which may be demonstrated through internal company documents, direct evidence such as disassembling a patented prototype, photographing its features, and using the photograph as a blueprint to build a replica, or access to the patented product combined with substantial similarity to the patented product.” .

Evidence that shows access to a competitor’s non-public information and use of that information to develop a product may be persuasive evidence of copying. *Liqwd, Inc. v. L’Oreal USA, Inc.*, 941 F.3d 1133, 1139 (Fed. Cir. 2019) (Liqwd presented evidence, such as emails and declarations, that showed L’Oreal had access to the then-confidential disclosure of the patent application and L’Oreal’s subsequent loss of interest in purchasing Liqwd’s technology). Evidence of copying was persuasive of nonobviousness when an alleged infringer tried for a substantial length of time to design a product or process similar to the claimed invention, but failed and then copied the claimed invention instead. *Dow Chem. Co. v. American Cyanamid Co.*, 816 F.2d 617, 2 USPQ2d 1350 (Fed. Cir. 1987) and *Panduit Corp. v. Dennison Manufacturing Co.*, 774 F.2d 1082, 1098-99, 227 USPQ 337, 348, 349 (Fed. Cir. 1985), vacated on other grounds, 475 U.S. 809, 229 USPQ 478 (1986), on remand, 810 F.2d 1561, 1 USPQ2d 1593 (Fed. Cir. 1987) (evidence of copying found persuasive of nonobviousness where admitted infringer failed to satisfactorily produce a solution after 10 years of effort and expense).

However, more than the mere fact of copying is necessary to make that action significant because copying may be attributable to other factors such as a lack of concern for patent property or contempt for the patentee’s ability to enforce the patent. *Cable Electric Products, Inc. v. Genmark, Inc.*, 770 F.2d 1015, 226 USPQ 881 (Fed. Cir. 1985) (overruled on other grounds by *Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 50 USPQ2d 1672 (Fed. Cir. 1999)). Alleged copying is not persuasive of nonobviousness when the copy is not identical to the claimed product, and the other manufacturer had not expended great effort to develop its own solution. *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 227 USPQ 766 (Fed. Cir. 1985). See also *Vandenberg v. Dairy Equipment Co.*, 740 F.2d 1560, 1568, 224 USPQ 195, 199 (Fed. Cir. 1984) (evidence of copying not found persuasive of nonobviousness because the basic concepts of a plastic support device using a ball and socket joint were developed prior to learning of their competitor’s device).

716.07 Inoperability of References [R-07.2022]

Since every patent is presumed valid ([35 U.S.C. 282](#)), and since that presumption includes the presumption of operability (*Metropolitan Eng. Co. v. Coe*, 78 F.2d 199, 25 USPQ 216 (D.C. Cir. 1935)), examiners should not express any opinion on the operability of a patent. Affidavits or declarations attacking the operability of a patent cited as a reference must rebut

the presumption of operability by a preponderance of the evidence. *In re Sasse*, 629 F.2d 675, 207 USPQ 107 (CCPA 1980).

Further, since in a patent it is presumed that a process if used by one skilled in the art will produce the product or result described therein, such presumption is not overcome by a mere showing that it is possible to operate within the disclosure without obtaining the alleged product. *In re Weber*, 405 F.2d 1403, 160 USPQ 549 (CCPA 1969). It is to be presumed also that skilled workers would as a matter of course, if they do not immediately obtain desired results, make certain experiments and adaptations, within the skill of the competent worker. The failures of experimenters who have no interest in succeeding should not be accorded great weight. *In re Michalek*, 162 F.2d 229, 74 USPQ 107 (CCPA 1947); *In re Reid*, 179 F.2d 998, 84 USPQ 478 (CCPA 1950).

Where the affidavit or declaration presented asserts inoperability in features of the reference which are not relied upon, the reference is still effective as to other features which are operative. *In re Shepherd*, 172 F.2d 560, 80 USPQ 495 (CCPA 1949).

Where the affidavit or declaration presented asserts that the reference relied upon is inoperative, the claims represented by applicant must distinguish from the alleged inoperative reference disclosure. *In re Crosby*, 157 F.2d 198, 71 USPQ 73 (CCPA 1946). See also *In re Epstein*, 32 F.3d 1559, 31 USPQ2d 1817 (Fed. Cir. 1994) (lack of diagrams, flow charts, and other details in the prior art references did not render them nonenabling in view of the fact that applicant's own specification failed to provide such detailed information, and that one skilled in the art would have known how to implement the features of the references).

If a patent teaches or suggests the claimed invention, an affidavit or declaration by patentee that they did not intend the disclosed invention to be used as claimed by applicant is immaterial. *In re Pio*, 217 F.2d 956, 104 USPQ 177 (CCPA 1954). Compare *In re Yale*, 434 F.2d 666, 168 USPQ 46 (CCPA 1970) (Correspondence from a co-author of a literature article confirming that the article misidentified a compound through a typographical error that would have been obvious to one of ordinary skill in the art was persuasive evidence that the erroneously typed compound was not put in the possession of the public.).

716.08 Utility and Operability of Applicant's Disclosure [R-08.2012]

See [MPEP § 2107.02](#), for guidance on when it is proper to require evidence of utility or operativeness, and how to evaluate any evidence which is submitted to overcome a rejection under [35 U.S.C. 101](#) for lack of utility. See [MPEP § 2107](#) - [§ 2107.03](#) generally for utility examination guidelines and an overview of legal precedent relevant to the utility requirement of [35 U.S.C. 101](#).

716.09 Sufficiency of Disclosure [R-11.2013]

See [MPEP § 2164](#) - [§ 2164.08\(c\)](#) for guidance in determining whether the specification provides an enabling disclosure in compliance with [35 U.S.C. 112\(a\)](#) or pre-AIA 35 U.S.C. 112, first paragraph.

Once the examiner has established a *prima facie* case of lack of enablement, the burden falls on the applicant to present persuasive arguments, supported by suitable proofs where necessary, that one skilled in the art would have been able to make and use the claimed invention using the disclosure as a guide. *In re Brandstadter*, 484 F.2d 1395, 179 USPQ 286 (CCPA 1973). Evidence to supplement a specification which on its face appears deficient under [35 U.S.C. 112](#) must establish that the information which must be read into the specification to make it complete would have been known to those of ordinary skill in the art. *In re Howarth*, 654 F.2d 103, 210 USPQ 689 (CCPA 1981) (copies of patent specifications which had been opened for inspection in Rhodesia, Panama, and Luxembourg prior to the U.S. filing date of the applicant were not sufficient to overcome a rejection for lack of enablement under [35 U.S.C. 112\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), first paragraph).

Affidavits or declarations presented to show that the disclosure of an application is sufficient to one skilled in the art are not acceptable to establish facts which the specification itself should recite. *In re Buchner*, 929 F.2d 660, 18 USPQ2d 1331 (Fed. Cir. 1991) (Expert described how he would construct elements necessary to the claimed invention whose construction was not described in the application or the prior art; this was not sufficient to demonstrate that such construction was well-known to those of ordinary skill in the art.); *In re Smyth*, 189 F.2d 982, 90 USPQ 106 (CCPA 1951).

Affidavits or declarations purporting to explain the disclosure or to interpret the disclosure of a pending application are usually not considered. *In re Oppenauer*, 143 F.2d 974, 62 USPQ 297 (CCPA 1944). But see *Glaser v. Strickland*, 220 USPQ 446 (Bd. Pat. Int. 1983) which reexamines the rationale on which *In re Oppenauer* was based in light of the Federal Rules of Evidence. The Board stated as a general proposition “Opinion testimony which merely purports to state that a claim or count, is ‘disclosed’ in an application involved in an interference . . . should not be given any weight. Opinion testimony which purports to state that a particular feature or limitation of a claim or count is disclosed in an application involved in an interference and which explains the underlying factual basis for the opinion may be helpful and can be admitted. The weight to which the latter testimony may be entitled must be evaluated strictly on a case-by-case basis.”

716.10 Attribution Affidavit or Declaration to Overcome Rejection

Under Pre-AIA 35 U.S.C. 102 or 103 [R-10.2019]

*[Editor Note: This MPEP section is **not applicable** to applications subject to the first inventor to file provisions of the AIA unless being relied upon to overcome a rejection under [pre-AIA 35 U.S.C. 102\(g\)](#). See [35 U.S.C. 100 \(note\)](#) and [MPEP § 2159](#). For a discussion of [37 CFR 1.130](#), affidavits or declarations of attribution or prior public disclosure in applications subject to the first inventor to file provisions of the AIA, see [MPEP § 717](#). “Derivation” or “derived” as used in the discussion below is in the context of pre-AIA law. “Derivation proceedings” as created in the AIA are discussed in [MPEP § 2310](#) et seq.]*

Under certain circumstances an affidavit or declaration may be submitted which attempts to attribute an activity, a reference or part of a reference to the inventor or at least one joint inventor to overcome a rejection based on [pre-AIA 35 U.S.C. 102](#) prior art. If successful, the activity or the reference is no longer applicable. When subject matter, disclosed in a patent or patent application (reference) naming an inventive entity including inventor S and another joint inventor is claimed in a later application naming inventor S without the joint inventor, the joint patent or joint patent application publication is a valid reference available as prior art under [pre-AIA 35 U.S.C. 102\(a\), \(e\), or \(f\)](#) until overcome by an affidavit or declaration under [37 CFR 1.131\(a\)](#) showing prior invention (see [MPEP § 715](#)) or by an affidavit or declaration under [37 CFR 1.132](#). An unequivocal declaration under [37 CFR 1.132](#) by S that he/she conceived or invented the subject matter that was disclosed but not claimed in the patent or patent application publication and relied on in the rejection has been sufficient to overcome the rejection. In re DeBaun, 687 F.2d 459, 214 USPQ 933 (CCPA 1982)(declaration corroborated by attached drawing). Depending on the situation, documentation created contemporaneously with the conception/invention and/or declarations/affidavits by the other inventor(s) named in the reference may be used to corroborate inventorship. See *EmeraChem Holdings, LLC v. Volkswagen Grp. of Am., Inc.*, 859 F.3d 1341, 123 USPQ2d 1146 (Fed. Cir. 2017). Where the reference is a U.S. patent or patent application publication which includes a claim reciting the subject matter relied upon in a rejection and that subject matter anticipates or would render obvious the subject matter of a claim in the application under examination, a declaration under [37 CFR 1.132](#) must also explain the presence of the additional inventor in the reference (e.g., the disclosure in claim 1 of the reference is relied upon to reject the claims; the affidavit or declaration explains that S is the sole inventor of claim 1, and the additional inventor and S are joint inventors of claim 2 of the reference). Testimony or disclaimer by the other inventor named in the reference is usually not required but, if submitted, should be considered by the examiner.

Note that an affidavit or declaration under [37 CFR 1.131\(a\)](#) cannot be used to overcome a rejection based on a U.S. patent or U.S. patent application publication naming a different

inventive entity which claims interfering subject matter as defined in [37 CFR 41.203\(a\)](#). See [MPEP § 715.05](#).

For applications subject to current [35 U.S.C. 102](#), see [MPEP §§ 717, 2153](#) and [2154](#).

Where there is a published article identifying the authorship ([MPEP § 715.01\(c\)](#)) or a patent or an application publication identifying the inventorship ([MPEP § 715.01\(a\)](#)) that discloses subject matter being claimed in an application undergoing examination, the designation of authorship or inventorship does not raise a presumption of inventorship with respect to the subject matter disclosed in the article or with respect to the subject matter disclosed but not claimed in the patent or published application so as to justify a rejection under [pre-AIA 35 U.S.C. 102\(f\)](#).

However, it is incumbent upon the applicant in the application, in response to an inquiry regarding the appropriate inventorship under [pre-AIA 35 U.S.C. 102\(f\)](#) or to rebut a rejection under [pre-AIA 35 U.S.C. 102\(a\) or \(e\)](#), to provide a satisfactory showing by way of affidavit or declaration under [37 CFR 1.132](#) that the inventorship of the application is correct in that the reference discloses subject matter derived from the inventor or at least one joint inventor of the application undergoing examination rather than invented by the author, patentee, or applicant of the published application notwithstanding the authorship of the article or the inventorship of the patent or published application. *In re Katz*, 687 F.2d 450, 455, 215 USPQ 14, 18 (CCPA 1982) (inquiry is appropriate to clarify any ambiguity created by an article regarding inventorship and it is then incumbent upon the applicant to provide “a satisfactory showing that would lead to a reasonable conclusion that [inventor or at least one joint inventor] is the ... inventor” of the subject matter disclosed in the article and claimed in the application).

An uncontradicted “unequivocal statement” from an inventor or joint inventor regarding the subject matter disclosed in an article, patent, or published application has been accepted as establishing inventorship. *In re DeBaun*, 687 F.2d 459, 463, 214 USPQ 933, 936 (CCPA 1982) (declaration corroborated by attached drawing). Depending on the situation, documentation created contemporaneously with the conception/invention and/or declarations/affidavits by the other inventor(s) named in the reference may be used to corroborate inventorship. See *EmeraChem Holdings, LLC v. Volkswagen Grp. of Am., Inc.*, 859 F.3d 1341, 123 USPQ2d 1146 (Fed. Cir. 2017). When additional documentary evidence contradicts statements made by the inventor or at least one joint inventor with respect to inventorship, it may be appropriate to maintain the rejection(s). *Ex parte Kroger*, 219 USPQ 370 (Bd. App. 1982) (a rejection under [pre-AIA 35 U.S.C. 102\(f\)](#) was affirmed notwithstanding declarations by the alleged actual inventors as to their inventorship in view of a nonapplicant author submitting a letter declaring the author’s inventorship); *In re Carreira*, 532 F.2d 1356, 189 USPQ 461 (CCPA

1976) (disclaiming declarations from patentees were directed at the generic invention and not at the claimed species, hence no need to consider derivation of the subject matter).

A successful [37 CFR 1.132](#) affidavit or declaration establishing derivation by the author, patentee, or applicant of the published application of a first reference does not enable an applicant to step into the shoes of that author, patentee, or applicant of the published application in regard to its date of publication so as to defeat a later second reference. *In re Costello*, 717 F.2d 1346, 1350, 219 USPQ 389, 392 (Fed. Cir. 1983).

Affidavits or declarations of attribution for applications subject to [pre-AIA 35 U.S.C. 102](#) are affidavits or declarations under [37 CFR 1.132](#) because these are not otherwise provided for in the rules of practice. The Office will treat affidavits or declarations of attribution for applications subject to the current [35 U.S.C. 102](#) as affidavits or declarations under [37 CFR 1.130](#), and affidavits or declarations of attribution for applications subject to [pre-AIA 35 U.S.C. 102](#) as affidavits or declarations under [37 CFR 1.132](#), regardless of whether the affidavit or declaration is designated as an affidavit or declaration under [37 CFR 1.130](#), [1.131](#), or [37 CFR 1.132](#).

EXAMPLES

The following examples demonstrate the application of an attribution affidavit or declaration.

Example 1

During the search the examiner finds a reference fully describing the claimed invention. The authorship or inventive entity of the reference is the same as the inventive entity of the application and the reference was published or patented less than one year prior to the filing date of the application. The reference cannot be used against applicant because it does not satisfy the 1-year time requirement of [pre-AIA 35 U.S.C. 102\(b\)](#).

Example 2

Same facts as above, but the authorship or inventive entity of the reference is different from the inventive entity of the application. Because the inventive entities are different, the reference is prior art under [pre-AIA 35 U.S.C. 102\(a\) or \(e\)](#).

In the situation described in Example 2, an affidavit under [37 CFR 1.132](#) may be submitted to show that the relevant portions of the reference originated with or were obtained from the inventor or at least one joint inventor named in the application undergoing examination. Thus the affidavit attempts to convert the fact situation from that described in Example 2 to the situation described in Example 1.

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2141-Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103

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2141 Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 [R-01.2024]

[Editor Note: This MPEP section is applicable regardless of whether an application is examined under the AIA or under pre-AIA law. For applications subject to the first inventor to file (FITF) provisions of the AIA, the relevant time is "before the effective filing date of the claimed invention". For applications subject to [pre-AIA 35 U.S.C. 102](#), the relevant time is "at the time of the invention". See [MPEP § 2150](#) et seq. Many of the court decisions discussed in this section involved applications or patents subject to [pre-AIA 35 U.S.C. 102](#). These court decisions may be applicable to applications and patents subject to [AIA 35 U.S.C. 102](#) but the relevant time is before the effective filing date of the claimed invention and not at the time of the invention.]

35 U.S.C. 103 Conditions for patentability; non-obvious subject matter.

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.

Pre-AIA 35 U.S.C. 103 Conditions for patentability; nonobvious subject matter.

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in [section 102](#), 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. Patentability shall not be negated by the manner in which the invention was made.

EXAMINATION GUIDELINES FOR DETERMINING OBVIOUSNESS UNDER 35 U.S.C. 103

These guidelines are intended to assist Office personnel to make a proper determination of obviousness under [35 U.S.C. 103](#), and to provide an appropriate supporting rationale in view of the decision by the Supreme Court in *KSR International Co. v. Teleflex Inc. (KSR)*, 550 U.S. 398, 82 USPQ2d 1385 (2007). The guidelines are based on the Office's current understanding of the law, and are believed to be fully consistent with the binding precedent of the Supreme Court. The *KSR* decision reinforced earlier decisions that validated a more flexible approach to providing reasons for obviousness. However, the Supreme Court's pronouncement in *KSR* overruled cases such as *In re Lee*, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002), insofar as those cases require record evidence of an express reason to modify the prior art. As the Federal Circuit has explained:

At the time [of the decision in *In re Lee*], we required the PTO to identify record evidence of a teaching, suggestion, or motivation to combine references because "[o]mission of a relevant factor required by precedent is both legal error and arbitrary agency action." However, this did not preclude examiners from employing common sense. More recently [in *DyStar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1366 (Fed. Cir. 2006)], we explained that use of common sense does not require a "specific hint or suggestion in a particular reference," only a reasoned explanation that avoids conclusory generalizations.

Perfect Web Technologies, Inc. v. InfoUSA, Inc., 587 F.3d 1324, 1329, 92 USPQ2d 1849, 1854 (Fed. Cir. 2009) (citations omitted).

In another case, the Federal Circuit also stated that:

"... we conclude that while 'common sense' can be invoked, even potentially to supply a limitation missing from the prior art, it must still be supported by evidence and a reasoned explanation....[T]his is particularly true where the missing limitation goes to the heart of an invention."

Arendi v. Apple, 832 F.3d 1355, 1363, 119 USPQ2d 1822, 1827 (Fed. Cir. 2016).

These guidelines do not constitute substantive rule making and hence do not have the force and effect of law. They have been developed as a matter of internal Office management and are not intended to create any right or benefit, substantive or procedural, enforceable by any party against the Office. Rejections continue to be based upon the substantive law, and it is these rejections that are appealable. Consequently, any failure by Office personnel to follow the guidelines is neither appealable nor petitionable.

I. THE KSR DECISION AND PRINCIPLES OF THE LAW OF OBVIOUSNESS

The Supreme Court in *KSR* reaffirmed the familiar framework for determining obviousness as set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), but stated that the Federal Circuit had erred by applying the teaching-suggestion-motivation (TSM) test in an overly rigid and formalistic way. *KSR*, 550 U.S. at 404, 82 USPQ2d at 1391. Specifically, the Supreme Court stated that the Federal Circuit had erred in four ways: (1) “by holding that courts and patent examiners should look only to the problem the patentee was trying to solve” (*Id.* at 420, 82 USPQ2d at 1397); (2) by assuming “that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem” (*Id.*); (3) by concluding “that a patent claim cannot be proved obvious merely by showing that the combination of elements was ‘obvious to try’” (*Id.* at 421, USPQ2d at 1397); and (4) by overemphasizing “the risk of courts and patent examiners falling prey to hindsight bias” and as a result applying “[r]igid preventative rules that deny factfinders recourse to common sense” (*Id.*). See also *Novartis Pharms. Corp. v. West-Ward Pharms. Int’l Ltd.*, 923 F.3d 1051, 1059, 2019 USPQ2d 171676 (Fed. Cir. 2019); *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1047-48, 120 USPQ2d 1400, 1410 (Fed. Cir. 2016); and *Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1332, 102 USPQ2d 1445, 1449 (Fed. Cir. 2012).

In *KSR*, the Supreme Court particularly emphasized “the need for caution in granting a patent based on the combination of elements found in the prior art,” *Id.* at 415, 82 USPQ2d at 1395, and discussed circumstances in which a patent might be determined to be obvious.

Importantly, the Supreme Court reaffirmed principles based on its precedent that “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *Id.* at 415-16, 82 USPQ2d at 1395. The Supreme Court stated that there are “[t]hree cases decided after *Graham* [that] illustrate this doctrine.” *Id.* at 416, 82 USPQ2d at 1395. (1) “In *United States v. Adams*, . . . [t]he Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result.” *Id.* (2) “In *Anderson’s-Black Rock, Inc. v. Pavement Salvage Co.*, . . . [t]he two [pre-existing elements] in combination did no more than they would in separate, sequential operation.” *Id.* at 416-17, 82 USPQ2d at 1395. (3) “[I]n *Sakraida v. AG Pro, Inc.*,

the Court derived . . . the conclusion that when a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious.” *Id.* at 417, 82 USPQ2d at 1395-96 (Internal quotations omitted.). The principles underlining these cases are instructive when the question is whether a patent application claiming the combination of elements of prior art would have been obvious. The Supreme Court further stated that:

When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, [§ 103](#) likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *Id.* at 417, 82 USPQ2d at 1396.

When considering obviousness of a combination of known elements, the operative question is thus “whether the improvement is more than the predictable use of prior art elements according to their established functions.” *Id.*

The Supreme Court’s flexible approach to the obviousness inquiry is reflected in numerous pre-*KSR* decisions; see [MPEP § 2144](#). That section provides many lines of reasoning to support a determination of obviousness based upon earlier legal precedent that had condoned the use of particular examples of what may be considered common sense or ordinary routine practice (e.g., making integral, changes in shape, making adjustable). Thus, the type of reasoning sanctioned by the opinion in *KSR* has long been part of the patent examination process.

II. THE BASIC FACTUAL INQUIRIES OF *GRAHAM v. JOHN DEERE CO.*

An invention that would have been obvious to a person of ordinary skill at the relevant time is not patentable. See [35 U.S.C. 103](#) or [pre-AIA 35 U.S.C. 103\(a\)](#). As reiterated by the Supreme Court in *KSR*, the framework for the objective analysis for determining obviousness under [35 U.S.C. 103](#) is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

- (A) Determining the scope and content of the prior art;
- (B) Ascertaining the differences between the claimed invention and the prior art; and
- (C) Resolving the level of ordinary skill in the pertinent art.

Objective evidence relevant to the issue of obviousness must be evaluated by Office personnel. *Id.* at 17-18, 148 USPQ at 467. Such evidence, sometimes referred to as

“secondary considerations,” may include evidence of commercial success, long-felt but unsolved needs, failure of others, and unexpected results. The evidence may be included in the specification as filed, accompany the application on filing, or be provided in a timely manner at some other point during the prosecution. The weight to be given any objective evidence is determined on a case-by-case basis. The mere fact that an applicant has presented evidence does not mean that the evidence is dispositive of the issue of obviousness.

The question of obviousness must be resolved on the basis of the factual inquiries set forth above. While each case is different and must be decided on its own facts, these factual inquiries, as well as secondary considerations when present, must be analyzed. The *Graham* factors were reaffirmed and relied upon by the Supreme Court in its consideration and determination of obviousness in the fact situation presented in *KSR*, 550 U.S. at 406-07, 82 USPQ2d at 1391 (2007). The Supreme Court has utilized the *Graham* factors in each of its obviousness decisions since *Graham*. See *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 189 USPQ 449, *reh’g denied*, 426 U.S. 955 (1976); *Dann v. Johnston*, 425 U.S. 219, 189 USPQ 257 (1976); and *Anderson’s-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 163 USPQ 673 (1969). As stated by the Supreme Court in *KSR*, “While the sequence of these questions might be reordered in any particular case, the [*Graham*] factors continue to define the inquiry that controls.” *KSR*, 550 U.S. at 407, 82 USPQ2d at 1391.

Office Personnel As Factfinders

Office personnel fulfill the critical role of factfinder when resolving the *Graham* inquiries. It must be remembered that while the ultimate determination of obviousness is a legal conclusion, the underlying *Graham* inquiries are factual. When making an obviousness rejection, Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. In certain circumstances, it may also be important to include explicit findings as to how a person of ordinary skill would have understood prior art teachings, or what a person of ordinary skill would have known or could have done. Factual findings made by Office personnel are the necessary underpinnings to establish obviousness.

Once the findings of fact are articulated, Office personnel must provide an explanation to support an obviousness rejection under [35 U.S.C. 103](#). [35 U.S.C. 132](#) requires that the applicant be notified of the reasons for the rejection of the claim so that the applicant can decide how best to proceed. Clearly setting forth findings of fact and the rationale(s) to support a rejection in an Office action leads to the prompt resolution of issues pertinent to patentability.

In short, the focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the relevant time, and on what such a person would have reasonably expected to have been able to do in view of that knowledge. This is so regardless of whether the source of that knowledge and ability was documentary prior art, general knowledge in the art, or common sense. What follows is a discussion of the *Graham* factual inquiries.

A. Determining the Scope and Content of the Prior Art

In determining the scope and content of the prior art, Office personnel must first obtain a thorough understanding of the invention disclosed and claimed in the application under examination by reading the specification, including the claims, to understand what has been invented. See [MPEP § 904](#). The scope of the claimed invention must be clearly determined by giving the claims the “broadest reasonable interpretation consistent with the specification.” See *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316, 75 USPQ2d 1321, 1329 (Fed. Cir. 2005) and [MPEP § 2111](#). Once the scope of the claimed invention is determined, Office personnel must then determine what to search for and where to search.

1. What To Search For:

The search should cover the claimed subject matter and should also cover the disclosed features which might reasonably be expected to be claimed. See [MPEP § 904.02](#). Although a rejection need not be based on a teaching or suggestion to combine, a preferred search will be directed to finding references that provide such a teaching or suggestion if they exist.

2. Where To Search:

Office personnel should continue to follow the general search guidelines set forth in [MPEP § 904](#) to [§ 904.03](#) regarding search of the prior art. Office personnel are reminded that, for purposes of [35 U.S.C. 103](#), prior art can be either in the field of the inventor’s endeavor or be reasonably pertinent to the particular problem with which the inventor was concerned. See [MPEP § 2141.01\(a\)](#) for a discussion of analogous art and [MPEP § 1504.03](#) for a discussion of analogous art for design applications. Furthermore, prior art that is in a field of endeavor other than that of the inventor (as noted by the Court in *KSR*, “[w]hen a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one,” 550 U.S. at 417, 82 USPQ2d at 1396 (emphasis added)), or solves a problem which is different from that which the inventor was trying to solve, may also be considered for the purposes of [35 U.S.C. 103](#). (The Court in *KSR* stated that “[t]he first error...in this case was...holding that courts and patent examiners should look only to the problem the patentee was trying to solve. The Court of Appeals failed to recognize that the problem motivating the patentee may be only one of many addressed by the patent’s subject matter...The second error [was]...that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem.” 550 U.S.

at 420, 82 USPQ2d at 1397. Federal Circuit case law prior to the Supreme Court's decision in *KSR* is generally in accord with these statements by the *KSR* Court. See e.g., *In re Dillon*, 919 F.2d 688, 693, 16 USPQ2d 1897, 1902 (Fed. Cir. 1990) (*en banc*) (“[I]t is not necessary in order to establish a *prima facie* case of obviousness that both a structural similarity between a claimed and prior art compound (or a key component of a composition) be shown and that there be a suggestion in or expectation from **the prior art** that the claimed compound or composition will have the same or a similar utility **as one newly discovered by applicant**”) (emphasis added); *In re Lintner*, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972) (“The fact that appellant uses sugar for a different purpose does not alter the conclusion that its use in a prior art composition would be *prima facie* obvious from the purpose disclosed in the references.”).

For a discussion of what constitutes prior art, see [MPEP § 901](#) to [§ 901.06\(d\)](#) and [§ 2121](#) to [§ 2129](#). See [MPEP § 2141.01\(a\)](#) for a discussion of analogous art and [MPEP § 1504.03](#) for a discussion of analogous art for design applications.

B. Ascertaining the Differences Between the Claimed Invention and the Prior Art

Ascertaining the differences between the claimed invention and the prior art requires interpreting the claim language, see [MPEP § 2111](#), and considering both the invention and the prior art as a whole. See [MPEP § 2141.02](#).

C. Resolving the Level of Ordinary Skill in the Art

Any obviousness rejection should include, either explicitly or implicitly in view of the prior art applied, an indication of the level of ordinary skill. See [MPEP § 2141.03](#), subsection II, regarding implicit indication of the level of ordinary skill. A finding as to the level of ordinary skill may be used as a partial basis for a resolution of the issue of obviousness.

The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the relevant time. Factors that may be considered in determining the level of ordinary skill in the art may include: (1) “type of problems encountered in the art;” (2) “prior art solutions to those problems;” (3) “rapidity with which innovations are made;” (4) “sophistication of the technology; and” (5) “educational level of active workers in the field.” *In re GPAC*, 57 F.3d 1573, 1579, 35 USPQ2d 1116, 1121 (Fed. Cir. 1995). “In a given case, every factor may not be present, and one or more factors may predominate.” *Id.* See also *Custom Accessories, Inc. v. Jeffrey-Allan Indust., Inc.*, 807 F.2d 955, 962, 1 USPQ2d 1196, 1201 (Fed. Cir. 1986); *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696, 218 USPQ 865, 868 (Fed. Cir. 1983).

“A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton.” *KSR*, 550 U.S. at 421, 82 USPQ2d at 1397. “[I]n many cases a person of ordinary

skill will be able to fit the teachings of multiple patents together like pieces of a puzzle.”*Id.* at 420, 82 USPQ2d at 1397. Office personnel may also take into account “the inferences and creative steps that a person of ordinary skill in the art would employ.”*Id.* at 418, 82 USPQ2d at 1396.

In addition to the factors above, Office personnel may rely on their own technical expertise to describe the knowledge and skills of a person of ordinary skill in the art. The Federal Circuit has stated that examiners and administrative patent judges on the Board are “persons of scientific competence in the fields in which they work” and that their findings are “informed by their scientific knowledge, as to the meaning of prior art references to persons of ordinary skill in the art.” *In re Berg*, 320 F.3d 1310, 1315, 65 USPQ2d 2003, 2007 (Fed. Cir. 2003). In addition, examiners “are assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill in the art.” *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 86 USPQ2d 1385 (Fed. Cir. 2008) (quoting *Am. Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d 1350, 1360, 220 USPQ 763, 770 (Fed. Cir. 1984). See [MPEP § 2141.03](#) for a discussion of the level of ordinary skill.

III. RATIONALES TO SUPPORT REJECTIONS UNDER 35 U.S.C. 103

Once the *Graham* factual inquiries are resolved, Office personnel must determine whether the claimed invention would have been obvious as of the relevant time to one of ordinary skill in the art.

The obviousness analysis cannot be confined by . . . overemphasis on the importance of published articles and the explicit content of issued patents. . . . In many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design trends.*KSR*, 550 U.S. at 419, 82 USPQ2d at 1396.

Prior art is not limited just to the references being applied, but includes the understanding of one of ordinary skill in the art. The prior art reference (or references when combined) need not teach or suggest all the claim limitations. However, Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art. The “mere existence of differences between the prior art and an invention does not establish the invention’s nonobviousness.” *Dann v. Johnston*, 425 U.S. 219, 230, 189 USPQ 257, 261 (1976). The gap between the prior art and the claimed invention may not be “so great as to render the [claim] nonobvious to one reasonably skilled in the art.” *Id.* In determining obviousness, neither the particular motivation to make the claimed invention nor the problem the inventor is solving controls. The proper analysis is whether the claimed invention would have been obvious as of the relevant time to one of ordinary skill in the art after consideration of all the facts. See [35 U.S.C. 103](#) or [pre-AIA 35](#)

[U.S.C. 103\(a\)](#). Factors other than the disclosures of the cited prior art may provide a basis for concluding that it would have been obvious to one of ordinary skill in the art to bridge the gap. The rationales discussed below outline reasoning that may be applied to find obviousness in such cases.

If the search of the prior art and the resolution of the *Graham* factual inquiries reveal that an obviousness rejection may be made using the familiar teaching-suggestion-motivation (TSM) rationale, then such a rejection is appropriate. Although the Supreme Court in *KSR* cautioned against an overly rigid application of TSM, it also recognized that TSM was one of a number of valid rationales that could be used to determine obviousness. (According to the Supreme Court, establishment of the TSM approach to the question of obviousness “captured a helpful insight.” 550 U.S. at 418, 82 USPQ2d at 1396 (citing *In re Bergel*, 292 F.2d 955, 956-57, 130 USPQ 206, 207-208 (1961)). Furthermore, the Court explained that “[t]here is no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis.” 550 U.S. at 419, 82 USPQ2d at 1396. The Supreme Court also commented that the Federal Circuit “no doubt has applied the test in accord with these principles [set forth in *KSR*] in many cases.” *Id.* Office personnel should also consider whether one or more of the other rationales set forth below supports a conclusion of obviousness. The Court in *KSR* identified a number of rationales to support a conclusion of obviousness which are consistent with the proper “functional approach” to the determination of obviousness as laid down in *Graham*. *KSR*, 550 U.S. at 415-21, 82 USPQ2d at 1395-97. Note that the list of rationales provided below is not intended to be an all-inclusive list. Other rationales to support a conclusion of obviousness may be relied upon by Office personnel. Consistent with *KSR*, the Federal Circuit stated that the obviousness analysis is not “confined by a formalistic conception of the words teaching, suggestion, and motivation.” *Intel Corp. v. Qualcomm Inc.*, 21 F.4th 784, 795, 2021 USPQ2d 1259 (Fed. Cir. 2021) (quoting *KSR*, 550 U.S. at 419, 82 USPQ2d at 1396). See also *In re Ethicon, Inc.*, 844 F.3d 1344, 1350, 121 USPQ2d 1139, 1143 (Fed. Cir. 2017) (recalling that the Supreme Court has instructed decisionmakers to “apply ‘an expansive and flexible approach’ to obviousness”) (quoting *KSR*, 550 U.S. at 415, 82 USPQ2d at 1395).

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* noted that the analysis supporting a rejection under [35 U.S.C. 103](#) should be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR*, 550 U.S. at 418, 82 USPQ2d at 1396. See also *Adapt Pharma Operations Ltd. v. Teva Pharms. USA, Inc.*, 25 F.4th 1354, 1365, 2022 USPQ2d 144 (Fed. Cir. 2022) (stating that a determination of obviousness “requires

‘identify[ing] a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does’” (quoting *KSR*, 550 U.S. at 418, 82 USPQ2d at 1395). Examples of rationales that may support a conclusion of obviousness include:

- (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](#) for a discussion of the rationales listed above along with examples illustrating how the cited rationales may be used to support a finding of obviousness. See also [MPEP § 2144 - § 2144.09](#) for additional guidance regarding support for obviousness determinations.

IV. APPLICANT’S REPLY

Once Office personnel have issued a rejection that establishes the *Graham* factual findings and concludes, in view of the relevant evidence of record at that time, that the claimed invention would have been obvious as of the relevant time, the burden then shifts to the applicant to (A) show that the Office erred in these findings or (B) provide other evidence to show that the claimed subject matter would have been nonobvious. [37 CFR 1.111\(b\)](#) requires applicant to distinctly and specifically point out the supposed errors in the Office’s action and reply to every ground of objection and rejection in the Office action. The reply must present arguments pointing out the specific distinction believed to render the claims patentable over any applied references.

If an applicant disagrees with any factual findings by the Office, an effective traverse of a rejection based wholly or partially on such findings must include a reasoned statement explaining why the applicant believes the Office has erred substantively as to the factual findings. A mere statement or argument that the Office has not established a *prima facie* case

of obviousness or that the Office's reliance on common knowledge is unsupported by documentary evidence will not be considered substantively adequate to rebut the rejection or an effective traverse of the rejection under [37 CFR 1.111\(b\)](#). Office personnel addressing this situation may repeat the rejection made in the prior Office action and make the next Office action final. See [MPEP § 706.07\(a\)](#).

An applicant's reply could also establish that a disclosure relied on in an obviousness rejection is not in fact prior art in view of a [35 U.S.C. 102\(b\)](#) exception, or that subject matter, although prior art, is disqualified for use in an obviousness rejection in view of [pre-AIA 35 U.S.C. 103\(c\)](#). See [MPEP §§ 2146, 2153.01](#) and [2154.02](#). See also [MPEP § 2155](#) regarding affidavits or declarations under [37 CFR 1.130](#) to overcome prior art rejections.

V. CONSIDERATION OF APPLICANT'S REBUTTAL EVIDENCE

Office personnel should consider all rebuttal evidence that is timely presented by the applicants when reevaluating any obviousness determination. Rebuttal evidence may include evidence of "secondary considerations," such as "commercial success, long felt but unsolved needs, [and] failure of others" (*Graham v. John Deere Co.*, 383 U.S. at 17, 148 USPQ at 467), and may also include evidence of unexpected results. As set forth above, Office personnel must articulate findings of fact that support the rationale relied upon in an obviousness rejection. As a result, applicants are likely to submit evidence to rebut the fact finding made by Office personnel. For example, in the case of a claim to a combination, applicants may submit evidence or argument to demonstrate that:

- (A) one of ordinary skill in the art could not have combined the claimed elements by known methods (e.g., due to technological difficulties);
- (B) the elements in combination do not merely perform the function that each element performs separately; or
- (C) the results of the claimed combination were unexpected.

Once the applicant has presented rebuttal evidence, Office personnel should reconsider any initial obviousness determination in view of the entire record. See, e.g., *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984); *In re Eli Lilly & Co.*, 902 F.2d 943, 945, 14 USPQ2d 1741, 1743 (Fed. Cir. 1990). All the rejections of record and proposed rejections and their bases should be reviewed to confirm their continued viability. The Office action should clearly communicate the Office's findings and conclusions, articulating how the conclusions are supported by the findings. The procedures set forth in [MPEP § 706.07\(a\)](#) are to be followed in determining whether an action may be made final.

See [MPEP § 2145](#) concerning consideration of applicant's rebuttal evidence. See also [MPEP § 716](#) to [§ 716.10](#) regarding affidavits or declarations filed under [37 CFR 1.132](#) for purposes

of traversing grounds of rejection.

2141.01 Scope and Content of the Prior Art [R-01.2024]

[Editor Note: This MPEP section is applicable regardless of whether an application is examined under the AIA or under pre-AIA law. For applications subject to the first inventor to file (FITF) provisions of the AIA, the relevant time is "before the effective filing date of the claimed invention". For applications subject to [pre-AIA 35 U.S.C. 102](#), the relevant time is "at the time of the invention". See [MPEP § 2150](#) et seq. Many of the court decisions discussed in this section involved applications or patents subject to [pre-AIA 35 U.S.C. 102](#). These court decisions may be applicable to applications and patents subject to [AIA 35 U.S.C. 102](#) but the relevant time is before the effective filing date of the claimed invention and not at the time of the invention.]

I. PRIOR ART AVAILABLE UNDER 35 U.S.C. 102 IS AVAILABLE UNDER 35 U.S.C. 103

"Before answering *Graham's* 'content' inquiry, it must be known whether a patent or publication is in the prior art under [35 U.S.C. § 102](#)." *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568, 1 USPQ2d 1593, 1597 (Fed. Cir.), *cert. denied*, 481 U.S. 1052 (1987). Subject matter that is prior art under [35 U.S.C. 102](#) can be used to support a rejection under [section 103](#). *Ex parte Andresen*, 212 USPQ 100, 102 (Bd. Pat. App. & Inter. 1981) ("it appears to us that the commentator [of 35 U.S.C.A.] and the [congressional] committee viewed [section 103](#) as including all of the various bars to a patent as set forth in [section 102](#)."). See also *In re Wertheim*, 646 F.2d 527, 532, 209 USPQ 554, 560 (CCPA 1981) ("Commensurate with the Senate Report and Mr. Federico's commentary, we have held that the term 'prior art' refers 'to at least the statutory prior art material named in [§ 102](#).'"); and *In re Hoeksema*, 399 F.2d 269, 273, 158 USPQ 596, 600 (CCPA 1968) ("[w]hile [35 U.S.C. 102](#) is not directly involved in the issue on review, the conditions for patentability, novelty and loss of right to patent, there stated, may have relevance as to the disclosure which must be found in the prior art to find obviousness of an invention under [section 103](#).").

Furthermore, admitted prior art can be relied upon for both anticipation and obviousness determinations, regardless of whether the admitted prior art would otherwise qualify as prior art under the statutory categories of [35 U.S.C. 102](#). *Riverwood Int'l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1354, 66 USPQ2d 1331, 1337 (Fed. Cir. 2003); *Constant v. Advanced Micro-Devices Inc.*, 848 F.2d 1560, 1570, 7 USPQ2d 1057, 1063 (Fed. Cir. 1988). See [MPEP § 2129](#) for discussion of admissions as prior art.

An obviousness rejection is ordinarily based on a disclosure that qualifies as prior art under [35 U.S.C. 102](#) or [pre-AIA 35 U.S.C. 102](#). If it is established that a disclosure does not qualify as prior art under an appropriate section of [35 U.S.C. 102](#), then the disclosure is also not prior

art that can be used in an obviousness rejection. For instance, for a claimed invention subject to [35 U.S.C. 102](#), a [35 U.S.C. 102\(a\)\(2\)](#) reference used in an anticipation rejection but overcome by submitting a declaration under [37 CFR 1.130\(a\)](#) cannot be used in an obviousness rejection. Likewise, for a claimed invention subject to [pre-AIA 35 U.S.C. 102](#), a [pre-AIA 35 U.S.C. 102\(a\)](#) reference used in an anticipation rejection but overcome by submitting a declaration under [37 CFR 1.131](#) cannot be used in an obviousness rejection.

For an overview of what constitutes prior art under [35 U.S.C. 102](#), see [MPEP § 901 - § 901.06\(d\)](#), [§ 2121 - § 2129](#) and [§ 2151 - § 2155](#).

II. SUBSTANTIVE CONTENT OF THE PRIOR ART

See [MPEP § 2121 - § 2129](#) for case law relating to the substantive content of the prior art (e.g., availability of inoperative devices, extent to which prior art must be enabling, broad disclosure rather than preferred embodiments, admissions, etc.).

III. CONTENT OF THE PRIOR ART IS DETERMINED AT THE RELEVANT TIME TO AVOID HINDSIGHT

The purpose of the [pre-AIA 35 U.S.C. 103\(a\)](#) requirement “at the time the invention was made” is to avoid impermissible hindsight. Likewise, the [AIA 35 U.S.C. 103](#) requirement “before the effective filing date of the claimed invention” serves the same purpose. See [MPEP § 2145](#), subsection X.A. for a discussion of rebutting applicants’ arguments that a rejection is based on hindsight.

In the pre-AIA context, the Federal Circuit stated, “[i]t is difficult but necessary that the decisionmaker forget what he or she has been taught . . . about the claimed invention and cast the mind back to the time the invention was made (often as here many years), to occupy the mind of one skilled in the art. . . .” *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Although the AIA has changed the relevant time focus to “before the effective filing date of the claimed invention,” the observation expressed by the Federal Circuit otherwise continues to apply.

IV. PRE-AIA 35 U.S.C. 103(c) COMMON OWNERSHIP— REQUIRED FOR THE CONDITIONS OF PRE-AIA 35 U.S.C. 103(c)

An applicant subject to [pre-AIA 35 U.S.C. 102](#) who wants to rely on [pre-AIA 35 U.S.C. 103\(c\)](#) to overcome an obviousness rejection has the burden of establishing that subject matter which only qualifies as prior art under subsection (e), (f) or (g) of [pre-AIA 35 U.S.C. 102](#) used in a rejection under [pre-AIA 35 U.S.C. 103\(a\)](#) and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. Likewise, an applicant who wants to rely on the joint research provisions of

[pre-AIA 35 U.S.C. 103\(c\)](#) (for applications pending on or after December 10, 2004) has the burden of establishing that:

- (A) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made;
- (B) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and
- (C) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

These prior art disqualifications under [pre-AIA 35 U.S.C. 103\(c\)](#) are only applicable for subject matter which only qualifies as prior art under subsection [\(e\)](#), [\(f\)](#) or [\(g\)](#) of [pre-AIA 35 U.S.C. 102](#) and is used in a rejection under [pre-AIA 35 U.S.C. 103\(a\)](#).

Note that for applications filed prior to November 29, 1999, and granted as patents prior to December 10, 2004, [pre-AIA 35 U.S.C. 103\(c\)](#) is limited on its face to subject matter developed by another person which qualifies as prior art only under subsection [\(f\)](#) or [\(g\)](#) of [pre-AIA 35 U.S.C. 102](#). See [MPEP § 2146.01](#). See also *In re Bartfeld*, 925 F.2d 1450, 1453-54, 17 USPQ2d 1885, 1888 (Fed. Cir. 1991) (Applicant attempted to overcome a [pre-AIA 35 U.S.C. 102\(e\)/103](#) rejection with a terminal disclaimer by alleging that the public policy intent of [pre-AIA 35 U.S.C. 103\(c\)](#) was to prohibit the use of “secret” prior art in obviousness determinations. The court rejected this argument, holding “We may not disregard the unambiguous exclusion of [§ 102\(e\)](#) from the statute’s purview.”).

See [MPEP § 2146.02](#) for the requirements which must be met to establish common ownership or a joint research agreement.

2141.01(a) Analogous and Nonanalogous Art [R-01.2024]

[Editor Note: This MPEP section is applicable regardless of whether an application is examined under the AIA or under pre-AIA law. For applications subject to the first inventor to file (FITF) provisions of the AIA, the relevant time is "before the effective filing date of the claimed invention". For applications subject to [pre-AIA 35 U.S.C. 102](#), the relevant time is "at the time of the invention". See [MPEP § 2150](#) et seq. Many of the court decisions discussed in this section involved applications or patents subject to [pre-AIA 35 U.S.C. 102](#). These court decisions may be applicable to applications and patents subject to [AIA 35 U.S.C. 102](#) but the relevant time is before the effective filing date of the claimed invention and not at the time of the invention.]

I. TO RELY ON A REFERENCE UNDER 35 U.S.C. 103, IT MUST BE ANALOGOUS ART TO THE CLAIMED INVENTION

In order for a reference to be proper for use in an obviousness rejection under [35 U.S.C. 103](#), the reference must be analogous art to the claimed invention. *In re Bigio*, 381 F.3d 1320, 1325, 72 USPQ2d 1209, 1212 (Fed. Cir. 2004). A reference is analogous art to the claimed invention if: (1) the reference is from the same field of endeavor as the claimed invention (even if it addresses a different problem); or (2) the reference is reasonably pertinent to the problem faced by the inventor (even if it is not in the same field of endeavor as the claimed invention). Note that “same field of endeavor” and “reasonably pertinent” are two separate tests for establishing analogous art; it is not necessary for a reference to fulfill both tests in order to qualify as analogous art. See *Bigio*, 381 F.3d at 1325, 72 USPQ2d at 1212. The examiner must determine whether a reference is analogous art to the claimed invention when analyzing the obviousness of the subject matter under examination. When more than one prior art reference is used as the basis of an obviousness rejection, it is not required that the references be analogous art to each other. See *Sanofi-Aventis Deutschland GmbH v. Mylan Pharms. Inc.*, 66 F.4th 1373, 1380, 2023 USPQ2d 552 (Fed. Cir. 2023) and *Corephotonics, Ltd. v. Apple Inc.*, 84 F.4th 990, 1007, 2023 USPQ2d 1202 (Fed. Cir. 2023). If a reference is not analogous art to the claimed invention, it may not be used in an obviousness rejection under [35 U.S.C. 103](#). However, there is no analogous art requirement for a reference being applied in an anticipation rejection under [35 U.S.C. 102](#). *In re Schreiber*, 128 F.3d 1473, 1478, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997).

When determining whether the “relevant field of endeavor” test is met, the examiner should consider “explanations of the invention’s subject matter in the patent application, including the embodiments, function, and structure of the claimed invention.” *Airbus S.A.S. v. Firepass Corp.*, 941 F.3d 1374, 1380, 2019 USPQ2d 430083 (Fed. Cir. 2019) (quoting *Bigio*, 381 F.3d at 1325, 72 USPQ2d at 1212). When determining whether a prior art reference meets the “same field of endeavor” test for the analogous art, the primary focus is on what the reference discloses. *Airbus*, 41 F.3d at 1380. The examiner must consider the disclosure of each reference “in view of the ‘the reality of the circumstances.’” *Airbus*, 41 F.3d at 1380 (quoting *Bigio*, 381 F.3d at 1326, 72 USPQ2d at 1212). These circumstances are to be weighed “from the vantage point of the common sense likely to be exerted by one of ordinary skill in the art in assessing the scope of the endeavor.” *Airbus*, 41 F.3d at 1380. See also *Donner Technology, LLC v. Pro Stage Gear, LLC*, 979 F.3d 1353, 2020 USPQ2d 11335 (Fed. Cir. 2020); *Sanofi-Aventis*, 66 F.4th at 1378; and *Netflix, Inc. v. DivX, LLC*, 80 F.4th 1352, 1358-59, 2023 USPQ2d 1057 (Fed. Cir. 2023) (“The field of endeavor is ‘not limited to the specific point of novelty, the narrowest possible conception of the field, or the particular focus within a given field.’”) (quoting *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1001, 120 USPQ2d 1593, 1597 (Fed. Cir. 2016)).

As for the “reasonably pertinent” test, the examiner should consider the problem faced by the inventor, as reflected - either explicitly or implicitly - in the specification. In order for a reference to be “reasonably pertinent” to the problem, it must “logically [] have commended itself to an inventor’s attention in considering his problem.” *In re ICON Health and Fitness, Inc.*, 496 F.3d 1374, 1379-80 (Fed. Cir. 2007) (quoting *In re Clay*, 966 F.2d 656,658, 23 USPQ2d 1058, 1061 (Fed. Cir. 1992)). See also *In re Klein*, 647 F.3d 1343, 1348, 98 USPQ2d 1991, 1993 (Fed. Cir. 2011) An inventor is not expected to have been aware of all prior art outside of the field of endeavor. *Airbus*, 41 F.3d at 1380-82. A reference outside of the field of endeavor is reasonably pertinent if a person of ordinary skill would have consulted it and applied its teachings when faced with the problem that the inventor was trying to solve. *Airbus*, 41 F.3d at 1380-82. In order to support a determination that a reference is reasonably pertinent, it may be appropriate to include a statement of the examiner’s understanding of the problem. The question of whether a reference is reasonably pertinent often turns on how the problem to be solved is perceived. If the problem to be solved is viewed in a narrow or constrained way, and such a view is not consistent with the specification, the scope of available prior art may be inappropriately limited. It may be necessary for the examiner to explain why an inventor seeking to solve the identified problem would have looked to the reference in an attempt to find a solution to the problem, i.e., factual reasons why the prior art is pertinent to the identified problem. See *Donner Tech., LLC v. Pro Stage Gear, LLC*, 979 F.3d 1353, 1359, 2020 USPQ2d 11335 (Fed. Cir. 2020) (“Thus, when addressing whether a reference is analogous art with respect to the claimed invention under a reasonable-pertinence theory, the problems to which both relate must be identified and compared.”).

The Supreme Court’s decision in *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007), did not change the test for analogous art as stated in *Bigio*. Under *Bigio*, a reference need not be from the same field of endeavor as the claimed invention in order to be analogous art. *Bigio*, 381 F.3d at 1325, 72 USPQ2d at 1212. This is consistent with the Supreme Court’s instruction in *KSR* that “[w]hen a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one.” *KSR*, 550 U.S. at 417, 82 USPQ2d at 1396. The Federal Circuit reads *KSR* as “direct[ing] us to construe the scope of analogous art broadly” because “*familiar items may have obvious uses beyond their primary purposes*, and a person of ordinary skill often will be able to fit the teachings of multiple patents together like pieces of a puzzle.” *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1238, 95 USPQ2d 1525, 1530 (Fed. Cir. 2010) (quoting *KSR*, 550 U.S. at 402, 127 S. Ct. at 1727).

Any argument by the applicant that the examiner has misconstrued the problem to be solved, and as a result has improperly relied on nonanalogous art, should be fully considered in light of the specification. In evaluating the applicant’s argument, the examiner should look to the

teachings of the specification and the inferences that would reasonably have been drawn from the specification by a person of ordinary skill in the art as a guide to understanding the problem to be solved. A prior art reference not in the same field of endeavor as the claimed invention must be reasonably pertinent to the problem to be solved in order to qualify as analogous art and be applied in an obviousness rejection.

II. CONSIDER SIMILARITIES AND DIFFERENCES IN STRUCTURE AND FUNCTION

While Patent Office classification of references and the cross-references in the official search notes of the class definitions are some evidence of “nonanalogy” or “analogy” respectively, the court has found “the similarities and differences in structure and function of the inventions disclosed in the references to carry far greater weight.” *In re Ellis*, 476 F.2d 1370, 1372, 177 USPQ 526, 527 (CCPA 1973) (The structural similarities and functional overlap between the structural gratings shown by one reference and the shoe scrapers of the type shown by another reference were readily apparent, and therefore the arts to which the reference patents belonged were reasonably pertinent to the art with which appellant’s invention dealt (pedestrian floor gratings).).

III. ANALOGY IN THE CHEMICAL ARTS

Examples of analogous art in the chemical arts include: *Ex parte Bland*, 3 USPQ2d 1103 (Bd. Pat App. & Inter. 1986) (Claims were drawn to a particulate composition useful as a preservative for an animal foodstuff (or a method of inhibiting fungus growth in an animal foodstuff therewith) comprising verxite having absorbed thereon propionic acid. All references were concerned with absorbing biologically active materials on carriers, and therefore the teachings in each of the various references would have been pertinent to the problems in the other references and the invention at hand.); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983) (Problem confronting inventor was preventing electrostatic buildup in PTFE tubing caused by hydrocarbon fuel flow while precluding leakage of fuel. Two prior art references relied upon were in the rubber hose art, both referencing the problem of electrostatic buildup caused by fuel flow. The court found that because PTFE and rubber are used by the same hose manufacturers and experience the same and similar problems, a solution found for a problem experienced with either PTFE or rubber hosing would be looked to when facing a problem with the other.); *In re Mlot-Fijalkowski*, 676 F.2d 666, 213 USPQ 713 (CCPA 1982) (Problem faced by inventor was enhancement and immobilization of dye penetrant indications. References which taught the use of dyes and finely divided developer materials to produce colored images preferably in, but not limited to, the duplicating paper art were properly relied upon because the court found that inventor’s problem was one of dye chemistry, and a search for its solution would include the dye arts in general.).

IV. ANALOGY IN THE MECHANICAL ARTS

Examples of analogous art in the mechanical arts include: *Stevenson v. Int'l Trade Comm.*, 612 F.2d 546, 550, 204 USPQ 276, 280 (CCPA 1979) (“In a simple mechanical invention a broad spectrum of prior art must be explored and it is reasonable to permit inquiry into other areas where one of ordinary skill in the art would be aware that similar problems exist.”). See also *In re Bigio*, 381 F.3d 1320, 1325-26, 72 USPQ2d 1209, 1211-12 (Fed. Cir. 2004). The patent application claimed a “hair brush” having a specific bristle configuration. The Board affirmed the examiner’s rejection of the claims as being obvious in view of prior art patents disclosing toothbrushes. *Id.* at 1323, 72 USPQ2d at 1210. The appellant disputed that the patent references constituted analogous art. On appeal, the court upheld the Board’s interpretation of the claim term “hair brush” to encompass any brush that may be used for any bodily hair, including facial hair. *Id.* at 1323-24, 72 USPQ2d at 1211. With this claim interpretation, the court applied the “field of endeavor test” for analogous art and determined that the references were within the field of the inventor’s endeavor and hence were analogous art because toothbrushes are structurally similar to small brushes for hair, and a toothbrush could be used to brush facial hair. *Id.* at 1326, 72 USPQ2d at 1212.

Also see *In re Deminski*, 796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986) (Appellant’s claims related to double-acting high pressure gas transmission line compressors in which the valves could be removed easily for replacement. The Board relied upon references which taught either a double-acting piston pump or a double-acting piston compressor. The court agreed that since the cited pumps and compressors have essentially the same function and structure, the field of endeavor includes both types of double-action piston devices for moving fluids.); *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 227 USPQ 766 (Fed. Cir. 1985) (Claims at issue were directed to an instrument marker pen body, the improvement comprising a pen arm holding means having an integrally molded hinged member for folding over against the pen body. Although the patent owners argued the hinge and fastener art was nonanalogous, the court held that the problem confronting the inventor was the need for a simple holding means to enable frequent, secure attachment and easy removal of a marker pen to and from a pen arm, and one skilled in the pen art trying to solve that problem would have looked to the fastener and hinge art.); and *Ex parte Goodyear Tire & Rubber Co.*, 230 USPQ 357 (Bd. Pat. App. & Inter. 1985) (A reference in the clutch art was held reasonably pertinent to the friction problem faced by the inventor, whose claims were directed to a braking material, because brakes and clutches utilize interfacing materials to accomplish their respective purposes.).

V. ANALOGY IN THE ELECTRICAL ARTS

See, for example, *Medtronic, Inc. v. Cardiac Pacemakers*, 721 F.2d 1563, 220 USPQ 97 (Fed. Cir. 1983) (Patent claims were drawn to a cardiac pacemaker which comprised, among other components, a runaway inhibitor means for preventing a pacemaker malfunction from causing pulses to be applied at too high a frequency. Two references disclosed circuits used in high

power, high frequency devices which inhibited the runaway of pulses from a pulse source. The court held that one of ordinary skill in the pacemaker designer art faced with a rate-limiting problem would look to the solutions of others faced with rate limiting problems, and therefore the references were in an analogous art.).

VI. EXAMPLES OF ANALOGY IN THE DESIGN ARTS

See [MPEP § 1504.03](#) for a discussion of the relevant case law setting forth the general requirements for analogous art in design applications.

2141.02 Differences Between Prior Art and Claimed Invention [R-01.2024]

[Editor Note: This MPEP section is applicable regardless of whether an application is examined under the AIA or under pre-AIA law. For applications subject to the first inventor to file (FITF) provisions of the AIA, the relevant time is "before the effective filing date of the claimed invention". For applications subject to [pre-AIA 35 U.S.C. 102](#), the relevant time is "at the time of the invention". See [MPEP § 2150](#) et seq. Many of the court decisions discussed in this section involved applications or patents subject to [pre-AIA 35 U.S.C. 102](#). These court decisions may be applicable to applications and patents subject to [AIA 35 U.S.C. 102](#) but the relevant time is before the effective filing date of the claimed invention and not at the time of the invention.]

Ascertaining the differences between the prior art and the claims at issue requires interpreting the claim language, and considering both the invention and the prior art references as a whole. See [MPEP § 2111 - § 2116.01](#) for case law pertaining to claim interpretation. See also [MPEP § 2143.03](#) for examples of types of claim language that may raise a question as to its limiting effect.

I. THE CLAIMED INVENTION AS A WHOLE MUST BE CONSIDERED

In determining the differences between the prior art and the claims, the question under [35 U.S.C. 103](#) is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983) (Claims were directed to a vibratory testing machine (a hard-bearing wheel balancer) comprising a holding structure, a base structure, and a supporting means which form "a single integral and gaplessly continuous piece." *Nortron* argued the invention is just making integral what had been made in four bolted pieces, improperly limiting the focus to a structural difference from the prior art and failing to consider the invention as a whole. The prior art perceived a need for mechanisms to dampen resonance, whereas the inventor eliminated the need for dampening via the one-piece gapless support structure.

“Because that insight was contrary to the understandings and expectations of the art, the structure effectuating it would not have been obvious to those skilled in the art.” 713 F.2d at 785, 218 USPQ at 700 (citations omitted).).

See also *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) (Claims were directed to a three step process for preparing sweetened foods and drinks. The first two steps were directed to a process of producing high purity maltose (the sweetener), and the third was directed to adding the maltose to foods and drinks. The parties agreed that the first two steps were nonobvious but formed a known product and the third step was obvious. The Solicitor argued the preamble was directed to a process for preparing foods and drinks sweetened mildly and thus the specific method of making the high purity maltose (the first two steps in the claimed process) should not be given weight, analogizing with product-by-process claims. The court disagreed and held “due to the admitted unobviousness of the first two steps of the claimed combination of steps, the subject matter as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made.” 535 F.2d at 69, 190 USPQ at 17 (emphasis in original). The preamble only recited the purpose of the process and did not limit the body of the claim. Therefore, the claimed process was a three-step process, not the product formed by two steps of the process or the third step of using that product.).

II. DISTILLING THE INVENTION DOWN TO A “GIST” OR “THRUST” OF AN INVENTION DISREGARDS “AS A WHOLE” REQUIREMENT

Distilling an invention down to the “gist” or “thrust” of an invention disregards the requirement of analyzing the subject matter “as a whole.” *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984) (restricting consideration of the claims to a 10% per second rate of stretching of unsintered PTFE and disregarding other limitations resulted in treating claims as though they read differently than allowed); *Bausch & Lomb v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 447-49, 230 USPQ 416, 419-20 (Fed. Cir. 1986), *cert. denied*, 484 U.S. 823 (1987) (District court focused on the “concept of forming ridgeless depressions having smooth rounded edges using a laser beam to vaporize the material,” but “disregarded express limitations that the product be an ophthalmic lens formed of a transparent cross-linked polymer and that the laser marks be surrounded by a smooth surface of unsublimated polymer.”). See also *Jones v. Hardy*, 727 F.2d 1524, 1530, 220 USPQ 1021, 1026 (Fed. Cir. 1984) (“treating the advantage as the invention disregards the statutory requirement that the invention be viewed ‘as a whole’”); *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1 USPQ2d 1593 (Fed. Cir. 1987), *cert. denied*, 481 U.S. 1052 (1987) (district court improperly distilled claims down to a one word solution to a problem).

III. DISCOVERING SOURCE/CAUSE OF A PROBLEM IS PART OF “AS A WHOLE” INQUIRY

“[A] patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. This is part of the ‘subject matter as a whole’ which should always be considered in determining the obviousness of an invention under [35 U.S.C. § 103](#).” *In re Sponnoble*, 405 F.2d 578, 585, 160 USPQ 237, 243 (CCPA 1969). However, “discovery of the cause of a problem . . . does not always result in a patentable invention. . . . [A] different situation exists where the solution is obvious from prior art which contains the same solution for a similar problem.” *In re Wiseman*, 596 F.2d 1019, 1022, 201 USPQ 658, 661 (CCPA 1979) (emphasis in original).

In *In re Sponnoble*, the claim was directed to a plural compartment mixing vial wherein a center seal plug was placed between two compartments for temporarily isolating a liquid-containing compartment from a solids-containing compartment. The claim differed from the prior art in the selection of butyl rubber with a silicone coating as the plug material instead of natural rubber. The prior art recognized that leakage from the liquid to the solids compartment was a problem, and considered the problem to be a result of moisture passing around the center plug because of microscopic fissures inherently present in molded or blown glass. The court found the inventor discovered the cause of moisture transmission was through the center plug, and there was no teaching in the prior art which would suggest the necessity of selecting applicant's plug material which was more impervious to liquids than the natural rubber plug of the prior art.

In *In re Wiseman*, 596 F.2d at 1022, 201 USPQ at 661, claims directed to grooved carbon disc brakes wherein the grooves were provided to vent steam or vapor during a braking action to minimize fading of the brakes were rejected as obvious over a reference showing carbon disc brakes without grooves in combination with a reference showing grooves in noncarbon disc brakes for the purpose of cooling the faces of the braking members and eliminating dust, thereby reducing fading of the brakes. The court affirmed the rejection, holding that even if the inventor discovered the cause of a problem, the solution would have been obvious from the prior art which contained the same solution (inserting grooves in disc brakes) for a similar problem.

IV. APPLICANTS ALLEGING DISCOVERY OF A SOURCE OF A PROBLEM MUST PROVIDE SUBSTANTIATING EVIDENCE

Applicants who allege the inventor discovered the source of a problem must provide evidence substantiating the allegation, either by way of affidavits or declarations, or by way of a clear and persuasive assertion in the specification. *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979) (unsubstantiated statement of counsel was insufficient to show appellants discovered source of the problem); *In re Kaslow*, 707 F.2d 1366, 217 USPQ 1089 (Fed. Cir. 1983) (Claims were directed to a method for redeeming merchandising coupons which contain a UPC “5-by-5” bar code wherein, among other steps, the memory at each

supermarket would identify coupons by manufacturer and transmit the data to a central computer to provide an audit, thereby eliminating the need for clearinghouses and preventing retailer fraud. In challenging the propriety of an obviousness rejection, appellant argued he discovered the source of a problem (retailer fraud and manual clearinghouse operations) and its solution. The court found appellant's specification did not support the argument that he discovered the source of the problem with respect to retailer fraud, and that the claimed invention failed to solve the problem of manual clearinghouse operations.).

V. DISCLOSED INHERENT PROPERTIES ARE PART OF “AS A WHOLE” INQUIRY

“In determining whether the invention as a whole would have been obvious under [35 U.S.C. 103](#), we must first delineate the invention as a whole. In delineating the invention as a whole, we look not only to the subject matter which is literally recited in the claim in question... but also to those properties of the subject matter which are inherent in the subject matter *and* are disclosed in the specification. . . Just as we look to a chemical and its properties when we examine the obviousness of a composition of matter claim, it is this invention *as a whole*, and not some part of it, which must be obvious under [35 U.S.C. 103](#).” *In re Antonie*, 559 F.2d 618, 620, 195 USPQ 6, 8 (CCPA 1977) (emphasis in original) (citations omitted) (The claimed wastewater treatment device had a tank volume to contactor area of 0.12 gal./sq. ft. The court found the invention as a whole was the ratio of 0.12 and its inherent property that the claimed devices maximized treatment capacity regardless of other variables in the devices. The prior art did not recognize that treatment capacity was a function of the tank volume to contactor ratio, and therefore the parameter optimized was not recognized in the art to be a result-effective variable.). Note, however, that after *KSR*, the presence of a known result-effective variable would be one, but not necessarily the only, motivation for a person of ordinary skill in the art to experiment to reach another workable product or process. See [MPEP § 2144.05](#), subsection II.B. See also *In re Papesch*, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963) (“From the standpoint of patent law, a compound and all its properties are inseparable.”).

Obviousness cannot be predicated on what is not known at the relevant time, even if the inherency of a certain feature is later established. See *In re Rijckaert*, 9 F.3d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993). See [MPEP § 2112](#) for the requirements of rejections based on inherency.

VI. PRIOR ART MUST BE CONSIDERED IN ITS ENTIRETY, INCLUDING DISCLOSURES THAT TEACH AWAY FROM THE CLAIMS

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984) (Claims were directed to a process of producing a porous article by expanding shaped, unsintered, highly crystalline poly(tetrafluoroethylene) (PTFE) by stretching said PTFE at a 10% per second rate

to more than five times the original length. The prior art teachings with regard to unsintered PTFE indicated the material does not respond to conventional plastics processing, and the material should be stretched slowly. A reference teaching rapid stretching of conventional plastic polypropylene with reduced crystallinity combined with a reference teaching stretching unsintered PTFE would not suggest rapid stretching of highly crystalline PTFE, in light of the disclosures in the art that teach away from the invention, i.e., that the conventional polypropylene should have reduced crystallinity before stretching, and that PTFE should be stretched slowly). *Allied Erecting v. Genesis Attachments*, 825 F.3d 1373, 1381, 119 USPQ2d 1132, 1138 (Fed. Cir. 2016) (“Although modification of the movable blades may impede the quick change functionality disclosed by Caterpillar, [a] given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine.” (quoting *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165, 77 USPQ2d 1865, 1870 (Fed Cir. 2006) (citation omitted))).

However, “the prior art’s mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed....” *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). See also [MPEP § 2123](#).

2141.03 Level of Ordinary Skill in the Art [R-01.2024]

[Editor Note: This MPEP section is applicable regardless of whether an application is examined under the AIA or under pre-AIA law. For applications subject to the first inventor to file (FITF) provisions of the AIA, the relevant time is "before the effective filing date of the claimed invention". For applications subject to [pre-AIA 35 U.S.C. 102](#), the relevant time is "at the time of the invention". See [MPEP § 2150](#) et seq. Many of the court decisions discussed in this section involved applications or patents subject to [pre-AIA 35 U.S.C. 102](#). These court decisions may be applicable to applications and patents subject to [AIA 35 U.S.C. 102](#) but the relevant time is before the effective filing date of the claimed invention and not at the time of the invention.]

I. FACTORS TO CONSIDER IN DETERMINING LEVEL OF ORDINARY SKILL

The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the relevant time. Factors that may be considered in determining the level of ordinary skill in the art may include: (A) “type of problems encountered in the art;” (B) “prior art solutions to those problems;” (C) “rapidity with which innovations are made;” (D) “sophistication of the technology; and” (E) “educational level of active workers in the field. In a given case, every factor may not be present, and one or more factors may predominate.” *In re GPAC*, 57 F.3d 1573, 1579, 35 USPQ2d 1116, 1121 (Fed. Cir. 1995); *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962, 1 USPQ2d 1196, 1201 (Fed. Cir. 1986);

Environmental Designs, Ltd. V. Union Oil Co., 713 F.2d 693, 696, 218 USPQ 865, 868 (Fed. Cir. 1983).

“A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421, 82 USPQ2d 1385, 1397 (2007). “[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle.” *Id.* at 420, 82 USPQ2d 1397. Office personnel may also take into account “the inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* at 418, 82 USPQ2d at 1396.

The level of disclosure in the specification of the application under examination or in relevant references may also be informative of the knowledge and skills of a person of ordinary skill in the art. For example, if the specification is entirely silent on how a certain step or function is achieved, that silence may suggest that figuring out how to achieve that step or function is within the ordinary skill in the art, provided that the specification complies with [35 U.S.C. 112](#). *Uber Techs., Inc. v. X One, Inc.*, 957 F.3d 1334, 1339, 2020 USPQ2d 10476 (Fed. Cir. 2020) (“The specification of the '593 patent is entirely silent on how to transmit user locations and maps from a server to a user's mobile device, suggesting that a person of ordinary skill in the art was more than capable of selecting between the known methods of accomplishing this. The '593 patent confirms that its invention, including any necessary plotting, ‘utilizes existing platforms and infrastructure’ and does not ‘require development of new cell phone or PDA technology, nor do[es it] require development of new cellular communication infrastructure.’”)

The “hypothetical ‘person having ordinary skill in the art’ to which the claimed subject matter pertains would, of necessity have the capability of understanding the scientific and engineering principles applicable to the pertinent art.” *Ex parte Hiyamizu*, 10 USPQ2d 1393, 1394 (Bd. Pat. App. & Inter. 1988) (The Board disagreed with the examiner’s definition of one of ordinary skill in the art (a doctorate level engineer or scientist working at least 40 hours per week in semiconductor research or development), finding that the hypothetical person is not definable by way of credentials, and that the evidence in the application did not support the conclusion that such a person would require a doctorate or equivalent knowledge in science or engineering.).

References which are not prior art may be relied upon to demonstrate the level of ordinary skill in the art at or around the relevant time. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 1098, 231 USPQ 375, 380 (Fed. Cir. 1986) (“Evidence of contemporaneous invention is probative of ‘the level of knowledge in the art at the time the invention was made.’” (citing *In re Farrenkopf*, 713 F.2d 714, 720, 219 USPQ 1, 6 (Fed. Cir. 1983))); *Ecolochem, Inc. v. S. California Edison Co.*, 227 F.3d 1361, 1379, 56 USPQ2d 1065, 1079 (Fed. Cir. 2000) (“The fact of near-simultaneous invention, though not determinative of statutory obviousness, is

strong evidence of what constitutes the level of ordinary skill in the art.” (quoting *The Int’l Glass Co. v. United States*, 408 F.2d 395, 405, 159 USPQ 434, 442 (Ct. Cl. 1969))). See also *Thomas & Betts Corp. v. Litton Sys., Inc.*, 720 F.2d 1572, 1580-81, 220 USPQ 1, 7 (Fed. Cir. 1983) (“Thus, the [unpublished internal materials], though not technically prior art, were, in effect, properly used as indicators of the level of ordinary skill in the art to which the invention pertained.”).

Moreover, references not available as prior art may be relevant to establishing “a motivation to combine which is implicit in the knowledge of one of ordinary skill in the art.” *Nat’l Steel Car, Ltd. v. Can. Pac. Ry., Ltd.*, 357 F.3d 1319, 1337-38, 69 USPQ2d 1641, 1656 (Fed. Cir. 2004) (holding that a drawing made by an engineer that was not prior art can, nonetheless, “... be used to demonstrate a motivation to combine implicit in the knowledge of one of ordinary skill in the art.”).

II. SPECIFYING A PARTICULAR LEVEL OF SKILL IS NOT NECESSARY WHERE THE PRIOR ART ITSELF REFLECTS AN APPROPRIATE LEVEL

If the only facts of record pertaining to the level of skill in the art are found within the prior art of record, the court has held that an invention may be held to have been obvious without a specific finding of a particular level of skill where the prior art itself reflects an appropriate level. *Chore-Time Equipment, Inc. v. Cumberland Corp.*, 713 F.2d 774, 218 USPQ 673 (Fed. Cir. 1983). See also *Okajima v. Bourdeau*, 261 F.3d 1350, 1355, 59 USPQ2d 1795, 1797 (Fed. Cir. 2001).

III. ASCERTAINING LEVEL OF ORDINARY SKILL IS NECESSARY TO MAINTAIN OBJECTIVITY

“The importance of resolving the level of ordinary skill in the art lies in the necessity of maintaining objectivity in the obviousness inquiry.” *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718, 21 USPQ2d 1053, 1057 (Fed. Cir. 1991). The examiner must ascertain what would have been obvious as of the relevant time to one of ordinary skill in the art, and not to the inventor, a judge, a layman, those skilled in remote arts, or to geniuses in the art at hand. *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 218 USPQ 865 (Fed. Cir. 1983), *cert. denied*, 464 U.S. 1043 (1984).

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2143-Examples of Basic Requirements of a Prima Facie Case of Obviousness

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2143 Examples of Basic Requirements of a *Prima Facie* Case of Obviousness [R-01.2024]

[Editor Note: This MPEP section is applicable regardless of whether an application is examined under the AIA or under pre-AIA law. For applications subject to the first inventor to file (FITF) provisions of the AIA, the relevant time is "before the effective filing date of the claimed invention". For applications subject to [pre-AIA 35 U.S.C. 102](#), the relevant time is "at the time of the invention". See [MPEP § 2150](#) et seq. Many of the court decisions discussed in this section involved applications or patents subject to [pre-AIA 35 U.S.C. 102](#). These court decisions may be applicable to applications and patents subject to [AIA 35 U.S.C. 102](#) but the relevant time is before the effective filing date of the claimed invention and not at the time of the invention.]

The Supreme Court in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415-421, 82 USPQ2d 1385, 1395-97 (2007) identified a number of rationales to support a conclusion of obviousness which are consistent with the proper “functional approach” to the determination of obviousness as laid down in *Graham*. 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* noted that the analysis supporting a rejection under [35 U.S.C. 103](#) should be made explicit. In *Ball Aerosol v. Ltd. Brands*, 555 F.3d 984, 89 USPQ2d 1870 (Fed. Cir. 2009), the Federal Circuit offered additional instruction as to the need for an explicit analysis. The Federal Circuit explained that the Supreme Court’s requirement for an explicit analysis does not require record evidence of an explicit teaching of a motivation to combine in the prior art.

“[T]he analysis that “should be made explicit” refers not to the teachings in the prior art of a motivation to combine, but to the court’s analysis. . . . Under the flexible inquiry set forth by

the Supreme Court, the district court therefore erred by failing to take account of ‘the inferences and creative steps,’ or even routine steps, that an inventor would employ and by failing to find a motivation to combine related pieces from the prior art.” *Ball Aerosol*, 555 F.3d at 993, 89 USPQ2d at 1877.

The Federal Circuit’s directive in *Ball Aerosol* was addressed to a lower court, but it applies to Office personnel as well. When setting forth a rejection, Office personnel are to continue to make appropriate findings of fact as explained in [MPEP § 2141](#) and [§ 2143](#), and must provide a reasoned explanation as to why the invention as claimed would have been obvious to a person of ordinary skill in the art at the relevant time. This requirement for explanation remains even in situations in which Office personnel may properly rely on common sense or ordinary ingenuity. *In re Van Os*, 844 F.3d 1359, 1361, 121 USPQ2d 1209, 1211 (Fed. Cir. 2017) (“Absent some articulated rationale, a finding that a combination of prior art would have been ‘common sense’ or ‘intuitive’ is no different than merely stating the combination ‘would have been obvious.’”).

I. EXAMPLES OF RATIONALES

Examples of rationales that may support a conclusion of obviousness include:

- (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.

Note that the list of rationales provided is not intended to be an all-inclusive list. Other rationales to support a conclusion of obviousness may be relied upon by Office personnel. Any rationale employed must provide a link between the factual findings and the legal conclusion of obviousness.

It is important for Office personnel to recognize that when they do choose to formulate an obviousness rejection using one of the rationales suggested by the Supreme Court in *KSR* and discussed herein, they are to adhere to the guidance provided regarding the necessary factual findings. It remains Office policy that appropriate factual findings are required in order to apply the enumerated rationales properly.

The subsections below include discussions of each rationale along with examples illustrating how the cited rationales may be used to support a finding of obviousness. Some examples use the facts of pre-*KSR* cases to show how the rationales suggested by the Court in *KSR* may be used to support a finding of obviousness. The cases cited (from which the facts were derived) may not necessarily stand for the proposition that the particular rationale is the basis for the court's holding of obviousness, but they do illustrate consistency of past decisions with the lines of reasoning laid out in *KSR*. Other examples are post-*KSR* decisions that show how the Federal Circuit has applied the principles of *KSR*. Cases are included that illustrate findings of obviousness as well as nonobviousness. Note that, in some instances, a single case is used in different subsections to illustrate the use of more than one rationale to support a finding of obviousness. It will often be the case that, once the *Graham* inquiries have been satisfactorily resolved, a conclusion of obviousness may be supported by more than one line of reasoning.

A. Combining Prior Art Elements According to Known Methods To Yield Predictable Results

To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Then, Office personnel must articulate the following:

- (1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference;
- (2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely performs the same function as it does separately;
- (3) a finding that one of ordinary skill in the art would have recognized that the results of the combination were predictable; and
- (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined

the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art. *KSR*, 550 U.S. at 416, 82 USPQ2d at 1395; *B/E Aerospace, Inc. v. C&D Zodiac, Inc.*, 962 F.3d 1373, 1379, 2020 USPQ2d 10706 (Fed. Cir. 2020); *Sakraida v. AG Pro, Inc.*, 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 62-63, 163 USPQ 673, 675 (1969); *Great Atl. & P. Tea Co. v. Supermarket Equip. Corp.*, 340 U.S. 147, 152, 87 USPQ 303, 306 (1950). “[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *KSR*, 550 U.S. at 418, 82 USPQ2d at 1396. If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

Example 1:

The claimed invention in *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 163 USPQ 673 (1969) was a paving machine which combined several well-known elements onto a single chassis. Standard prior art paving machines typically combined equipment for spreading and shaping asphalt onto a single chassis. The patent claim included the well-known element of a radiant-heat burner attached to the side of the paver for the purpose of preventing cold joints during continuous strip paving. The prior art used radiant heat for softening the asphalt to make patches, but did not use radiant heat burners to achieve continuous strip paving. All of the component parts were known in the prior art. The only difference was the combination of the “old elements” into a single device by mounting them on a single chassis. The Court found that the operation of the heater was in no way dependent on the operation of the other equipment, and that a separate heater could also be used in conjunction with a standard paving machine to achieve the same results. The Court concluded that “[t]he convenience of putting the burner together with the other elements in one machine, though perhaps a matter of great convenience, did not produce a ‘new’ or ‘different function’” and that to those skilled in the art the use of the old elements in combination would have been obvious. *Id.* at 60, 163 USPQ at 674.

Note that combining known prior art elements is not sufficient to render the claimed invention obvious if the results would not have been predictable to one of ordinary skill in the art. *United States v. Adams*, 383 U.S. 39, 51-52, 148 USPQ 479, 483-84 (1966). In *Adams*, the claimed invention was to a battery with one magnesium electrode and one cuprous chloride electrode that could be stored dry and activated by the addition of plain water or salt water. Although magnesium and cuprous chloride were individually known battery components, the Court concluded that the claimed battery was nonobvious. The Court stated that “[d]espite the fact that each of the elements of the Adams battery was well known in the prior art, to combine them as did Adams required that a person reasonably skilled in the prior art must ignore” the

teaching away of the prior art that such batteries were impractical and that water-activated batteries were successful only when combined with electrolytes detrimental to the use of magnesium electrodes. *Id.* at 42-43, 50-52, 148 USPQ at 480, 483. “[W]hen the prior art teaches away from combining certain known elements, discovery of successful means of combining them is more likely to be nonobvious.” *KSR*, 550 U.S. at 416, 82 USPQ2d at 1395.

Example 2:

The claimed invention in *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 69 USPQ2d 1686 (Fed. Cir. 2004) was directed to a system which employs a screw anchor for underpinning existing foundations and a metal bracket to transfer the building load onto the screw anchor. The prior art (Fuller) used screw anchors for underpinning existing structural foundations. Fuller used a concrete haunch to transfer the load of the foundation to the screw anchor. The prior art (Gregory) used a push pier for underpinning existing structural foundations. Gregory taught a method of transferring load using a bracket, wherein a metal bracket transfers the foundation load to the push pier. The pier is driven into the ground to support the load. Neither reference showed the two elements of the claimed invention – screw anchor and metal bracket – used together. The court found that “artisans knew that a foundation underpinning system requires a means of connecting the foundation to the load-bearing member.” *Id.* at 1276, 69 USPQ2d at 1691.

The nature of the problem to be solved – underpinning unstable foundations – as well as the need to connect the member to the foundation to accomplish this goal, would have led one of ordinary skill in the art to choose an appropriate load bearing member and a compatible attachment. Therefore, it would have been obvious to use a metal bracket (as shown in Gregory) in combination with the screw anchor (as shown in Fuller) to underpin unstable foundations.

Example 3:

The case of *In re Omeprazole Patent Litigation*, 536 F.3d 1361, 87 USPQ2d 1865 (Fed. Cir. 2008), is one in which the claims in question were found to be nonobvious in the context of an argument to combine prior art elements. The invention involved applying enteric coatings to a drug in pill form for the purpose of ensuring that the drug did not disintegrate before reaching its intended site of action. The drug at issue was omeprazole, the generic name for gastric acid inhibitor marketed as Prilosec[®]. The claimed formulation included two layers of coatings over the active ingredient.

The district court found that Astra’s patent in suit was infringed by defendants Apotex and Impax. The district court rejected Apotex’s defense that the patents were invalid for obviousness. Apotex had argued that the claimed invention was obvious because coated omeprazole tablets were known from a prior art reference, and because secondary

subcoatings in pharmaceutical preparations generally were also known. There was no evidence of unpredictability associated with applying two different enteric coatings to omeprazole. However, Astra's reason for applying an intervening subcoating between the prior art coating and omeprazole had been that the prior art coating was actually interacting with omeprazole, thereby contributing to undesirable degradation of the active ingredient. This degradation of omeprazole by interaction with the prior art coating had not been recognized in the prior art. Therefore, the district court reasoned that based on the evidence available, a person of ordinary skill in the art would have had no reason to include a subcoating in an omeprazole pill formulation.

The Federal Circuit affirmed the district court's decision that the claimed invention was not obvious. Even though subcoatings for enteric drug formulation were known, and there was no evidence of undue technical hurdles or lack of a reasonable expectation of success, the formulation was nevertheless not obvious because the flaws in the prior art formulation that had prompted the modification had not been recognized. Thus there would have been no reason to modify the initial formulation, even though the modification could have been done. Moreover, a person of ordinary skill in the art likely would have chosen a different modification even if they had recognized the problem.

Office personnel should note that in this case the modification of the prior art that had been presented as an argument for obviousness was an extra process step that added an additional component to a known, successfully marketed formulation. The proposed modification thus amounted to extra work and greater expense for no apparent reason. This is not the same as combining known prior art elements A and B when each would have been expected to contribute its own known properties to the final product. In the *Omeprazole* case, in view of the expectations of those of ordinary skill in the art, adding the subcoating would not have been expected to confer any particular desirable property on the final product. Rather, the final product obtained according to the proposed modifications would merely have been expected to have the same functional properties as the prior art product.

The *Omeprazole* case can also be analyzed in view of the discovery of a previously unknown problem by the patentee. If the adverse interaction between active agent and coating had been known, it might well have been obvious to use a subcoating. However, since the problem had not been previously known, there would have been no reason to incur additional time and expense to add another layer, even though the addition would have been technologically possible. This is true because the prior art of record failed to mention any stability problem, despite the acknowledgment during testimony at trial that there was a known theoretical reason that omeprazole might be subject to degradation in the presence of the known coating material.

Example 4:

The case of *Crocs, Inc. v. U.S. Int'l Trade Comm'n*, 598 F.3d 1294, 93 USPQ 1777 (Fed. Cir. 2010), is a decision in which the claimed foam footwear was held by the Federal Circuit to be nonobvious over a combination of prior art references.

The claims involved in the obviousness issue were from Crocs' U.S. Patent No. 6,993,858, and were drawn to footwear in which a one-piece molded foam base section formed the top of the shoe (the upper) and the sole. A strap also made of foam was attached to the foot opening of the upper, such that the strap could provide support to the Achilles portion of the wearer's foot. The strap was attached via connectors that allowed it to be in contact with the base section, and to pivot relative to the base section. Because both the base portion and the strap were made of foam, friction between the strap and the base section allowed the strap to maintain its position after pivoting. In other words, the foam strap did not fall under the force of gravity to a position adjacent to the heel of the base section.

The International Trade Commission (ITC) determined that the claims were obvious over the combination of two pieces of prior art. The first was the Aqua Clog, which was a shoe that corresponded to the base section of the footwear of the '858 patent. The second was the Aguerre patent, which taught heel straps made of elastic or another flexible material. In the ITC's view, the claimed invention was obvious because the prior art Aqua Clog differed from the claimed invention only as to the presence of the strap, and a suitable strap was taught by Aguerre.

The Federal Circuit disagreed. The Federal Circuit stated that the prior art did not teach foam heel straps, or that a foam heel strap should be placed in contact with a foam base. The Federal Circuit pointed out that the prior art actually counseled against using foam as a material for the heel strap of a shoe.

The record shows that the prior art would actually discourage and teach away from the use of foam straps. An ordinary artisan in this field would not add a foam strap to the foam Aqua Clog because foam was likely to stretch and deform, in addition to causing discomfort for a wearer. The prior art depicts foam as unsuitable for straps.

Id. at 1309, 93 USPQ2d at 1787-88.

The Federal Circuit continued, stating that even if – contrary to fact – the claimed invention had been a combination of elements that were known in the prior art, the claims still would have been nonobvious. There was testimony in the record that the loose fit of the heel strap made the shoe more comfortable for the wearer than prior art shoes in which the heel strap was constantly in contact with the wearer's foot. In the claimed footwear, the foam heel strap contacted the wearer's foot only when needed to help reposition the foot properly in the shoe,

thus reducing wearer discomfort that could arise from constant contact. This desirable feature was a result of the friction between the base section and the strap that kept the strap in place behind the Achilles portion of the wearer's foot. The Federal Circuit pointed out that this combination "yielded more than predictable results." *Id.* at 1310, 93 USPQ2d at 1788. Aguerre had taught that friction between the base section and the strap was a problem rather than an advantage, and had suggested the use of nylon washers to reduce friction. Thus the Federal Circuit stated that even if all elements of the claimed invention had been taught by the prior art, the claims would not have been obvious because the combination yielded more than predictable results.

The Federal Circuit's discussion in *Crocs* serves as a reminder to Office personnel that merely pointing to the presence of all claim elements in the prior art is not a complete statement of a rejection for obviousness. In accordance with [MPEP § 2143](#), subsection I.A.(3), a proper rejection based on the rationale that the claimed invention is a combination of prior art elements also includes a finding that results flowing from the combination would have been predictable to a person of ordinary skill in the art. [MPEP § 2143](#), subsection I.A.(3). If results would not have been predictable, Office personnel should not enter an obviousness rejection using the combination of prior art elements rationale, and should withdraw such a rejection if it has been made.

Example 5:

Sundance, Inc. v. DeMonte Fabricating Ltd., 550 F.3d 1356, 89 USPQ2d 1535 (Fed. Cir. 2008), involved a segmented and mechanized cover for trucks, swimming pools, or other structures. The claim was found to be obvious over the prior art applied.

A first prior art reference taught that a reason for making a segmented cover was ease of repair, in that a single damaged segment could be readily removed and replaced when necessary. A second prior art reference taught the advantages of a mechanized cover for ease of opening. The Federal Circuit noted that the segmentation aspect of the first reference and the mechanization function of the second perform in the same way after combination as they had before. The Federal Circuit further observed that a person of ordinary skill in the art would have expected that adding replaceable segments as taught by the first reference to the mechanized cover of the other would result in a cover that maintained the advantageous properties of both of the prior art covers.

Thus, the *Sundance* case points out that a hallmark of a proper obviousness rejection based on combining known prior art elements is that one of ordinary skill in the art would reasonably have expected the elements to maintain their respective properties or functions after they have been combined.

Example 6:

In the case of *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 91 USPQ2d 1225 (Fed. Cir. 2009), an “apparent reason to combine” in conjunction with the technical ability to optimize led to the conclusion that the claimed invention would have been obvious.

The invention in question was a method of treating meat to reduce the incidence of pathogens, by spraying the meat with an antibacterial solution under specified conditions. The parties did not dispute that a single prior art reference had taught all of the elements of the claimed invention, except for the pressure limitation of “at least 50 psi.”

FMC had argued at the district court that the claimed invention would have been obvious in view of the first prior art reference mentioned above in view of a second reference that had taught the advantages of spray-treating at pressures of 20 to 150 psi when treating meat with a different antibacterial agent. The district court did not find FMC’s argument to be convincing, and denied the motion for judgment as a matter of law that the claim was obvious.

Disagreeing with the district court, the Federal Circuit stated that “there was an apparent reason to combine these known elements – namely to increase contact between the [antibacterial solution] and the bacteria on the meat surface and to use the pressure to wash additional bacteria off the meat surface.” *Id.* at 1350, 91 USPQ2d at 1234. The Federal Circuit explained that because the second reference had taught “using high pressure to improve the effectiveness of an antimicrobial solution when sprayed onto meat, and because an ordinarily skilled artisan would have recognized the reasons for applying [the claimed antibacterial solution] using high pressure and would have known how to do so, Ecolab’s claims combining high pressure with other limitations disclosed in FMC’s patent are invalid as obvious.” *Id.*

When considering the question of obviousness, Office personnel should keep in mind the capabilities of a person of ordinary skill. In *Ecolab*, the Federal Circuit stated:

Ecolab’s expert admitted that one skilled in the art would know how to adjust application parameters to determine the optimum parameters for a particular solution. The question then is whether it would have been obvious to combine the high pressure parameter disclosed in the Bender patent with the PAA methods disclosed in FMC’s ’676 patent. The answer is yes. *Id.*

If optimization of the application parameters had not been within the level of ordinary skill in the art, the outcome of the *Ecolab* case may well have been different.

Example 7:

In the case of *Wyers v. Master Lock Co.*, 616 F.3d 1231, 95 USPQ2d 1525 (Fed. Cir. 2010), the Federal Circuit held that the claimed barbell-shaped hitch pin locks used to secure trailers

to vehicles were obvious.

The court discussed two different sets of claims in *Wyers*, both drawn to improvements over the prior art hitch pin locks. The first improvement was a removable sleeve that could be placed over the shank of the hitch pin lock so that the same lock could be used with towing apertures of varying sizes. The second improvement was an external flat flange seal adapted to protect the internal lock mechanism from contaminants. Wyers had admitted that each of several prior art references taught every element of the claimed inventions except for the removable sleeve and the external covering. Master Lock had argued that these references, in combination with additional references teaching the missing elements, would have rendered the claims obvious. The court first addressed the question of whether the additional references relied on by Master Lock were analogous prior art. As to the reference teaching the sleeve improvement, the court concluded that it dealt specifically with using a vehicle to tow a trailer, and was therefore in the same field of endeavor as Wyers' sleeve improvement. The reference teaching the sealing improvement dealt with a padlock rather than a lock for a tow hitch. The court noted that Wyers' specification had characterized the claimed invention as being in the field of locking devices, thus at least suggesting that the sealed padlock reference was in the same field of endeavor. However, the court also observed that even if sealed padlocks were not in the same field of endeavor, they were nevertheless reasonably pertinent to the problem of avoiding contamination of a locking mechanism for tow hitches. The court explained that the Supreme Court's decision in *KSR* "directs [it] to construe the scope of analogous art broadly." *Id.* at 1238, 95 USPQ2d at 1530. For these reasons, the court found that Master Lock's asserted references were analogous prior art, and therefore relevant to the obviousness inquiry.

The court then turned to the question of whether there would have been adequate motivation to combine the prior art elements as had been urged by Master Lock. The court recalled the *Graham* inquiries, and also emphasized the "expansive and flexible" post-*KSR* approach to obviousness that must not "deny factfinders recourse to common sense." *Id.* at 1238, 95 USPQ2d at 1530-31. (quoting *KSR*, 550 U.S. at 415, 421, 82 USPQ2d at 1395, 1397). The court stated:

KSR and our later cases establish that the legal determination of obviousness may include recourse to logic, judgment, and common sense, in lieu of expert testimony. . . . Thus, in appropriate cases, the ultimate inference as to the existence of a motivation to combine references may boil down to a question of "common sense," appropriate for resolution on summary judgment or JMOL.

Id. at 1240, 82 USPQ2d at 1531 (citing *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1330, 92 USPQ2d, 1849, 1854 (Fed. Cir. 2009); *Ball Aerosol*, 555 F.3d at 993, 89

USPQ2d 1870, 1875 (Fed. Cir. 2009)).

After reviewing these principles, the court proceeded to explain why adequate motivation to combine had been established in this case. With regard to the sleeve improvement, it pointed out that the need for different sizes of hitch pins was well known in the art, and that this was a known source of inconvenience and expense for users. The court also mentioned the marketplace aspect of the issue, noting that space on store shelves was at a premium, and that removable sleeves addressed this economic concern. As to the sealing improvement, the court pointed out that both internal and external seals were well-known means to protect locks from contaminants. The court concluded that the constituent elements were being employed in accordance with their recognized functions, and would have predictably retained their respective functions when combined as suggested by Master Lock. The court cited *In re O'Farrell*, 853 F.2d 894, 904 (Fed. Cir. 1988) for the proposition that a reasonable expectation of success is a requirement for a proper determination of obviousness.

Office personnel should note that although the Federal Circuit invoked the idea of common sense in support of a conclusion of obviousness, it did not end its explanation there. Rather, the court explained why a person of ordinary skill in the art at the time of the invention, in view of the facts relevant to the case, would have found the claimed inventions to have been obvious. 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* noted that the analysis supporting a rejection under [35 U.S.C. 103](#) should be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that “[R]jections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” See [MPEP § 2141](#), subsection III. Office personnel should continue to provide a reasoned explanation for every obviousness rejection.

Example 8:

The claim in *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 90 USPQ2d 1865 (Fed. Cir. 2009), was directed to a polyaxial pedicle screw used in spinal surgeries that included a compression member for pressing a screw head against a receiver member. A prior art reference (Puno) disclosed all of the elements of the claim except for the compression member. Instead, the screw head in Puno was separated from the receiver member to achieve a shock absorber effect, allowing some motion between receiver member and the vertebrae. The missing compression member was readily found in another prior art reference (Anderson), which disclosed an external fracture immobilization splint for immobilizing long bones with a swivel clamp capable of polyaxial movement until rigidly secured by a compression member. It was asserted during trial that a person of ordinary skill

would have recognized that the addition of Anderson's compression member to Puno's device would have achieved a rigidly locked polyaxial pedicle screw covered by the claim.

In conducting its analysis, the Federal Circuit noted that the "predictable result" discussed in *KSR* refers not only to the expectation that prior art elements are capable of being physically combined, but also that the combination would have worked for its intended purpose. In this case, it was successfully argued that Puno "teaches away" from a rigid screw because Puno warned that rigidity increases the likelihood that the screw will fail within the human body, rendering the device inoperative for its intended purpose. In fact, the reference did not merely express a general preference for pedicle screws having a "shock absorber" effect, but rather expressed concern for failure and stated that the shock absorber feature "decrease[s] the chance of failure of the screw of the bone-screw interface" because "it prevent[s] direct transfer of load from the rod to the bone-screw interface." Thus, the alleged reason to combine the prior art elements of Puno and Anderson—increasing the rigidity of the screw—ran contrary to the prior art that taught that increasing rigidity would result in a greater likelihood of failure. In view of this teaching and the backdrop of collective teachings of the prior art, the Federal Circuit determined that Puno teaches away from the proposed combination such that a person of ordinary skill would have been deterred from combining the references as proposed. Secondary considerations evaluated by the Federal Circuit relating to failure by others and copying also supported the view that the combination would not have been obvious at the time of the invention.

B. Simple Substitution of One Known Element for Another To Obtain Predictable Results

To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Then, Office personnel must articulate the following:

- (1) a finding that the prior art contained a device (method, product, etc.) which differed from the claimed device by the substitution of some components (step, element, etc.) with other components;
- (2) a finding that the substituted components and their functions were known in the art;
- (3) a finding that one of ordinary skill in the art could have substituted one known element for another, and the results of the substitution would have been predictable; and
- (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claim would have been obvious is that the substitution of one known element for another yields predictable results to one of ordinary skill

in the art. If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

Example 1:

The claimed invention in *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982) was directed to a method for decaffeinating coffee or tea. The prior art (Pagliaro) method produced a decaffeinated vegetable material and trapped the caffeine in a fatty material (such as oil). The caffeine was then removed from the fatty material by an aqueous extraction process. Applicant (Fout) substituted an evaporative distillation step for the aqueous extraction step. The prior art (Waterman) suspended coffee in oil and then directly distilled the caffeine through the oil. The court found that “[b]ecause both Pagliaro and Waterman teach a method for separating caffeine from oil, it would have been *prima facie* obvious to substitute one method for the other. Express suggestion to substitute one equivalent for another need not be present to render such substitution obvious.” *Id.* at 301, 213 USPQ at 536.

Example 2:

The claimed invention in *In re O’Farrell*, 853 F.2d 894, 7 USPQ2d 1673 (Fed. Cir. 1988) was directed to a method for synthesizing a protein in a transformed bacterial host species by substituting a heterologous gene for a gene native to the host species. Generally speaking, protein synthesis *in vivo* follows a path from DNA to mRNA. Although the prior art Polisky article (authored by two of the three joint inventors of the application) had explicitly suggested employing the method described for protein synthesis, the inserted heterologous gene exemplified in the article was one that normally did not proceed all the way to the protein production step, but instead terminated with the mRNA. A second reference to Bahl had described a general method of inserting chemically synthesized DNA into a plasmid. Thus, it would have been obvious to one of ordinary skill in the art to replace the prior art gene with another gene known to lead to protein production, because one of ordinary skill in the art would have been able to carry out such a substitution, and the results were reasonably predictable.

In response to applicant’s argument that there had been significant unpredictability in the field of molecular biology at the time of the invention, the court stated that the level of skill was quite high and that the teachings of Polisky, even taken alone, contained detailed enabling methodology and included the suggestion that the modification would be successful for synthesis of proteins.

This is not a situation where the rejection is a statement that it would have been “obvious to try” without more. Here there was a reasonable expectation of success. “Obviousness does not require absolute predictability of success.” *Id.* at 903, 7 USPQ2d at 1681.

Example 3:

The fact pattern in *Ruiz v. AB Chance Co.*, 357 F.3d 1270, 69 USPQ2d 1686 (Fed. Cir. 2004) is set forth above in Example 2 in subsection I.A., above.

The prior art showed differing load-bearing members and differing means of attaching the foundation to the member. Therefore, it would have been obvious to one of ordinary skill in the art to substitute the metal bracket taught in Gregory for Fuller's concrete haunch for the predictable result of transferring the load.

Example 4:

The claimed invention in *Ex parte Smith*, 83 USPQ2d 1509 (Bd. Pat. App. & Int. 2007), was a pocket insert for a bound book made by gluing a base sheet and a pocket sheet of paper together to form a continuous two-ply seam defining a closed pocket. The prior art (Wyant) disclosed at least one pocket formed by folding a single sheet and securing the folder portions along the inside margins using any convenient bonding method. The prior art (Wyant) did not disclose bonding the sheets to form a continuous two-ply seam. The prior art (Dick) disclosed a pocket that is made by stitching or otherwise securing two sheets along three of its four edges to define a closed pocket with an opening along its fourth edge.

In considering the teachings of Wyant and Dick, the Board "found that (1) each of the claimed elements is found within the scope and content of the prior art; (2) one of ordinary skill in the art could have combined the elements as claimed by methods known at the time the invention was made; and (3) one of ordinary skill in the art would have recognized at the time the invention was made that the capabilities or functions of the combination were predictable." Citing *KSR*, the Board concluded that "[t]he substitution of the continuous, two-ply seam of Dick for the folded seam of Wyant thus is no more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement.

Example 5:

The claimed invention in *In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 83 USPQ2d 1746 (Fed. Cir. 2007), was directed to a treadmill with a folding tread base that swivels into an upright storage position, including a gas spring connected between the tread base and the upright structure to assist in stably retaining the tread base in the storage position. On reexamination, the examiner rejected the claims as obvious based on a combination of references including an advertisement (Damark) for a folding treadmill demonstrating all of the claim elements other than the gas spring, and a patent (Teague) with a gas spring. Teague was directed to a bed that folds into a cabinet using a novel dual-action spring that reverses force as the mechanism passes a neutral position, rather than a single-action spring that would provide a force pushing the bed closed at all times. The dual-action spring reduced the

force required to open the bed from the closed position, while reducing the force required to lift the bed from the open position.

The Federal Circuit addressed the propriety of making the combination since Teague was in a different field than the application. Teague was found to be reasonably pertinent to the problem addressed in the application because the folding mechanism did not require any particular focus on treadmills, but rather generally addressed problems of supporting the weight of such a mechanism and providing a stable resting position.

The court also considered whether one skilled in the art would have been led to combine the teachings of Damark and Teague. Appellant argued that Teague teaches away from the invention because it directs one skilled in the art not to use single-action springs and does not satisfy the claim limitations as the dual-action springs would render the invention inoperable. The Federal Circuit considered these arguments and found that, while Teague at most teaches away from using single-action springs to decrease the opening force, it actually instructed that single-action springs provide the result desired by the inventors, which was to increase the opening force provided by gravity. As to inoperability, the claims were not limited to single-action springs and were so broad as to encompass anything that assists in stably retaining the tread base, which is the function that Teague accomplished. Additionally, the fact that the counterweight mechanism from Teague used a large spring, which appellant argued would overpower the treadmill mechanism, ignores the modifications that one skilled in the art would make to a device borrowed from the prior art. One skilled in the art would size the components from Teague appropriately for the application.

ICON is another useful example for understanding the scope of analogous art. The art applied concerned retaining mechanisms for folding beds, not treadmills. When determining whether a reference may properly be applied to an invention in a different field of endeavor, it is necessary to consider the problem to be solved. It is certainly possible that a reference may be drawn in such a way that its usefulness as a teaching is narrowly restricted. However, in *ICON*, the problem to be solved was not limited to the teaching of the “treadmill” concept. The Teague reference was analogous art because “Teague and the current application both address the need to stably retain a folding mechanism,” and because “nothing about *ICON*’s folding mechanism requires any particular focus on treadmills,” *Id.* at 1378, 1380, 83 USPQ2d at 1749-50.

ICON is also informative as to the relationship between the problem to be solved and existence of a reason to combine. “Indeed, while perhaps not dispositive of the issue, the finding that Teague, by addressing a similar problem, provides analogous art to *ICON*’s application goes a long way towards demonstrating a reason to combine the two references. Because *ICON*’s broad claims read on embodiments addressing that problem as described by

Teague, the prior art here indicates a reason to incorporate its teachings.” *Id.* at 1380-81, 83 USPQ2d at 1751.

The Federal Circuit’s discussion in *ICON* also makes clear that if the reference does not teach that a combination is undesirable, then it cannot be said to teach away. An assessment of whether a combination would render the device inoperable must not “ignore the modifications that one skilled in the art would make to a device borrowed from the prior art.” *Id.* at 1382, 83 USPQ2d at 1752.

Example 6:

Agrizap, Inc. v. Woodstream Corp., 520 F.3d 1337, 86 USPQ2d 1110 (Fed. Cir. 2008), involved a stationary pest control device for electrocution of pests such as rats and gophers, in which the device is set in an area where the pest is likely to encounter it. The only difference between the claimed device and the prior art stationary pest control device was that the claimed device employed a resistive electrical switch, while the prior art device used a mechanical pressure switch. A resistive electrical switch was taught in two prior art patents, in the contexts of a hand-held pest control device and a cattle prod.

In determining that the claimed invention was obvious, the Federal Circuit noted that “[t]he asserted claims simply substitute a resistive electrical switch for the mechanical pressure switch” employed in the prior art device. *Id.* at 1344, 86 USPQ2d at 1115. In this case, the prior art concerning the hand-held devices revealed that the function of the substituted resistive electrical switch was well known and predictable, and that it could be used in a pest control device. According to the Federal Circuit, the references that taught the hand-held devices showed that “the use of an animal body as a resistive switch to complete a circuit for the generation of an electric charge was already well known in the prior art.” *Id.* Finally, the Federal Circuit noted that the problem solved by using the resistive electrical switch in the prior art hand-held devices – malfunction of mechanical switches due to dirt and dampness – also pertained to the prior art stationary pest control device.

The Federal Circuit recognized *Agrizap* as “a textbook case of when the asserted claims involve a combination of familiar elements according to known methods that does no more than yield predictable results.” *Id.* *Agrizap* exemplifies a strong case of obviousness based on simple substitution that was not overcome by the objective evidence of nonobviousness offered. It also demonstrates that analogous art is not limited to the field of the inventor’s endeavor, in that one of the references that used an animal body as a resistive switch to complete a circuit for the generation of an electric charge was not in the field of pest control.

Example 7:

The invention at issue in *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 87 USPQ2d1350 (Fed. Cir. 2008), was a method for auctioning municipal bonds over the Internet. A municipality could offer a package of bond instruments of varying principal amounts and maturity dates, and an interested buyer would then submit a bid comprising a price and interest rate for each maturity date. It was also possible for the interested buyer to bid on a portion of the offering. The claimed invention considered all of the noted parameters to determine the best bid. It operated on conventional Web browsers and allowed participants to monitor the course of the auction.

The only difference between the prior art bidding system and the claimed invention was the use of a conventional Web browser. At trial, the district court had determined that Muniauction's claims were not obvious. Thomson argued that the claimed invention amounted to incorporating a Web browser into a prior art auction system, and was therefore obvious in light of *KSR*. Muniauction rebutted the argument by offering evidence of skepticism by experts, copying, praise, and commercial success. Although the district court found the evidence to be persuasive of nonobviousness, the Federal Circuit disagreed. It noted that a nexus between the claimed invention and the proffered evidence was lacking because the evidence was not coextensive with the claims at issue. For this reason, the Federal Circuit determined that Muniauction's evidence of secondary considerations was not entitled to substantial weight.

The Federal Circuit analogized this case to *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 82 USPQ2d 1687 (Fed. Cir. 2007). The *Leapfrog* case involved a determination of obviousness based on application of modern electronics to a prior art mechanical children's learning device. In *Leapfrog*, the court noted that market pressures would have prompted a person of ordinary skill to use modern electronics in the prior art device. Similarly in *Muniauction*, market pressures would have prompted a person of ordinary skill to use a conventional Web browser in a method of auctioning municipal bonds.

Example 8:

In *Aventis Pharma Deutschland v. Lupin Ltd.*, 499 F.3d 1293, 84 USPQ2d 1197 (Fed. Cir. 2007), the claims were drawn to the 5(S) stereoisomer of the blood pressure drug ramipril in stereochemically pure form, and to compositions and methods requiring 5(S) ramipril. The 5(S) stereoisomer is one in which all five stereocenters in the ramipril molecule are in the S rather than the R configuration. A mixture of various stereoisomers including 5(S) ramipril had been taught by the prior art. The question before the court was whether the purified single stereoisomer would have been obvious over the known mixture of stereoisomers.

The record showed that the presence of multiple S stereocenters in drugs similar to ramipril was known to be associated with enhanced therapeutic efficacy. For example, when all of the

stereocenters were in the S form in the related drug enalapril (SSS enalapril) as compared with only two stereocenters in the S form (SSR enalapril), the therapeutic potency was 700 times as great. There was also evidence to indicate that conventional methods could be used to separate the various stereoisomers of ramipril.

The district court saw the issue as a close case, because, in its view, there was no clear motivation in the prior art to isolate 5(S) ramipril. However, the Federal Circuit disagreed, and found that the claims would have been obvious. The Federal Circuit cautioned that requiring such a clearly stated motivation in the prior art to isolate 5(S) ramipril ran counter to the Supreme Court's decision in *KSR*, and the court stated:

Requiring an explicit teaching to purify the 5(S) stereoisomer from a mixture in which it is the active ingredient is precisely the sort of rigid application of the TSM test that was criticized in *KSR*.

Id. at 1301, 84 USPQ2d at 1204. The *Aventis* court also relied on the settled principle that in chemical cases, structural similarity can provide the necessary reason to modify prior art teachings. The Federal Circuit also addressed the kind of teaching that would be sufficient in the absence of an explicitly stated prior art-based motivation, explaining that an expectation of similar properties in light of the prior art can be sufficient, even without an explicit teaching that the compound will have a particular utility.

In the chemical arts, the cases involving so-called “lead compounds” form an important subgroup of the obviousness cases that are based on substitution. The Federal Circuit has had a number of opportunities since the *KSR* decision to discuss the circumstances under which it would have been obvious to modify a known compound to arrive at a claimed compound. The following cases explore the selection of a lead compound, the need to provide a reason for any proposed modification, and the predictability of the result.

Example 9:

Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd., 533 F.3d 1353, 87 USPQ2d 1452 (Fed. Cir. 2008), concerns the pharmaceutical compound rabeprazole. Rabeprazole is a proton pump inhibitor for treating stomach ulcers and related disorders. The Federal Circuit affirmed the district court's summary judgment of nonobviousness, stating that no reason had been advanced to modify the prior art compound in a way that would destroy an advantageous property.

Co-defendant Teva based its obviousness argument on the structural similarity between rabeprazole and lansoprazole. The compounds were recognized as sharing a common core, and the Federal Circuit characterized lansoprazole as a “lead compound.” The prior art compound lansoprazole was useful for the same indications as rabeprazole, and differed from rabeprazole only in that lansoprazole has a trifluoroethoxy substituent at the 4-position of the

pyridine ring, while rabeprazole has a methoxypropoxy substituent. The trifluoro substituent of lansoprazole was known to be a beneficial feature because it conferred lipophilicity to the compound. The ability of a person of ordinary skill to carry out the modification to introduce the methoxypropoxy substituent, and the predictability of the result were not addressed.

Despite the significant similarity between the structures, the Federal Circuit did not find any reason to modify the lead compound. According to the Federal Circuit:

Obviousness based on structural similarity thus can be proved by identification of some motivation that would have led one of ordinary skill in the art to select and then modify a known compound (i.e. a lead compound) in a particular way to achieve the claimed compound. . . . In keeping with the flexible nature of the obviousness inquiry, the requisite motivation can come from any number of sources and need not necessarily be explicit in the art. Rather “it is sufficient to show that the claimed and prior art compounds possess a ‘sufficiently close relationship . . . to create an expectation,’ in light of the totality of the prior art, that the new compound will have ‘similar properties’ to the old.” *Id.* at 1357, 87 USPQ2d at 1455. (citations omitted)

The prior art taught that introducing a fluorinated substituent was known to increase lipophilicity, so a skilled artisan would have expected that replacing the trifluoroethoxy substituent with a methoxypropoxy substituent would have reduced the lipophilicity of the compound. Thus, the prior art created the expectation that rabeprazole would be less useful than lansoprazole as a drug for treating stomach ulcers and related disorders because the proposed modification would have destroyed an advantageous property of the prior art compound. The compound was not obvious as argued by Teva because, upon consideration of all of the facts of the case, a person of ordinary skill in the art at the time of the invention would not have had a reason to modify lansoprazole so as to form rabeprazole.

Office personnel are cautioned that the term “lead compound” in a particular opinion can have a contextual meaning that may vary from the way a pharmaceutical chemist might use the term. In the field of pharmaceutical chemistry, the term “lead compound” has been defined variously as “a chemical compound that has pharmacological or biological activity and whose chemical structure is used as a starting point for chemical modifications in order to improve potency, selectivity, or pharmacokinetic parameters;” “[a] compound that exhibits pharmacological properties which suggest its development;” and “a potential drug being tested for safety and efficacy.” See, e.g., http://en.wikipedia.org/wiki/Lead_compound, accessed January 13, 2010; www.combichemistry.com/glossary_k.html, accessed January 13, 2010; and www.buildingbiotechnology.com/glossary4.php, accessed January 13, 2010.

The Federal Circuit in *Eisai* makes it clear that from the perspective of the law of obviousness, any known compound might possibly serve as a lead compound: “Obviousness based on structural similarity thus can be proved by identification of some motivation that would have led one of ordinary skill in the art to select and then modify a known compound (i.e. a lead compound) in a particular way to achieve the claimed compound.” *Eisai*, 533 F.3d at 1357, 87 USPQ2d at 1455. Thus, Office personnel should recognize that a proper obviousness rejection of a claimed compound that is useful as a drug might be made beginning with an inactive compound, if, for example, the reasons for modifying a prior art compound to arrive at the claimed compound have nothing to do with pharmaceutical activity. The inactive compound would not be considered to be a lead compound by pharmaceutical chemists, but could potentially be used as such when considering obviousness. Office personnel might also base an obviousness rejection on a known compound that pharmaceutical chemists would not select as a lead compound due to expense, handling issues, or other business considerations. However, there must be some reason for starting with that particular lead compound other than the mere fact that the “lead compound” exists. See *Altana Pharma AG v. Teva Pharm. USA, Inc.*, 566 F.3d 999, 1007, 91 USPQ2d 1018, 1024 (Fed. Cir. 2009) (holding that there must be some reason “to select and modify a known compound”); *Ortho-McNeil Pharm., Inc. v. Mylan Labs, Inc.*, 520 F.3d 1358, 1364, 86 USPQ2d 1196, 1201 (Fed. Cir. 2008).

Example 10:

The claimed chemical compound was also found to be nonobvious in *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 90 USPQ2d 1947 (Fed. Cir. 2009). The compound at issue was risedronate – the active ingredient of Procter & Gamble’s osteoporosis drug Actonel[®]. Risedronate is an example of a bisphosphonate, which is a class of compounds known to inhibit bone resorption.

When Procter & Gamble sued Teva for infringement, Teva defended by arguing invalidity for obviousness over one of Procter & Gamble’s earlier patents. The prior art patent did not teach risedronate, but instead taught thirty-six other similar compounds including 2-pyr EHDP that were potentially useful with regard to osteoporosis. Teva argued obviousness on the basis of structural similarity to 2-pyr EHDP, which is a positional isomer of risedronate.

The district court found no reason to select 2-pyr EHDP as a lead compound in light of the unpredictable nature of the art, and no reason to modify it so as to obtain risedronate. In addition, there were unexpected results as to potency and toxicity. Therefore the district court found that Teva had not made a *prima facie* case, and even if it had, it was rebutted by evidence of unexpected results.

The Federal Circuit affirmed the district court's decision. The Federal Circuit did not deem it necessary in this case to consider the question of whether 2-pyr EHDP had been appropriately selected as a lead compound. Rather, the Federal Circuit reasoned that, if 2-pyr EHDP is presumed to be an appropriate lead compound, there must be both a reason to modify it so as to make risedronate and a reasonable expectation of success. Here, there was no evidence that the necessary modifications would have been routine, so there would have been no reasonable expectation of success.

Procter & Gamble is also informative in its discussion of the treatment of secondary considerations of non-obviousness. Although the court found that no *prima facie* case of obviousness had been presented, it proceeded to analyze Procter & Gamble's proffered evidence countering the alleged *prima facie* case in some detail, thus shedding light on the proper treatment of such evidence.

The Federal Circuit noted in dicta that even if a *prima facie* case of obviousness had been established, sufficient evidence of unexpected results was introduced to rebut such a showing. At trial, the witnesses consistently testified that the properties of risedronate were not expected, offering evidence that researchers did not predict either the potency or the low dose at which the compound was effective. Tests comparing risedronate to a compound in the prior art reference showed that risedronate outperformed the other compound by a substantial margin, could be administered in a greater amount without an observable toxic effect, and was not lethal at the same levels as the other compound. The weight of the evidence and the credibility of the witnesses were sufficient to show unexpected results that would have rebutted an obviousness determination. Thus, nonobviousness can be shown when a claimed invention is shown to have unexpectedly superior properties when compared to the prior art.

The court then addressed the evidence of commercial success of risedronate and the evidence that risedronate met a long felt need. The court pointed out that little weight was to be afforded to the commercial success because the competing product was also assigned to Procter & Gamble. However, the Federal Circuit affirmed the district court's conclusion that risedronate met a long-felt, but unsatisfied need. The court rejected Teva's contention that because the competing drug was available before Actonel[®], there was no unmet need that the invention satisfied. The court emphasized that whether there was a long-felt but unsatisfied need is to be evaluated based on the circumstances as of the filing date of the challenged invention – not as of the date that the invention is brought to market.

It should be noted that the lead compound cases do not stand for the proposition that identification of a single lead compound is necessary in every obviousness rejection of a chemical compound. For example, one might envision a suggestion in the prior art to formulate a compound having certain structurally defined moieties, or moieties with certain

properties. If a person of ordinary skill would have known how to synthesize such a compound, and the structural and/or functional result could reasonably have been predicted, then a *prima facie* case of obviousness of the claimed chemical compound might exist even without identification of a particular lead compound. As a second example, it could be possible to view a claimed compound as consisting of two known compounds attached via a chemical linker. The claimed compound might properly be found to have been obvious if there would have been a reason to link the two, if one of ordinary skill would have known how to do so, and if the resulting compound would have been the predictable result of the linkage procedure. Thus, Office personnel should recognize that in certain situations, it may be proper to reject a claimed chemical compound as obvious even without identifying a single lead compound.

Example 11:

The decision reached by the Federal Circuit in *Altana Pharma AG v. Teva Pharm. USA, Inc.*, 566 F.3d 999, 91 USPQ2d 1018 (Fed. Cir. 2009), as discussed below, involved a motion for preliminary injunction and did not include a final determination of obviousness. However, the case is instructive as to the issue of selecting a lead compound.

The technology involved in *Altana* was the compound pantoprazole, which is the active ingredient in Altana's antiulcer drug Protonix[®]. Pantoprazole belongs to a class of compounds known as proton pump inhibitors that are used to treat gastric acid disorders in the stomach.

Altana accused Teva of infringement. The district court denied Altana's motion for preliminary injunction for failure to establish a likelihood of success on the merits, determining that Teva had demonstrated a substantial question of invalidity for obviousness in light of one of Altana's prior patents. Altana's patent discussed a compound referred to as compound 12, which was one of eighteen compounds disclosed. The claimed compound pantoprazole was structurally similar to compound 12. The district court found that one of ordinary skill in the art would have selected compound 12 as a lead compound for modification, and the Federal Circuit affirmed.

Obviousness of a chemical compound in view of its structural similarity to a prior art compound may be shown by identifying some line of reasoning that would have led one of ordinary skill in the art to select and modify the prior art compound in a particular way to produce the claimed compound. The necessary line of reasoning can be drawn from any number of sources and need not necessarily be explicitly found in the prior art of record. The Federal Circuit determined that ample evidence supported the district court's finding that compound 12 was a natural choice for further development. For example, Altana's prior art patent claimed that its compounds, including compound 12, were improvements over the prior art; compound 12 was disclosed as one of the more potent of the eighteen compounds

disclosed; the patent examiner had considered the compounds of Altana's prior art patent to be relevant during the prosecution of the patent in suit; and experts had opined that one of ordinary skill in the art would have selected the eighteen compounds to pursue further investigation into their potential as proton pump inhibitors.

In response to Altana's argument that the prior art must point to only a single lead compound for further development, the Federal Circuit stated that a "restrictive view of the lead compound test would present a rigid test similar to the teaching-suggestion-motivation test that the Supreme Court explicitly rejected in *KSR* The district court in this case employed a flexible approach – one that was admittedly preliminary – and found that the defendants had raised a substantial question that one of skill in the art would have used the more potent compounds of [Altana's prior art] patent, including compound 12, as a starting point from which to pursue further development efforts. That finding was not clearly erroneous." *Id.* at 1008, 91 USPQ2d at 1025.

C. Use of Known Technique To Improve Similar Devices (Methods, or Products) in the Same Way

To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Then, Office personnel must articulate the following:

- (1) a finding that the prior art contained a "base" device (method, or product) upon which the claimed invention can be seen as an "improvement;"
- (2) a finding that the prior art contained a "comparable" device (method, or product that is not the same as the base device) that has been improved in the same way as the claimed invention;
- (3) a finding that one of ordinary skill in the art could have applied the known "improvement" technique in the same way to the "base" device (method, or product) and the results would have been predictable to one of ordinary skill in the art; and
- (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claim would have been obvious is that a method of enhancing a particular class of devices (methods, or products) has been made part of the ordinary capabilities of one skilled in the art based upon the teaching of such improvement in other situations. One of ordinary skill in the art would have been capable of applying this known method of enhancement to a "base" device (method, or product) in the prior art and the results would have been predictable to one of ordinary skill in the art. "It's enough ... to show that there was a known problem ... in the art, that [another reference] ... helped address that issue, and that combining the teachings of [the two references] wasn't beyond the skill of an

ordinary artisan. Nothing more is required to show a motivation to combine under *KSR*.” See *Intel Corp. v. PACT XPP Schweiz AG*, 61 F.4th 1373, 1380-81, 2023 USPQ2d 297 (Fed. Cir. 2023) (finding that both prior art references “address the same problem and that [the secondary reference’s] cache was a known way to address that problem is precisely the reason that there’s a motivation to combine under *KSR* and our precedent.”).

The Supreme Court in *KSR* noted that if the actual application of the technique would have been beyond the skill of one of ordinary skill in the art, then using the technique would not have been obvious. *KSR*, 550 U.S. at 417, 82 USPQ2d at 1396. If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

Example 1:

The claimed invention in *In re Nilssen*, 851 F.2d 1401, 7 USPQ2d 1500 (Fed. Cir. 1988) was directed to a “means by which the self-oscillating inverter in a power-line-operated inverter-type fluorescent lamp ballast is disabled in case the output current from the inverter exceeds some pre-established threshold level for more than a very brief period.” *Id.* at 1402, 7 USPQ2d at 1501 That is, the current output was monitored, and if the current output exceeded some threshold for a specified short time, an actuation signal was sent and the inverter was disabled to protect it from damage.

The prior art (a USSR certificate) described a device for protecting an inverter circuit in an undisclosed manner via a control means. The device indicated the high-load condition by way of the control means, but did not indicate the specific manner of overload protection. The prior art (Kammiller) disclosed disabling the inverter in the event of a high-load current condition in order to protect the inverter circuit. That is, the overload protection was achieved by disabling the inverter by means of a cutoff switch.

The court found “it would have been obvious to one of ordinary skill in the art to use the threshold signal produced in the USSR device to actuate a cutoff switch to render the inverter inoperative as taught by Kammiller.” *Id.* at 1403, 7 USPQ2d at 1502. That is, using the known technique of a cutoff switch for protecting a circuit to provide the protection desired in the inverter circuit of the USSR document would have been obvious to one of ordinary skill.

Example 2:

The fact pattern in *Ruiz v. AB Chance Co.*, 357 F.3d 1270, 69 USPQ2d 1686 (Fed. Cir. 2004) is set forth above in Example 2 in subsection I.A.

The nature of the problem to be solved may lead inventors to look at references relating to possible solutions to that problem. *Id.* at 1277, 69 USPQ2d at 1691. Therefore, it would have

been obvious to use a metal bracket (as shown in Gregory) with the screw anchor (as shown in Fuller) to underpin unstable foundations.

D.Applying a Known Technique to a Known Device (Method, or Product) Ready for Improvement To Yield Predictable Results

To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Then, Office personnel must articulate the following:

- (1) a finding that the prior art contained a “base” device (method, or product) upon which the claimed invention can be seen as an “improvement;”
- (2) a finding that the prior art contained a known technique that is applicable to the base device (method, or product);
- (3) a finding that one of ordinary skill in the art would have recognized that applying the known technique would have yielded predictable results and resulted in an improved system; and
- (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claim would have been obvious is that a particular known technique was recognized as part of the ordinary capabilities of one skilled in the art. One of ordinary skill in the art would have been capable of applying this known technique to a known device (method, or product) that was ready for improvement and the results would have been predictable to one of ordinary skill in the art. If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

Example 1:

The claimed invention in *Dann v. Johnston*, 425 U.S. 219, 189 USPQ 257 (1976) was directed towards a system (i.e., computer) for automatic record keeping of bank checks and deposits. In this system, a customer would put a numerical category code on each check or deposit slip. The check processing system would record these on the check in magnetic ink, just as it does for amount and account information. With this system in place, the bank can provide statements to customers that are broken down to give subtotals for each category. The claimed system also allowed the bank to print reports according to a style requested by the customer. As characterized by the Court, “[u]nder respondent’s invention, then, a general purpose computer is programmed to provide bank customers with an individualized and categorized breakdown of their transactions during the period in question.” *Id.* at 222, 189 USPQ at 259.

BASE SYSTEM - The nature of the use of data processing equipment and computer software in the banking industry was that banks routinely did much of the record-keeping automatically. In routine check processing, the system read any magnetic ink characters identifying the account and routing. The system also read the amount of the check and then printed that value in a designated area of the check. The check was then sent through a further data processing step which used the magnetic ink information to generate the appropriate records for transactions and for posting to the appropriate accounts. These systems included generating periodic statements for each account, such as the monthly statement sent to checking account customers.

IMPROVED SYSTEM - The claimed invention supplemented this system by recording a category code which could be used to track expenditures by category. Again, the category code will be a number recorded on the check (or deposit slip) which will be read, converted into a magnetic ink imprint, and then processed in the data system to include the category code. This enabled reporting of data by category as opposed to only allowing reporting by account number.

KNOWN TECHNIQUE - This is an application of a technique from the prior art – the use of account numbers (generally used to track an individual's total transactions) to solve the problem of how to track categories of expenditures to more finely account for a budget. That is, account numbers (identifying data capable of processing in the automatic data processing system) were used to distinguish between different customers. Furthermore, banks have long segregated debits attributable to service charges within any given separate account and have rendered their customers subtotals for those charges. Previously, one would have needed to set up separate accounts for each category and thus receive separate reports. Supplementing the account information with additional digits (the category codes) solved the problem by effectively creating a single account that can be treated as distinct accounts for tracking and reporting services. That is, the category code merely allowed what might previously have been separate accounts to be handled as a single account, but with a number of sub-accounts indicated in the report.

The basic technique of putting indicia on data to enable standard sorting, searching, and reporting yielded no more than the predictable outcome which one of ordinary skill would have expected to achieve with this common tool of the trade and was therefore an obvious expedient. The Court held that “[t]he gap between the prior art and respondent’s system is simply not so great as to render the system nonobvious to one reasonably skilled in the art.” *Id.* at 230, 189 USPQ at 261.

Example 2:

The fact pattern in *In re Nilssen*, 851 F.2d 1401, 7 USPQ2d 1500 (Fed. Cir. 1988) is set forth above in Example 1 in subsection C.

The court found “it would have been obvious to one of ordinary skill in the art to use the threshold signal produced in the USSR device to actuate a cutoff switch to render the inverter inoperative as taught by Kammiller.” *Id.* at 1403, 7 USPQ2d at 1502. The known technique of using a cutoff switch would have predictably resulted in protecting the inverter circuit. Therefore, it would have been within the skill of the ordinary artisan to use a cutoff switch in response to the actuation signal to protect the inverter.

Example 3:

The claimed invention in *In re Urbanski*, 809 F.3d 1237, 1244, 117 USPQ2d 1499, 1504 (Fed. Cir. 2016) was directed to a method of enzymatic hydrolysis of soy fiber to reduce water holding capacity, requiring reacting the soy fiber and enzyme in water for about 60-120 minutes. The claims were rejected over two references, wherein the primary reference, Gross, taught using a reaction time of 5 to 72 hours and the secondary reference, Wong, taught using a reaction time of 100 to 240 minutes, preferably 120 minutes. The applicant argued that modifying the primary reference in the manner suggested by the secondary reference would forego the benefits taught by the primary reference, thereby teaching away from the combination. The court found there was sufficient motivation to combine because both references recognized reaction time and degree of hydrolysis as result-effective variables, which can be varied to have a predictable effect on the final product; and the primary reference does not contain an express teaching away from the proposed modification. “Substantial evidence thus supports the Board’s finding that a person of ordinary skill would have been motivated to modify the Gross process by using a shorter reaction time, in order to obtain the favorable properties disclosed in Wong.”

E. “Obvious To Try” – Choosing From a Finite Number of Identified, Predictable Solutions, With a Reasonable Expectation of Success

To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Then, Office personnel must articulate the following:

- (1) a finding that at the relevant time, there had been a recognized problem or need in the art, which may include a design need or market pressure to solve a problem;
- (2) a finding that there had been a finite number of identified, predictable potential solutions to the recognized need or problem;
- (3) a finding that one of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success; and

- (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claim would have been obvious is that “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 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](#).” *KSR*, 550 U.S. at 421, 82 USPQ2d at 1397. If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

The question of whether a claimed invention can be shown to be obvious based on an “obvious to try” line of reasoning has been explored extensively by the Federal Circuit in several cases since the *KSR* decision. The case law in this area is developing quickly in the chemical arts, although the rationale has been applied in other art areas as well.

Some commentators on the *KSR* decision have expressed a concern that because inventive activities are always carried out in the context of what has come before and not in a vacuum, few inventions will survive scrutiny under an obvious to try standard. The cases decided since *KSR* have proved this fear to have been unfounded. Courts appear to be applying the *KSR* requirement for “a finite number of identified predictable solutions” in a manner that places particular emphasis on predictability and the reasonable expectations of those of ordinary skill in the art.

The Federal Circuit pointed out the challenging nature of the task faced by the courts – and likewise by Office personnel – when considering the viability of an obvious to try argument: “The evaluation of the choices made by a skilled scientist, when such choices lead to the desired result, is a challenge to judicial understanding of how technical advance is achieved in the particular field of science or technology.” *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1352, 89 USPQ2d 1161, 1171 (Fed. Cir. 2008). The Federal Circuit cautioned that an obviousness inquiry based on an obvious to try rationale must always be undertaken in the context of the subject matter in question, “including the characteristics of the science or technology, its state of advance, the nature of the known choices, the specificity or generality of the prior art, and the predictability of results in the area of interest.” *Id.*

Example 1:

The claimed invention in *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 82 USPQ2d 1321 (Fed. Cir. 2007), was directed to the amlodipine besylate drug product, which was sold in tablet

form in the United States under the trademark Norvasc[®]. Amlodipine and the use of besylate anions were both known at the time of the invention. Amlodipine was known to have the same therapeutic properties as were being claimed for the amlodipine besylate, but Pfizer discovered that the besylate form had better manufacturing properties (e.g., reduced “stickiness”).

Pfizer argued that the results of forming amlodipine besylate would have been unpredictable and therefore nonobvious. The court rejected the notion that unpredictability could be equated with nonobviousness here, because there were only a finite number (53) of **pharmaceutically acceptable** salts to be tested for improved properties.

The court found that one of ordinary skill in the art having problems with the machinability of amlodipine would have looked to forming a salt of the compound and would have been able to narrow the group of potential salt-formers to a group of 53 anions known to form pharmaceutically acceptable salts, which would be an acceptable number to form “a reasonable expectation of success.”

Example 2:

The claimed invention in *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 80 USPQ2d 1001 (Fed. Cir. 2006) was drawn to sustained-release formulations of the drug oxybutynin in which the drug is released at a specified rate over a 24-hour period. Oxybutynin was known to be highly water-soluble, and the specification had pointed out that development of sustained-release formulations of such drugs presented particular problems.

A prior art patent to Morella had taught sustained-release compositions of highly water-soluble drugs, as exemplified by a sustained-release formulation of morphine. Morella had also identified oxybutynin as belonging to the class of highly water-soluble drugs. The Baichwal prior art patent had taught a sustained-release formulation of oxybutynin that had a different release rate than the claimed invention. Finally, the Wong prior art patent had taught a generally applicable method for delivery of drugs over a 24-hour period. Although Wong mentioned applicability of the disclosed method to several categories of drugs to which oxybutynin belonged, Wong did not specifically mention its applicability to oxybutynin.

The court found that because the absorption properties of oxybutynin would have been reasonably predictable at the time of the invention, there would have been a reasonable expectation of successful development of a sustained-release formulation of oxybutynin as claimed. The prior art, as evidenced by the specification, had recognized the obstacles to be overcome in development of sustained-release formulations of highly water-soluble drugs, and had suggested a finite number of ways to overcome these obstacles. The claims were obvious because it would have been obvious to try the known methods for formulating

sustained-release compositions, with a reasonable expectation of success. The court was not swayed by arguments of a lack of absolute predictability.

Example 3:

The Federal Circuit's decision in *In re Kubin*, 561 F.3d 1351, 90 USPQ2d 1417 (Fed. Cir. 2009), affirmed the Office's determination in *Ex parte Kubin*, 83 USPQ2d 1410 (Bd. Pat. App. & Int. 2007) that the claims in question, directed to an isolated nucleic acid molecule, would have been obvious over the prior art applied. The claim stated that the nucleic acid encoded a particular polypeptide. The encoded polypeptide was identified in the claim by its partially specified sequence, and by its ability to bind to a specified protein.

A prior art patent to Valiante taught the polypeptide encoded by the claimed nucleic acid, but did not disclose either the sequence of the polypeptide, or the claimed isolated nucleic acid molecule. However, Valiante did disclose that by employing conventional methods such as those disclosed by a prior art laboratory manual by Sambrook, the sequence of the polypeptide could be determined, and the nucleic acid molecule could be isolated. In view of Valiante's disclosure of the polypeptide, and of routine prior art methods for sequencing the polypeptide and isolating the nucleic acid molecule, the Board found that a person of ordinary skill in the art would have had a reasonable expectation that a nucleic acid molecule within the claimed scope could have been successfully obtained.

Relying on *In re Deuel*, 51 F.3d 1552, 34 USPQ2d 1210 (Fed. Cir. 1995), appellant argued that it was improper for the Office to use the polypeptide of the Valiante patent together with the methods described in Sambrook to reject a claim drawn to a specific nucleic acid molecule without providing a reference showing or suggesting a structurally similar nucleic acid molecule. Citing *KSR*, the Board stated that "when there is motivation 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 anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." *KSR*, 550 U.S. at 402-03, 82 USPQ2d at 1390. The Board noted that the problem facing those in the art was to isolate a specific nucleic acid, and there were a limited number of methods available to do so. The Board concluded that the skilled artisan would have had reason to try these methods with the reasonable expectation that at least one would be successful. Thus, isolating the specific nucleic acid molecule claimed was "the product not of innovation but of ordinary skill and common sense." *Id.*

The Board's reasoning was substantially adopted by the Federal Circuit. However, it is important to note that in the *Kubin* decision, the Federal Circuit held that "the Supreme Court in *KSR* unambiguously discredited" the Federal Circuit's decision in *Deuel*, insofar as it "implies the obviousness inquiry cannot consider that the combination of the claim's

constituent elements was ‘obvious to try.’” *Kubin*, 561 F.3d at 1358, 90 USPQ2d at 1422. Instead, *Kubin* stated that *KSR* “resurrects” the Federal Circuit’s own wisdom in *O’Farrell*, in which “to differentiate between proper and improper applications of ‘obvious to try,’” the Federal Circuit “outlined two classes of situations where ‘obvious to try’ is erroneously equated with obviousness under [§ 103](#).” *Kubin*, 561 F.3d at 1359, 90 USPQ2d at 1423. These two classes of situations are: (1) when what would have been “obvious to try” would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, 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; and (2) when what was “obvious to try” was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it. *Id.* (citing *In re O’Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988)).

Example 4:

Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd., 492 F.3d 1350, 83 USPQ2d 1169 (Fed. Cir. 2007), is an example of a chemical case in which the Federal Circuit found that the claimed invention was not obvious. The claimed compound was pioglitazone, a member of a class of drugs known as thiazolidinediones (TZDs) marketed by Takeda as a treatment for Type 2 diabetes. The *Takeda* case brings together the concept of a “lead compound” and the obvious-to-try argument.

Alphapharm had filed an Abbreviated New Drug Application with the Food and Drug Administration, which was a technical act of infringement of Takeda’s patent. When Takeda brought suit, Alphapharm’s defense was that Takeda’s patent was invalid due to obviousness. Alphapharm argued that a two-step modification – involving homologation and ring-walking – of a known compound identified as “compound b” would have produced pioglitazone, and that it was therefore obvious.

The district court found that there would have been no reason to select compound b as a lead compound. There were a large number of similar prior art TZD compounds; fifty-four were specifically identified in Takeda’s prior patent, and the district court observed that “hundreds of millions” were more generally disclosed. Although the parties agreed that compound b represented the closest prior art, one reference taught certain disadvantageous properties associated with compound b, which according to the district court would have taught the skilled artisan not to select that compound as a lead compound. The district court found no *prima facie* case of obviousness, and stated that even if a *prima facie* case had been established, it would have been overcome in this case in view of the unexpected lack of toxicity of pioglitazone.

The Federal Circuit affirmed the decision of the district court, citing the need for a reason to modify a prior art compound. The Federal Circuit quoted *KSR*, stating:

The *KSR* Court recognized that “[w]hen 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.” *KSR*, 550 U.S. at 421, 82 USPQ2d at 1397. In such circumstances, “the fact that a combination was obvious to try might show that it was obvious under § 103.” *Id.* That is not the case here. Rather than identify predictable solutions for antidiabetic treatment, the prior art disclosed a broad selection of compounds any one of which could have been selected as a lead compound for further investigation. Significantly, the closest prior art compound (compound b, the 6-methyl) exhibited negative properties that would have directed one of ordinary skill in the art away from that compound. Thus, this case fails to present the type of situation contemplated by the Court when it stated that an invention may be deemed obvious if it was “obvious to try.” The evidence showed that it was not obvious to try.

Takeda, 492 F.3d at 1359, 83 USPQ2d at 1176.

Accordingly, Office personnel should recognize that the obvious to try rationale does not apply when the appropriate factual findings cannot be made. In *Takeda*, there was a recognized need for treatment of diabetes. However, there was no finite number of identified, predictable solutions to the recognized need, and no reasonable expectation of success. There were numerous known TZD compounds, and although one clearly represented the closest prior art, its known disadvantages rendered it unsuitable as a starting point for further research, and taught the skilled artisan away from its use. Furthermore, even if there had been reason to select compound b, there had been no reasonable expectation of success associated with the particular modifications necessary to transform compound b into the claimed compound pioglitazone. Thus, an obviousness rejection based on an obvious to try rationale was not appropriate in this situation.

Example 5:

The case of *Ortho-McNeil Pharm., Inc. v. Mylan Labs, Inc.*, 520 F.3d 1358, 86 USPQ2d 1196 (Fed. Cir. 2008), provides another example in which a chemical compound was determined not to be obvious. The claimed subject matter was topiramate, which is used as an anti-convulsant.

In the course of working toward a new anti-diabetic drug, Ortho-McNeil’s scientist had unexpectedly discovered that a reaction intermediate had anti-convulsant properties. Mylan’s defense of invalidity due to obviousness rested on an obvious to try argument. However,

Mylan did not explain why it would have been obvious to begin with an anti-diabetic drug precursor, especially the specific one that led to topiramate, if one had been seeking an anti-convulsant drug. The district court ruled on summary judgment that Ortho-McNeil's patent was not invalid for obviousness.

The Federal Circuit affirmed. The Federal Circuit pointed out that there was no apparent reason a person of ordinary skill would have chosen the particular starting compound or the particular synthetic pathway that led to topiramate as an intermediate. Furthermore, there would have been no reason to test that intermediate for anticonvulsant properties if treating diabetes had been the goal. The Federal Circuit recognized an element of serendipity in this case, which runs counter to the requirement for predictability. Summarizing their conclusion with regard to Mylan's obvious to try argument, the Federal Circuit stated:

[T]his invention, contrary to Mylan's characterization, does not present a finite (and small in the context of the art) number of options easily traversed to show obviousness. . . . *KSR* posits a situation with a finite, and in the context of the art, small or easily traversed, number of options that would convince an ordinarily skilled artisan of obviousness. . . . [T]his clearly is not the easily traversed, small and finite number of alternatives that *KSR* suggested might support an inference of obviousness. *Id.* at 1364, 86 USPQ2d at 1201.

Thus, *Ortho-McNeil* helps to clarify the Supreme Court's requirement in *KSR* for "a finite number" of predictable solutions when an obvious to try rationale is applied: under the Federal Circuit's case law "finite" means "small or easily traversed" in the context of the art in question. As taught in *Abbott*, discussed above, it is essential that the inquiry be placed in the context of the subject matter at issue, and each case must be decided on its own facts.

Example 6:

In *Bayer Schering Pharma A.G. v. Barr Labs., Inc.*, 575 F.3d 1341, 91 USPQ2d 1569 (Fed. Cir. 2009), the claimed invention was an oral contraceptive containing micronized drospirenone marketed as Yasmin[®]. The prior art compound drospirenone was known to be a poorly water-soluble, acid-sensitive compound with contraceptive effects. It was also known in the art that micronization improves the solubility of poorly water soluble drugs.

Based on the known acid sensitivity, Bayer had studied how effectively an enteric-coated drospirenone tablet delivered a formulation as compared to an intravenous injection of the same formulation to measure the "absolute bioavailability" of the drug. Bayer added an unprotected (normal) drospirenone tablet and compared its bioavailability to that of the enteric-coated formulation and the intravenous delivery. Bayer expected to find that the enteric-coated tablet would produce a lower bioavailability than an intravenous injection, while

the normal pill would produce an even lower bioavailability than the enteric-coated tablet. However, they found that despite observations that drospirenone would quickly isomerize in a highly acidic environment (supporting the belief that an enteric coating would be necessary to preserve bioavailability), the normal pill and the enteric-coated pill resulted in the same bioavailability. Following this study, Bayer developed micronized drospirenone in a normal pill, the basis for the disputed patent.

The district court found that a person having ordinary skill in the art would have considered the prior art result that a structurally related compound, spirorenone, though acid-sensitive, would nevertheless absorb *in vivo*, would have suggested the same result for drospirenone. It also found that while another reference taught that drospirenone isomerizes *in vitro* when exposed to acid simulating the human stomach, a person of ordinary skill would have been aware of the study's shortcomings, and would have verified the findings as suggested by a treatise on the science of dosage form design, which would have then showed that no enteric coating was necessary.

The Federal Circuit held that the patent was invalid because the claimed formulation was obvious. The Federal Circuit reasoned that the prior art would have funneled the formulator toward two options. Thus, the formulator would not have been required to try all possibilities in a field unreduced by the prior art. The prior art was not vague in pointing toward a general approach or area of exploration, but rather guided the formulator precisely to the use of either a normal pill or an enteric-coated pill.

It is important for Office personnel to recognize that the mere existence of a large number of options does not in and of itself lead to a conclusion of nonobviousness. Where the prior art teachings lead one of ordinary skill in the art to a narrower set of options, then that reduced set is the appropriate one to consider when determining obviousness using an obvious to try rationale.

Example 7:

The case of *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 89 USPQ2d 1370 (Fed. Cir. 2008), also sheds light on the obvious to try line of reasoning. The claimed compound was clopidogrel, which is the dextrorotatory isomer of methyl alpha- 5(4,5,6,7-tetrahydro(3,2-c)thienopyridyl)(2-chlorophenyl)-acetate. Clopidogrel is an anti-thrombotic compound used to treat or prevent heart attack or stroke. The racemate, or mixture of dextrorotatory and levorotatory (D- and L-) isomers of the compound, was known in the prior art. The two forms had not previously been separated, and although the mixture was known to have anti-thrombotic properties, the extent to which each of the individual isomers contributed to the observed properties of the racemate was not known and was not predictable.

The district court assumed that in the absence of any additional information, the D-isomer would have been *prima facie* obvious over the known racemate. However, in view of the evidence of unpredicted therapeutic advantages of the D-isomer presented in the case, the district court found that any *prima facie* case of obviousness had been overcome. At trial, the experts for both parties testified that persons of ordinary skill in the art could not have predicted the degree to which the isomers would have exhibited different levels of therapeutic activity and toxicity. Both parties' experts also agreed that the isomer with greater therapeutic activity would most likely have had greater toxicity. Sanofi witnesses testified that Sanofi's own researchers had believed that the separation of the isomers was unlikely to have been productive, and experts for both parties agreed that it was difficult to separate isomers at the time of the invention. Nevertheless, when Sanofi ultimately undertook the task of separating the isomers, it found that they had the "rare characteristic of 'absolute stereoselectivity,'" whereby the D-isomer provided all of the favorable therapeutic activity but no significant toxicity, while the L-isomer produced no therapeutic activity but virtually all of the toxicity. Based on this record, the district court concluded that Apotex had not met its burden of proving by clear and convincing evidence that Sanofi's patent was invalid for obviousness. The Federal Circuit affirmed the district court's conclusion.

Office personnel should recognize that even when only a small number of possible choices exist, the obvious to try line of reasoning is not appropriate when, upon consideration of all of the evidence, the outcome would not have been reasonably predictable and the inventor would not have had a reasonable expectation of success. In *Bayer*, there were art-based reasons to expect that both the normal pill and the enteric-coated pill would be therapeutically suitable, even though not all prior art studies were in complete agreement. Thus, the result obtained was not unexpected. In *Sanofi*, on the other hand, there was strong evidence that persons of ordinary skill in the art, prior to the separation of the isomers, would have had no reason to expect that the D-isomer would have such strong therapeutic advantages as compared with the L-isomer. In other words, the result in *Sanofi* was unexpected.

Example 8:

In *Rolls-Royce, PLC v. United Tech. Corp.*, 603 F.3d 1325, 95 USPQ2d 1097 (Fed. Cir. 2010), the Federal Circuit addressed the obvious to try rationale in the context of a fan blade for jet engines. The case had arisen out of an interference proceeding. Finding that the district court had correctly determined that there was no interference-in-fact because Rolls-Royce's claims would not have been obvious in light of United's application, the Federal Circuit affirmed.

The Federal Circuit described the fan blade of the count as follows:

Each fan blade has three regions – an inner, an intermediate, and an outer region. The area closest to the axis of rotation at the hub is the inner region. The area farthest from

the center of the engine and closest to the casing surrounding the engine is the outer region. The intermediate region falls in between. The count defines a fan blade with a swept-forward inner region, a swept-rearward intermediate region, and forward-leaning outer region.

Id. at 1328, 95 USPQ2d at 1099.

United had argued that it would have been obvious for a person of ordinary skill in the art to try a fan blade design in which the sweep angle in the outer region was reversed as compared with prior art fan blades from rearward to forward sweep, in order to reduce endwall shock. The Federal Circuit disagreed with United's assessment that the claimed fan blade would have been obvious based on an obvious to try rationale. The Federal Circuit pointed out that in a proper obvious to try approach to obviousness, the possible options for solving a problem must have been "known and finite." *Id.* at 1339, 95 USPQ2d at 1107 (citing *Abbott*, 544 F.3d at 1351, 89 USPQ2d at 1171). In this case, nothing in the prior art would have suggested that changing the sweep angle as Rolls-Royce had done would have addressed the issue of endwall shock. Thus, the Federal Circuit concluded that changing the sweep angle "would not have presented itself as an option at all, let alone an option that would have been obvious to try." *Id.* The decision in *Rolls-Royce* is a reminder to Office personnel that the obvious to try rationale can properly be used to support a conclusion of obviousness only when the claimed solution would have been selected from a finite number of potential solutions known to persons of ordinary skill in the art.

Example 9:

The case of *Perfect Web Tech., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1328-29, 92 USPQ2d 1849, 1854 (Fed. Cir. 2009), provides an example in which the Federal Circuit held that a claimed method for managing bulk email distribution was obvious on the basis of an obvious to try argument. In *Perfect Web*, the method required selecting the intended recipients, transmitting the emails, determining how many of the emails had been successfully received, and repeating the first three steps if a pre-determined minimum number of intended recipients had not received the email.

The Federal Circuit affirmed the district court's determination on summary judgment that the claimed invention would have been obvious. Failure to meet a desired quota of email recipients was a recognized problem in the field of email marketing. The prior art had also recognized three potential solutions: increasing the size of the initial recipient list; resending emails to recipients who did not receive them on the first attempt; and selecting a new recipient list and sending emails to them. The last option corresponded to the fourth step of the invention as claimed.

The Federal Circuit noted that based on “simple logic,” selecting a new list of recipients was more likely to result in the desired outcome than resending to those who had not received the email on the first attempt. There had been no evidence of any unexpected result associated with selecting a new recipient list, and no evidence that the method would not have had a reasonable likelihood of success. Thus, the Federal Circuit concluded that, as required by *KSR*, there were a “finite number of identified, predictable solutions,” and that the obvious to try inquiry properly led to the legal conclusion of obviousness.

The Federal Circuit in *Perfect Web* also discussed the role of common sense in the determination of obviousness. The district court had cited *KSR* for the proposition that “[a] person of ordinary skill is also a person of ordinary creativity, not an automaton,” and found that “the final step [of the claimed invention] is merely the logical result of common sense application of the maxim ‘try, try again.’” In affirming the district court, the Federal Circuit undertook an extended discussion of common sense as it has been applied to the obviousness inquiry, both before and since the *KSR* decision.

The Federal Circuit pointed out that application of common sense is not really an innovation in the law of obviousness when it stated, “Common sense has long been recognized to inform the analysis of obviousness if explained with sufficient reasoning.” *Perfect Web*, 587 F.3d at 1328, 92 USPQ2d at 1853 (emphasis added). The Federal Circuit then provided a review of a number of precedential cases that inform the understanding of common sense, including *In re Bozek*, 416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969) (explaining that a patent examiner may rely on “common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference”) and *In re Zurko*, 258 F.3d 1379, 1383, 1385, 59 USPQ2d 1693 at 1695, 1697 (Fed. Cir. 2001) (clarifying that a factual foundation is needed in order for an examiner to invoke “good common sense” in a case in which “basic knowledge and common sense was not based on any evidence in the record”). The Federal Circuit implicitly acknowledged in *Perfect Web* that the kind of strict evidence-based teaching, suggestion, or motivation required in *In re Lee*, 277 F.3d 1338, 1344, 61 USPQ2d 1430, 1434 (Fed. Cir. 2002), is not an absolute requirement for an obviousness rejection in light of the teachings of *KSR*. The Federal Circuit explained that “[a]t the time [of the Lee decision], we required the PTO to identify record evidence of a teaching, suggestion, or motivation to combine references.” However, *Perfect Web* went on to state that even under *Lee*, common sense could properly be applied when analyzing evidence relevant to obviousness. Citing *DyStar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 80 USPQ2d 1641 (Fed. Cir. 2006), and *In re Kahn*, 441 F.3d 977, 78 USPQ2d 1329 (Fed. Cir. 2006), two cases decided shortly before the Supreme Court’s decision in *KSR*, the Federal Circuit noted that although “a reasoned explanation that avoids conclusory generalizations” is required to use common sense, identification of a “specific hint or suggestion in a particular

reference” is not. See also *B/E Aerospace, Inc. v. C&D Zodiac, Inc.*, 962 F.3d 1373, 1380-81, 2020 USPQ2d 10706 (Fed. Cir. 2020) (stating that “the Board’s invocation of common sense was properly accompanied by reasoned analysis and evidentiary support” to show why it would be obvious to incorporate a second recess to receive an airplane seat support). But see *Arendi v. Apple*, 832 F.3d 1355, 119 USPQ2d 1822 (Fed. Cir. 2016) (finding that the Board had not provided a reasoned analysis, supported by the evidence of record, for why “common sense” taught the missing process step).

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

To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Then, Office personnel must articulate the following:

- (1) a finding that the scope and content of the prior art, whether in the same field of endeavor as that of the applicant’s invention or a different field of endeavor, included a similar or analogous device (method, or product);
- (2) a finding that there were design incentives or market forces which would have prompted adaptation of the known device (method, or product);
- (3) a finding that the differences between the claimed invention and the prior art were encompassed in known variations or in a principle known in the prior art;
- (4) a finding that one of ordinary skill in the art, in view of the identified design incentives or other market forces, could have implemented the claimed variation of the prior art, and the claimed variation would have been predictable to one of ordinary skill in the art; and
- (5) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claimed invention would have been obvious is that design incentives or other market forces could have prompted one of ordinary skill in the art to vary the prior art in a predictable manner to result in the claimed invention. If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

Example 1:

The fact pattern in *Dann v. Johnston*, 425 U.S. 219, 189 USPQ 257 (1976) is set forth above in Example 1 in subsection D.

The Court found that the problem addressed by applicant – the need to give more detailed breakdown by a category of transactions – was closely analogous to the task of keeping track

of the transaction files of individual business units. *Id.* at 229, 189 USPQ at 261. Thus, an artisan in the data processing area would have recognized the similar class of problem and the known solutions of the prior art and it would have been well within the ordinary skill level to implement the system in the different environment. The Court held that “[t]he gap between the prior art and respondent’s system is simply not so great as to render the system nonobvious to one reasonably skilled in the art.” *Id.* at 230, 189 USPQ at 261.

Example 2:

The claimed invention in *Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 82 USPQ2d 1687 (Fed. Cir. 2007) was directed to a learning device to help young children read phonetically. The claim read as follows:

An interactive learning device, comprising:

a housing including a plurality of switches;

a sound production device in communication with the switches and including a processor and a memory;

at least one depiction of a sequence of letters, each letter being associable with a switch; and

a reader configured to communicate the identity of the depiction to the processor,

wherein selection of a depicted letter activates an associated switch to communicate with the processor, causing the sound production device to generate a signal corresponding to a sound associated with the selected letter, the sound being determined by a position of the letter in the sequence of letter.

The court concluded that the claimed invention would have been obvious in view of the combination of two pieces of prior art, (1) Bevan (which showed an electro-mechanical toy for phonetic learning), (2) the Super Speak & Read device (SSR) (an electronic reading toy), and the knowledge of one of ordinary skill in the art.

The court made clear that there was no technological advance beyond the skill shown in the SSR device. The court stated that “one of ordinary skill in the art of children’s learning toys would have found it obvious to combine the Bevan device with the SSR to update it using modern electronic components in order to gain the commonly understood benefits of such adaptation, such as decreased size, increased reliability, simplified operation, and reduced cost. While the SSR only permits generation of a sound corresponding to the first letter of a word, it does so using electronic means. The combination is thus the adaptation of an old idea or invention (Bevan) using newer technology that is commonly available and understood in the art (the SSR).”

The court found that the claimed invention was but a variation on already known children's toys. This variation presented no nonobvious advance over other toys. The court made clear that there was no technological advance beyond the skill shown in the SSR device. The court found that "[a]ccommodating a prior art mechanical device that accomplishes that goal to modern electronics would have been reasonably obvious to one of ordinary skill in designing children's learning devices. Applying modern electronics to older mechanical devices has been commonplace in recent years."

Example 3:

The claimed invention in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007), was an adjustable pedal assembly with a fixed pivot point and an electronic pedal-position sensor attached to the assembly support. The fixed pivot point meant that the pivot was not changed as the pedal was adjusted. The placement of the sensor on the assembly support kept the sensor fixed while the pedal was adjusted.

Conventional gas pedals operated by a mechanical link which adjusted the throttle based on the travel of the pedal from a set position. The throttle controlled the combustion process and the available power generated by the engine. Newer cars used computer controlled throttles in which a sensor detected the motion of the pedal and sent signals to the engine to adjust the throttle accordingly. At the time of the invention, the marketplace provided a strong incentive to convert mechanical pedals to electronic pedals, and the prior art taught a number of methods for doing so. The prior art (Asano) taught an adjustable pedal with a fixed pivot point with mechanical throttle control. The prior art ('936 patent to Byler) taught an electronic pedal sensor which was placed on a pivot point in the pedal assembly and that it was preferable to detect the pedal's position in the pedal mechanism rather than in the engine. The prior art (Smith) taught that to prevent the wires connecting the sensor to the computer from chafing and wearing out, the sensor should be put on a fixed part of the pedal assembly rather than in or on the pedal's footpad. The prior art (Rixon) taught an adjustable pedal assembly (sensor in the footpad) with an electronic sensor for throttle control. There was no prior art electronic throttle control that was combined with a pedal assembly which kept the pivot point fixed when adjusting the pedal.

The Court stated that "[t]he proper question to have asked was whether a pedal designer of ordinary skill, facing the wide range of needs created by developments in the field of endeavor, would have seen a benefit to upgrading Asano with a sensor." *Id.* at 424, 82 USPQ2d at 1399. The Court found that technological developments in the automotive design would have prompted a designer to upgrade Asano with an electronic sensor. The next question was where to attach the sensor. Based on the prior art, a designer would have known to place the sensor on a nonmoving part of the pedal structure and the most obvious nonmoving point on the structure from which a sensor can easily detect the pedal's position

was a pivot point. The Court concluded that it would have been obvious to upgrade Asano's fixed pivot point adjustable pedal by replacing the mechanical assembly for throttle control with an electronic throttle control and to mount the electronic sensor on the pedal support structure.

Example 4:

The claimed invention in *Ex parte Catan*, 83 USPQ2d 1569 (Bd. Pat. App. & Int. 2007), was a consumer electronics device using bioauthentication to authorize sub-users of an authorized credit account to place orders over a communication network up to a pre-set maximum sub-credit limit.

The prior art (Nakano) disclosed a consumer electronics device like the claimed invention, except that security was provided by a password authentication device rather than a bioauthentication device. The prior art (Harada) disclosed that the use of a bioauthentication device (fingerprint sensor) on a consumer electronics device (remote control) to provide bioauthentication information (fingerprint) was known in the prior art at the time of the invention. The prior art (Dethloff) also disclosed that it was known in the art at the time of the invention to substitute bioauthentication for PIN authentication to enable a user to access credit via a consumer electronics device.

The Board found that the prior art "shows that one of ordinary skill in the consumer electronic device art at the time of the invention would have been familiar with using bioauthentication information interchangeably with or in lieu of PINs to authenticate users." The Board concluded that one of ordinary skill in the art of consumer electronic devices would have found it obvious to update the prior art password device with the modern bioauthentication component and thereby gain, predictably, the commonly understood benefits of such adaptation, that is, a secure and reliable authentication procedure.

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

To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Then, Office personnel must articulate the following:

- (1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings;
- (2) a finding that there was reasonable expectation of success; and

- (3) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claim would have been obvious is that "a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and whether there would have been a reasonable expectation of success in doing so." *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006). If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

The courts have made clear that the teaching, suggestion, or motivation test is flexible and an explicit suggestion to combine the prior art is not necessary. The motivation to combine may be implicit and may be found in the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. *Id.* at 1366, 80 USPQ2d at 1649. "[A]n implicit motivation to combine exists not only when a suggestion may be gleaned from the prior art as a whole, but when the 'improvement' is technology-independent and the combination of references results in a product or process that is more desirable, for example because it is stronger, cheaper, cleaner, faster, lighter, smaller, more durable, or more efficient. Because the desire to enhance commercial opportunities by improving a product or process is universal—and even common-sensical—we have held that there exists in these situations a motivation to combine prior art references even absent any hint of suggestion in the references themselves. In such situations, the proper question is whether the ordinary artisan possesses knowledge and skills rendering him *capable* of combining the prior art references." *Id.* at 1368, 80 USPQ2d at 1651.

2143.01 Suggestion or Motivation To Modify the References [R-01.2024]

[Editor Note: This MPEP section is applicable regardless of whether an application is examined under the AIA or under pre-AIA law. For applications subject to the first inventor to file (FITF) provisions of the AIA, the relevant time is "before the effective filing date of the claimed invention". For applications subject to [pre-AIA 35 U.S.C. 102](#), the relevant time is "at the time of the invention". See [MPEP § 2150](#) et seq. Many of the court decisions discussed in this section involved applications or patents subject to [pre-AIA 35 U.S.C. 102](#). These court decisions may be applicable to applications and patents subject to [AIA 35 U.S.C. 102](#) but the relevant time is before the effective filing date of the claimed invention and not at the time of the invention.]

Obviousness can be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so. *In re Kahn*, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006) (discussing rationale underlying the motivation-suggestion-teaching test as a guard against using hindsight in an obviousness analysis). *Axonics, Inc. v. Medtronic, Inc.*, 73 F.4th 950, 957-58, 2023 USPQ2d 795 (Fed. Cir. 2023) (the court found an erroneous framing of the motivation inquiry led to an incorrect conclusion of nonobviousness). A “motivation to combine may be found explicitly or implicitly in market forces; design incentives; the ‘interrelated teachings of multiple patents’; ‘any need or problem known in the field of endeavor at the time of invention and addressed by the patent’; and the background knowledge, creativity, and common sense of the person of ordinary skill.” *Zup v. Nash Mfg.*, 896 F.3d 1365, 1371, 127 USPQ2d 1423, 1427 (Fed. Cir. 2018) (quoting *Plantronics, Inc. v. Aliph, Inc.*, 724 F.3d 1343, 1354 [107 USPQ2d 1706] (Fed. Cir. 2013) (citing *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1328 [92 USPQ2d 1849] (Fed. Cir. 2009) (quoting *KSR*, 550 U.S. at 418-21)). See [MPEP § 2143](#) regarding the need to provide a reasoned explanation even in situations involving common sense or ordinary ingenuity. See also [MPEP § 2144.05](#), subsection II, B.

I. PRIOR ART SUGGESTION OF THE CLAIMED INVENTION NOT NECESSARILY NEGATED BY DESIRABLE ALTERNATIVES

The disclosure of desirable alternatives does not necessarily negate a suggestion for modifying the prior art to arrive at the claimed invention. In *In re Fulton*, 391 F.3d 1195, 73 USPQ2d 1141 (Fed. Cir. 2004), the claims of a utility patent application were directed to a shoe sole with increased traction having hexagonal projections in a “facing orientation.” 391 F.3d at 1196-97, 73 USPQ2d at 1142. The Board combined a design patent having hexagonal projections in a facing orientation with a utility patent having other limitations of the independent claim. 391 F.3d at 1199, 73 USPQ2d at 1144. Applicant argued that the combination was improper because (1) the prior art did not suggest having the hexagonal projections in a facing (as opposed to a “pointing”) orientation was the “most desirable” configuration for the projections, and (2) the prior art “taught away” by showing desirability of the “pointing orientation.” 391 F.3d at 1200-01, 73 USPQ2d at 1145-46. The court stated that “the prior art’s mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed....” *Id.* In affirming the Board’s obviousness rejection, the court held that the prior art as a whole suggested the desirability of the combination of shoe sole limitations claimed, thus providing a motivation to combine, which need not be supported by a finding that the prior art suggested that the combination claimed by the applicant was the preferred, or most desirable combination over the other alternatives. *Id.* See also *In re Urbanski*, 809 F.3d 1237, 1244, 117 USPQ2d 1499, 1504 (Fed. Cir. 2016).

In *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 69 USPQ2d 1686 (Fed. Cir. 2004), the patent claimed underpinning a slumping building foundation using a screw anchor attached to the foundation by a metal bracket. One prior art reference taught a screw anchor with a concrete bracket, and a second prior art reference disclosed a pier anchor with a metal bracket. The court found motivation to combine the references to arrive at the claimed invention in the “nature of the problem to be solved” because each reference was directed “to precisely the same problem of underpinning slumping foundations.” *Id.* at 1276, 69 USPQ2d at 1690. The court also *rejected* the notion that “an express written motivation to combine must appear in prior art references....” *Id.* at 1276, 69 USPQ2d at 1690.

II. WHERE THE TEACHINGS OF THE PRIOR ART CONFLICT, THE EXAMINER MUST WEIGH THE SUGGESTIVE POWER OF EACH REFERENCE

The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art, and all teachings in the prior art must be considered to the extent that they are in analogous arts. Where the teachings of two or more prior art references conflict, the examiner must weigh the power of each reference to suggest solutions to one of ordinary skill in the art, considering the degree to which one reference might accurately discredit another. *In re Young*, 927 F.2d 588, 18 USPQ2d 1089 (Fed. Cir. 1991) (Prior art patent to Carlisle disclosed controlling and minimizing bubble oscillation for chemical explosives used in marine seismic exploration by spacing seismic sources close enough to allow the bubbles to intersect before reaching their maximum radius so the secondary pressure pulse was reduced. An article published several years later by Knudsen opined that the Carlisle technique did not yield appreciable improvement in bubble oscillation suppression. However, the article did not test the Carlisle technique under comparable conditions because Knudsen did not use Carlisle’s spacing or seismic source. Furthermore, where the Knudsen model most closely approximated the patent technique there was a 30% reduction of the secondary pressure pulse. On these facts, the court found that the Knudsen article would not have deterred one of ordinary skill in the art from using the Carlisle patent teachings.).

III. FACT THAT REFERENCES CAN BE COMBINED OR MODIFIED MAY NOT BE SUFFICIENT TO ESTABLISH *PRIMA FACIE* OBVIOUSNESS

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 417, 82 USPQ2d 1385, 1396 (2007) (“If a person of ordinary skill can implement a predictable variation, [§ 103](#) likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the

same way, using the technique is obvious unless its actual application is beyond his or her skill.”).

IV. MERE STATEMENT THAT THE CLAIMED INVENTION IS WITHIN THE CAPABILITIES OF ONE OF ORDINARY SKILL IN THE ART IS NOT SUFFICIENT BY ITSELF TO ESTABLISH *PRIMA FACIE* OBVIOUSNESS

A statement that modifications of the prior art to meet the claimed invention would have been “well within the ordinary skill of the art at the time the claimed invention was made” because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR*, 550 U.S. at 418, 82 USPQ2d at 1396 (quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)).

V. THE PROPOSED MODIFICATION CANNOT RENDER THE PRIOR ART UNSATISFACTORY FOR ITS INTENDED PURPOSE

If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, there may be no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) (Claimed device was a blood filter assembly for use during medical procedures wherein both the inlet and outlet for the blood were located at the bottom end of the filter assembly, and wherein a gas vent was present at the top of the filter assembly. The prior art reference taught a liquid strainer for removing dirt and water from gasoline and other light oils wherein the inlet and outlet were at the top of the device, and wherein a pet-cock (stopcock) was located at the bottom of the device for periodically removing the collected dirt and water. The reference further taught that the separation is assisted by gravity. The Board concluded the claims were *prima facie* obvious, reasoning that it would have been obvious to turn the reference device upside down. The court reversed, finding that if the prior art device were turned upside down it would be inoperable for its intended purpose because the gasoline to be filtered would be trapped at the top, the water and heavier oils sought to be separated would flow out of the outlet instead of the purified gasoline, and the screen would become clogged.). But see *In re Urbanski*, 809 F.3d 1237, 1244, 117 USPQ2d 1499, 1504 (Fed. Cir. 2016) (The patent claims were directed to a method of enzymatic hydrolysis of soy fiber to reduce water holding capacity, requiring reacting the soy fiber and enzyme in water for about 60-120 minutes. The claims were rejected over two prior art references, wherein the primary reference taught using a longer reaction time of 5 to 72 hours and the secondary reference taught using a reaction

time of 100 to 240 minutes, preferably 120 minutes. The applicant argued that modifying the primary reference in the manner suggested by the secondary reference would forego the benefits taught by the primary reference, thereby teaching away from the combination. The court held that both prior art references “suggest[ed] that hydrolysis time may be adjusted to achieve *different* fiber properties. Nothing in the prior art teaches that the proposed modification would have resulted in an ‘inoperable’ process or a dietary fiber product with undesirable properties.” (emphasis in original)).

“Although statements limiting the function or capability of a prior art device require fair consideration, simplicity of the prior art is rarely a characteristic that weighs against obviousness of a more complicated device with added function.” *In re Dance*, 160 F.3d 1339, 1344, 48 USPQ2d 1635, 1638 (Fed. Cir. 1998) (Court held that claimed catheter for removing obstruction in blood vessels would have been obvious in view of a first reference which taught all of the claimed elements except for a “means for recovering fluid and debris” in combination with a second reference describing a catheter including that means. The court agreed that the first reference, which stressed simplicity of structure and taught emulsification of the debris, did not teach away from the addition of a channel for the recovery of the debris.). Similarly, in *Allied Erecting v. Genesis Attachments*, 825 F.3d 1373, 1381, 119 USPQ2d 1132, 1138 (Fed. Cir. 2016), the court stated “[a]lthough modification of the movable blades may impede the quick change functionality disclosed by Caterpillar, ‘[a] given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine’” (quoting *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165, 77 USPQ2d 1865, 1870 (Fed. Cir. 2006) (citation omitted)).

VI. THE PROPOSED MODIFICATION CANNOT CHANGE THE PRINCIPLE OF OPERATION OF A REFERENCE

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 813, 123 USPQ 349, 352 (CCPA 1959) (Claims were directed to an oil seal comprising a bore engaging portion with outwardly biased resilient spring fingers inserted in a resilient sealing member. The primary reference relied upon in a rejection based on a combination of references disclosed an oil seal wherein the bore engaging portion was reinforced by a cylindrical sheet metal casing. The seal construction taught in the primary reference required rigidity for operation, whereas the seal in the claimed invention required resiliency. The court reversed the rejection holding the “suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate.”).

2143.02 Reasonable Expectation of Success Is Required [R-01.2024]

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I. OBVIOUSNESS REQUIRES A REASONABLE EXPECTATION OF SUCCESS

Where there is a reason to modify or combine the prior art to achieve the claimed invention, the claims may be rejected as *prima facie* obvious provided there is also a reasonable expectation of success. The reasonable expectation of success requirement refers to "the likelihood of success" in combining or modifying prior art disclosures to meet the limitations of the claimed invention. See *Elekta Ltd. v. ZAP Surgical Sys., Inc.*, 81 F.4th 1368, 1375, 2023 USPQ2d 1100 (Fed. Cir. 2023) and *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367, 119 USPQ2d 1171, 1176 (Fed. Cir. 2016). See [MPEP § 2143](#) for guidance on rationales for modifying or combining the prior art. In *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986), the Board affirmed a rejection of claims directed to a method of treating depression with amitriptyline (or nontoxic salts thereof) as *prima facie* obvious. The prior art disclosed that amitriptyline is a compound known to possess psychotropic properties and that imipramine is a structurally similar psychotropic compound known to possess antidepressive properties. Additional prior art, suggested that these compounds would have been expected to have similar activity because the structural difference between them involved a known bioisosteric replacement, and because a research paper comparing the pharmacological properties of these two compounds suggested clinical testing of amitriptyline as an antidepressant. The court affirmed the Board's determination, finding that the teachings of the prior art provided a sufficient basis for a reasonable expectation of success.) In *Ex parte Blanc*, 13 USPQ2d 1383 (Bd. Pat. App. & Inter. 1989) (the claims were directed to a process of sterilizing a polyolefinic composition with high-energy radiation in the presence of a phenolic polyester antioxidant to inhibit discoloration or degradation of the polyolefin. Appellant argued that it is unpredictable whether a particular antioxidant will solve the problem of discoloration or degradation. However, the Board found that because the prior art taught that appellant's preferred antioxidant is very efficient and provides better results compared with other prior art antioxidants, there would have been a reasonable expectation of success.).

As discussed above, reasonable expectation of success can be implicitly shown via the prior art teachings or as part of the obviousness analysis. See *Elekta Ltd. v. ZAP Surgical Sys., Inc.*, 81 F.4th 1368, 1376-77, 2023 USPQ2d 1100 (Fed. Cir. 2023) (“[W]e can reasonably discern that the Board considered and implicitly addressed reasonable expectation of success based on the arguments and evidence presented to the Board on motivation to combine.”). In this decision, the court found the Board’s explanation on why the patent owner’s arguments and evidence presented on motivation to combine were not persuasive implicitly addressed reasonable expectation of success and was supported by substantial evidence. On the other hand, depending on the situation (e.g., the technology, the prior art teachings and the obviousness analysis), reliance on an implicit showing of reasonable expectation of success may not be sufficient to establish a *prima facie* showing of obviousness. *Eli Lilly & Co. v. Teva Pharms. Int’l GmbH*, 8 F.4th 1331, 1344, 2021 USPQ2d 862 (Fed. Cir. 2021) (A finding that a patent challenger in an *inter partes* review had demonstrated a motivation to combine references does not necessarily imply that the challenger had also met its burden of showing a reasonable expectation of success in achieving a claimed method of treatment.). In this case, the court found that the challenged method of treating claims “contain limitations related to their intended purpose for treating vasomotor symptoms [as stated in the preamble], and thus those limitations are undoubtedly relevant to the reasonable expectation of success.” *Id.* at 1345. In other words, the court found that the preamble was limiting and applicable to reasonable expectation of success. However, the limitations in the preamble were not addressed in the motivation to combine analysis. Any obviousness rejection should include, either explicitly or implicitly, an indication of a reasonable expectation of success.

Conclusive proof of efficacy is not required to show a reasonable expectation of success. *OSI Pharm., LLC v. Apotex Inc.*, 939 F.3d 1375, 1385, 2019 USPQ2d 379681 (Fed. Cir. 2019) (“To be clear, we do not hold today that efficacy data is always required for a reasonable expectation of success. Nor are we requiring ‘absolute predictability of success.’”); *Acorda Therapeutics, Inc. v. Roxane Lab., Inc.*, 903 F.3d 1310, 1333, 128 USPQ2d 1001, 1018 (Fed. Cir. 2018) (“This court has long rejected a requirement of ‘[c]onclusive proof of efficacy’ for obviousness.” (citing to *Hoffmann-La Roche Inc. v. Apotex Inc.*, 748 F.3d 1326, 1331 (Fed. Cir. 2014); *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1364 (Fed. Cir. 2007); *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364, 1367–68 (Fed. Cir. 2007) (reasoning that “the expectation of success need only be reasonable, not absolute”))).

II. AT LEAST SOME DEGREE OF PREDICTABILITY IS REQUIRED; APPLICANTS MAY PRESENT EVIDENCE SHOWING THERE WAS NO REASONABLE EXPECTATION OF SUCCESS

Obviousness does not require absolute predictability, but at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success

may support a conclusion of nonobviousness. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) (Claims directed to a method for the commercial scale production of polyesters in the presence of a solvent at superatmospheric pressure were rejected as obvious over a reference which taught the claimed method at atmospheric pressure in view of a reference which taught the claimed process except for the presence of a solvent. The court reversed, finding there was no reasonable expectation that a process combining the prior art steps could be successfully scaled up in view of unchallenged evidence showing that the prior art processes individually could not be commercially scaled up successfully.). See also *OSI Pharm., LLC v. Apotex Inc.*, 939 F.3d 1375, 1385, 2019 USPQ2d 379681 (Fed. Cir. 2019) (“These references provide no more than hope—and hope that a potentially promising drug will treat a particular cancer is not enough to create a reasonable expectation of success in a highly unpredictable art such as this. Indeed, given a 99.5% failure rate and no efficacy data or any other reliable indicator of success, the only reasonable expectation at the time of the invention was failure, not success.”); *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1207-08, 18 USPQ2d 1016, 1022-23 (Fed. Cir. 1991), *cert. denied*, 502 U.S. 856 (1991) (In the context of a biotechnology case, testimony supported the conclusion that the references did not show that there was a reasonable expectation of success.); *In re O’Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) (The court held the claimed method would have been obvious over the prior art relied upon because one reference contained a detailed enabling methodology, a suggestion to modify the prior art to produce the claimed invention, and evidence suggesting the modification would be successful.).

III. PREDICTABILITY IS DETERMINED AT THE RELEVANT TIME

Whether an art is predictable or whether the proposed modification or combination of the prior art has a reasonable expectation of success is determined at the time the invention was made for pre-AIA obviousness analysis. *Ex parte Erlich*, 3 USPQ2d 1011, 1016 (Bd. Pat. App. & Inter. 1986) (Although an earlier case reversed a rejection because of unpredictability in the field of monoclonal antibodies, the court found “in this case at the time this invention was made, one of ordinary skill in the art would have been motivated to produce monoclonal antibodies specific for human fibroblast interferon using the method of [the prior art] with a reasonable expectation of success.”) (emphasis in original). For obviousness analysis under the AIA, the relevant time is “before the effective filing date of the claimed invention.”

2143.03 All Claim Limitations Must Be Considered [R-01.2024]

“All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

Examiners must consider all claim limitations when determining patentability of an invention over the prior art. *In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 403-04 (Fed. Cir. 1983).

The subject matter of a properly construed claim is defined by the terms that limit the scope of the claim when given their broadest reasonable interpretation. In *Axonics, Inc. v. Medtronic, Inc.*, 73 F.4th 950, 958-59, 2023 USPQ2d 795 (Fed. Cir. 2023), the court found the claims were improperly narrowed based on a preferred embodiment to sacral anatomy or sacral neuromodulation, whereas the patent claims made no reference to sacral anatomy or sacral neuromodulation. Thus, the relevant prior art was improperly limited to a narrow subset of claim scope. See also [MPEP § 2111](#) *et seq.* It is the subject matter of the properly construed claim that must be examined. The determination of whether particular language is a limitation in a claim depends on the specific facts of the case. See, e.g., *Griffin v. Bertina*, 285 F.3d 1029, 1034, 62 USPQ2d 1431 (Fed. Cir. 2002).

As a general matter, the grammar and ordinary meaning of terms as understood by one having ordinary skill in the art used in a claim will dictate whether, and to what extent, the language limits the claim scope. Language that suggests or makes a feature or step optional but does not require that feature or step does not limit the scope of a claim under the broadest reasonable claim interpretation. In addition, when a claim requires selection of an element from a list of alternatives, the prior art teaches the element if one of the alternatives is taught by the prior art. See, e.g., *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 582 F.3d 1288, 1298, 92 USPQ2d 1163, 1171 (Fed. Cir. 2009).

The following types of claim language may raise a question as to its limiting effect (this list is not exhaustive):

- • preamble ([MPEP § 2111.02](#));
- • clauses such as “adapted to,” “adapted for,” “wherein,” and “whereby” ([MPEP § 2111.04](#), subsection I);
- • contingent limitations ([MPEP § 2111.04](#), subsection II);
- • printed matter ([MPEP § 2111.05](#)); and
- • functional language associated with a claim term ([MPEP § 2181](#)).

If an independent claim is nonobvious under [35 U.S.C. 103](#), then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). However, this conclusion of the *Fine* court may not apply if a claim is not properly dependent or if the effective filing date of a dependent claim is later than the effective filing date of an independent claim from which the dependent claim depends. See [MPEP § 608.01\(n\)](#) for a discussion of dependent claims and [MPEP § 2133.01](#) and [§ 2152.01](#) for a discussion of effective filing date of a claimed invention determined on a claim-by-claim basis.

I. INDEFINITE LIMITATIONS MUST BE CONSIDERED

A claim limitation which is considered indefinite cannot be disregarded. If a claim is subject to more than one interpretation, at least one of which would render the claim unpatentable over the prior art, the examiner should reject the claim as indefinite under [35 U.S.C. 112\(b\)](#) or [pre-AIA 35 U.S.C. 112](#), second paragraph (see [MPEP § 2175](#)) and should reject the claim over the prior art based on the interpretation of the claim that renders the prior art applicable. *Ex parte Ionescu*, 222 USPQ 537 (Bd. Pat. App. & Inter. 1984) (Claims on appeal were rejected on indefiniteness grounds only; the rejection was reversed and the case remanded to the examiner for consideration of pertinent prior art.). Making both rejections, when appropriate, avoids piecemeal appellate review. See *Ionescu*, 222 USPQ at 540 n.9 (citing CCPA and Federal Circuit cases.). See also *In re Wilson*, 424 F.2d 1382, 165 USPQ 494 (CCPA 1970) (The Board erred because it ignored claim language that it considered to be indefinite, and reached a conclusion that the claim would have been obvious based only on the rest of the claim.). However, an examiner should not simply speculate about the meaning of the claim language and then enter an obviousness rejection in view of that speculative interpretation. *In re Steele*, 305 F.2d 859, 134 USPQ 292 (CCPA 1962) (The “considerable speculation” by the examiner and the Board as to the scope of the claims did not provide a proper basis for an obviousness rejection.). A claim should not be rejected over prior art just because it is indefinite. *Ionescu*, 222 USPQ at 540 (citing *Steele*). Although a claim that is indefinite because it is susceptible to more than one interpretation may be rejected over prior art, an examiner should not base a prior art rejection on a claim interpretation that is not reasonable; see [MPEP § 2111](#) regarding proper claim interpretation.

II. LIMITATIONS WHICH DO NOT FIND SUPPORT IN THE ORIGINAL SPECIFICATION MUST BE CONSIDERED

When evaluating claims for obviousness under [35 U.S.C. 103](#), all the limitations of the claims must be considered and given weight, including limitations which do not find support in the specification as originally filed (i.e., new matter). *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983) *aff’d mem.* 738 F.2d 453 (Fed. Cir. 1984) (Claim to a catalyst expressly excluded the presence of sulfur, halogen, uranium, and a combination of vanadium and phosphorous. Although the negative limitations excluding these elements did not appear in the specification as filed, it was error to disregard these limitations when determining whether the claimed invention would have been obvious in view of the prior art.). “All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Miller*, 441 F.2d 689, 694, 169 USPQ 597, 600 (CCPA 1971) (quoting *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970)).

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