

REPORT

**PTO PUBLISHES SUPPLEMENTAL EXAMINATION
GUIDELINES FOR DETERMINING OBVIOUSNESS**

September 3, 2010

On September 1, 2010, the U.S. Patent and Trademark Office (PTO) published "Examination Guidelines Update: Developments in the Obviousness Inquiry After *KSR v. Teleflex*." The Guidelines are effective immediately.¹

The Guidelines consist of an 18-page discussion of 24 Federal Circuit obviousness opinions that have been issued since *KSR*, with a "teaching point" extracted from each case. The cases and teaching points are grouped in four categories: (1) Combining Prior Art Elements; (2) Substituting One Known Element for Another; (3) Obvious to Try; and (4) Consideration of Evidence. The Guidelines provide a useful summary of 24 Federal Circuit cases, 13 of which addressed patent claims found obvious and 11 of which addressed patent claims found non-obvious.² The PTO's publication concludes with a table of the teaching points, which we have reformatted into a more convenient form as an Appendix to this Special Report. Our attached Appendix also includes a column indicating the "case result" as "+" if the decision held the claims to be patentable (non-obvious) or "-" if the decision held the claims to have been obvious.

The PTO's new Guidelines supplement the Guidelines issued by the PTO on October 10, 2007 (see our Special Report of that date), which have since been

¹ The full Guidelines are available with this Special Report in the News & Events section of our website, www.oliff.com.

² Additional comments on the three earliest cases, *PharmaStem*, *Takeda Chemical*, and *ICON*, are found in our August 17, 2007 Special Report.

incorporated into the PTO's Manual of Patent Examining Procedure §§ 2141 & 2143. As with that guidance, the new Guidelines are not rules and do not have the force of law. Thus, failure of an examiner to follow the Guidelines is not reviewable by petition or appeal. As the Guidelines state: "these cases begin to clarify the contours of the obviousness inquiry after *KSR*, and help to show when a rejection on this basis is proper and when it is not."

Before discussing the 24 decisions, the Guidelines summarize the 2007 PTO guidelines, and emphasize that the approach for determining obviousness should be flexible, reiterating the PTO's previously presented six rationales—in addition to the teaching-suggestion-motivation (TSM) test—specifically discussed in *KSR*.

We recommend that those confronting obviousness issues, whether in patent prosecution or other contexts, review the table of teaching points to determine whether any of the cases address relevant arguments. If a teaching point appears pertinent, the complete PTO discussion in the Guidelines and the case itself should be consulted. Some of the teaching points are very general, such that the Federal Circuit opinion cited as an example of the teaching point might not be applicable to the facts of the obviousness issue that is being considered. On the other hand, other teaching points are narrow and thus limited to a very narrow category of cases. Of course, all obviousness issues are fact-specific and more than one argument deriving from *KSR* or other cases may be applicable. The additional recommendations in our Special Report of August 17, 2007 remain applicable.

September 3, 2010

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This Special Report is intended to provide information about legal issues of current interest. It is not intended as legal advice and does not constitute an opinion of Oliff & Berridge, PLC. Readers should seek the advice of professional counsel before acting upon any of the information contained herein.

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Case	Teaching point	Case Result ¹
Combining Prior Art Elements		
<i>In re Omeprazole Patent Litigation</i> , 536 F.3d 1361 (Fed. Cir. 2008).	Even where a general method that could have been applied to make the claimed product was known and within the level of skill of the ordinary artisan, the claim may nevertheless be nonobvious if the problem which had suggested use of the method had been previously unknown.	+
<i>Crocs, Inc. v. U.S. Int'l Trade Comm'n.</i> , 598 F.3d 1294 (Fed. Cir. 2010).	A claimed combination of prior art elements may be nonobvious where the prior art teaches away from the claimed combination and the combination yields more than predictable results.	+
<i>Sundance, Inc. v. DeMonte Fabricating Ltd.</i> , 550 F.3d 1356 (Fed. Cir. 2008).	A claimed invention is likely to be obvious if it is a combination of known prior art elements that would reasonably have been expected to maintain their respective properties or functions after they have been combined.	-
<i>Ecolab, Inc. v. FMC Corp.</i> , 569 F.3d 1335 (Fed. Cir. 2009).	A combination of known elements would have been <i>prima facie</i> obvious if an ordinarily skilled artisan would have recognized an apparent reason to combine those elements and would have known how to do so.	-
<i>Wyers v. Master Lock Co.</i> , No. 2009-1412, —F.3d—, 2010 WL 2901839 (Fed. Cir. July 22, 2010).	The scope of analogous art is to be construed broadly and includes references that are reasonably pertinent to the problem that the inventor was trying to solve. Common sense may be used to support a legal conclusion of obviousness so long as it is explained with sufficient reasoning.	-
<i>DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.</i> , 567 F.3d 1314 (Fed. Cir. 2009).	Predictability as discussed in <i>KSR</i> encompasses the expectation that prior art elements are capable of being combined, as well as the expectation that the combination would have worked for its intended purpose. An inference that a claimed combination would not have been obvious is especially strong where the prior art's teachings undermine the very reason being proffered as to why a person of ordinary skill would have combined the known elements.	+
Substituting One Known Element for Another		
<i>In re ICON Health & Fitness, Inc.</i> , 496 F.3d 1374 (Fed. Cir. 2007).	When determining whether a reference in a different field of endeavor may be used to support a case of obviousness (<i>i.e.</i> , is analogous), it is necessary to consider the problem to be solved.	-
<i>Agripap, Inc. v. Woodstream Corp.</i> , 520 F.3d 1337 (Fed. Cir. 2008).	Analogous art is not limited to references in the field of endeavor of the invention, but also includes references that would have been recognized by those of ordinary skill in the art as useful for applicant's purpose.	-
<i>Muniauction, Inc. v. Thomson Corp.</i> , 532 F.3d 1318 (Fed. Cir. 2008).	Because Internet and Web browser technologies had become commonplace for communicating and displaying information, it would have been obvious to adapt existing processes to incorporate them for those functions.	-
<i>Aventis Pharma Deutschland v. Lupin, Ltd.</i> , 499 F.3d 1293 (Fed. Cir. 2007).	A chemical compound would have been obvious over a mixture containing that compound as well as other compounds where it was known or the skilled artisan had reason to believe that some desirable property of the mixture was derived in whole or in part from the claimed compound, and separating the claimed compound from the mixture was routine in the art.	-
<i>Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.</i> , 533 F.3d 1353 (Fed. Cir. 2008).	A claimed compound would not have been obvious where there was no reason to modify the closest prior art lead compound to obtain the claimed compound and the prior art taught that modifying the lead compound would destroy its advantageous property. Any known compound may serve as a lead compound when there is some reason for starting with that lead compound and modifying it to obtain the claimed compound.	+
<i>Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.</i> , 566 F.3d 989 (Fed. Cir. 2009).	It is not necessary to select a single compound as a "lead compound" in order to support an obviousness rejection. However, where there was reason to select and modify the lead compound to obtain the claimed compound, but no reasonable expectation of success, the claimed compound would not have been obvious.	+
<i>Altana Pharma AG v. Teva Pharms. USA, Inc.</i> , 566 F.3d 999 (Fed. Cir. 2009).	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 a prior art lead compound in a particular way to produce the claimed compound. It is not necessary for the reasoning to be explicitly found in the prior art of record, nor is it necessary for the prior art to point to only a single lead compound.	-

¹ + = patent held nonobvious (or an obviousness finding vacated);

- = patent held obvious.

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Case	Teaching point	Case Result ¹
The Obvious To Try Rationale		
<i>In re Kubin</i> , 561 F.3d 1351 (Fed. Cir. 2009).	A claimed polynucleotide would have been obvious over the known protein that it encodes where the skilled artisan would have had a reasonable expectation of success in deriving the claimed polynucleotide using standard biochemical techniques, and the skilled artisan would have had a reason to try to isolate the claimed polynucleotide. <i>KSR</i> applies to all technologies, rather than just the "predictable" arts.	-
<i>Takeda Chem. Indus. v. Alphapharm Pty., Ltd.</i> , 492 F.3d 1350 (Fed. Cir. 2007).	A claimed compound would not have been obvious where it was not obvious to try to obtain it from a broad range of compounds, any one of which could have been selected as the lead compound for further investigation, and the prior art taught away from using a particular lead compound, and there was no predictability or reasonable expectation of success in making the particular modifications necessary to transform the lead compound into the claimed compound.	+
<i>Ortho-McNeil Pharmaceutical, Inc. v. Mylan Labs, Inc.</i> , 520 F.3d 1358 (Fed. Cir. 2008).	Where the claimed anti-convulsant drug had been discovered somewhat serendipitously in the course of research aimed at finding a new anti-diabetic drug, it would not have been obvious to try to obtain a claimed compound where the prior art did not present a finite and easily traversed number of potential starting compounds, and there was no apparent reason for selecting a particular starting compound from among a number of unpredictable alternatives.	+
<i>Bayer Schering Pharma A.G. v. Barr Labs., Inc.</i> , 575 F.3d 1341 (Fed. Cir. 2009).	A claimed compound would have been obvious where it was obvious to try to obtain it from a finite and easily traversed number of options that was narrowed down from a larger set of possibilities by the prior art, and the outcome of obtaining the claimed compound was reasonably predictable.	-
<i>Sanofi-Synthelabo v. Apotex, Inc.</i> , 550 F.3d 1075 (Fed. Cir. 2008).	A claimed isolated stereoisomer would not have been obvious where the claimed stereoisomer exhibits unexpectedly strong therapeutic advantages over the prior art racemic mixture without the correspondingly expected toxicity, and the resulting properties of the enantiomers separated from the racemic mixture were unpredictable.	+
<i>Rolls-Royce, PLC v. United Technologies Corp.</i> , 603 F.3d 1325 (Fed. Cir. 2010).	An obvious to try rationale may be proper when the possible options for solving a problem were known and finite. However, if the possible options were not either known or finite, then an obvious to try rationale cannot be used to support a conclusion of obviousness.	+
<i>Perfect Web Techs., Inc. v. InfoUSA, Inc.</i> , 587 F.3d 1324 (Fed. Cir. 2009).	Where there were a finite number of identified, predictable solutions and there is no evidence of unexpected results, an obvious to try inquiry may properly lead to a legal conclusion of obviousness. Common sense may be used to support a legal conclusion of obviousness so long as it is explained with sufficient reasoning.	-
Consideration of Evidence		
<i>PharmaStem Therapeutics, Inc. v. ViaCell, Inc.</i> , 491 F.3d 1342 (Fed. Cir. 2007).	Even though all evidence must be considered in an obviousness analysis, evidence of nonobviousness may be outweighed by contradictory evidence in the record or by what is in the specification. Although a reasonable expectation of success is needed to support a case of obviousness, absolute predictability is not required.	-
<i>In re Sullivan</i> , 498 F.3d 1345 (Fed. Cir. 2007).	All evidence, including evidence rebutting a <i>prima facie</i> case of obviousness, must be considered when properly presented.	+
<i>Hearing Components, Inc. v. Shure Inc.</i> , 600 F.3d 1357 (Fed. Cir. 2010).	Evidence that has been properly presented in a timely manner must be considered on the record. Evidence of commercial success is pertinent where a nexus between the success of the product and the claimed invention has been demonstrated.	+
<i>Aysst Techs., Inc. v. Entrak, Inc.</i> , 544 F.3d 1310 (Fed. Cir. 2008).	Evidence of secondary considerations of obviousness such as commercial success and long-felt need may be insufficient to overcome a <i>prima facie</i> case of obviousness if the <i>prima facie</i> case is strong. An argument for nonobviousness based on commercial success or long-felt need is undermined when there is a failure to link the commercial success or long-felt need to a claimed feature that distinguishes over the prior art.	-

¹ + = patent held nonobvious (or an obviousness finding vacated);

- = patent held obvious.

(8) Narrow woven ribbons comprised at least 85 percent by weight of threads having a denier of 225 or higher;

(9) Narrow woven ribbons constructed from pile fabrics (*i.e.*, fabrics with a surface effect formed by tufts or loops of yarn that stand up from the body of the fabric);

(10) Narrow woven ribbon affixed (including by tying) as a decorative detail to non-subject merchandise, such as a gift bag, gift box, gift tin, greeting card or plush toy, or affixed (including by tying) as a decorative detail to packaging containing non-subject merchandise;

(11) Narrow woven ribbon that is (a) affixed to non-subject merchandise as a working component of such non-subject merchandise, such as where narrow woven ribbon comprises an apparel trimming, book marker, bag cinch, or part of an identity card holder, or (b) affixed (including by tying) to non-subject merchandise as a working component that holds or packages such non-subject merchandise or attaches packaging or labeling to such non-subject merchandise, such as a "belly band" around a pair of pajamas, a pair of socks or a blanket;

(12) Narrow woven ribbon(s) comprising a belt attached to and imported with an item of wearing apparel, whether or not such belt is removable from such item of wearing apparel; and

(13) Narrow woven ribbon(s) included with non-subject merchandise in kits, such as a holiday ornament craft kit or a scrapbook kit, in which the individual lengths of narrow woven ribbon(s) included in the kit are each no greater than eight inches, the aggregate amount of narrow woven ribbon(s) included in the kit does not exceed 48 linear inches, none of the narrow woven ribbon(s) included in the kit is on a spool, and the narrow woven ribbon(s) is only one of multiple items included in the kit.

The merchandise subject to this order is classifiable under the HTSUS statistical categories 5806.32.1020; 5806.32.1030; 5806.32.1050 and 5806.32.1060. Subject merchandise also may enter under subheadings 5806.31.00; 5806.32.20; 5806.39.20; 5806.39.30; 5808.90.00; 5810.91.00; 5810.99.90; 5903.90.10; 5903.90.25; 5907.00.60; and 5907.00.80 and under statistical categories 5806.32.1080; 5810.92.9080; 5903.90.3090; and 6307.90.9889. The HTSUS statistical categories and subheadings are provided for convenience and customs purposes; however, the written description of the merchandise under the order is dispositive.

Countervailing Duty Order

According to section 706(b)(2) of the Act, duties shall be assessed on subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the ITC's notice of final determination if that determination is based upon the threat of material injury. Section 706(b)(1) of the Act states, "If the Commission, in its final determination under section 705(b), finds material injury or threat of material injury which, but for the suspension of liquidation under section 703(d)(2), would have led to a finding of material injury, then entries of the merchandise subject to the countervailing duty order, the liquidation of which has been suspended under section 703(d)(2), shall be subject to the imposition of countervailing duties under section 701(a)." In addition, section 706(b)(2) of the Act requires CBP to refund any cash deposits or bonds of estimated countervailing duties posted since the Department's preliminary countervailing duty determination, if the ITC's final determination is threat-based. Because the ITC's final determination in this case is based on the threat of material injury and is not accompanied by a finding that injury would have resulted but for the imposition of suspension of liquidation of entries since the Department's *Preliminary Determination*¹ was published in the **Federal Register**, section 706(b)(2) of the Act is applicable.

As a result of the ITC's determination, and in accordance with section 706(a)(1) of the Act, the Department will direct U.S. Customs and Border Protection ("CBP") to assess, upon further instruction by the Department, countervailing duties equal to the amount of the net countervailable subsidy for all relevant entries of narrow woven ribbons from the PRC. In accordance with section 706 of the Act, the Department will direct CBP to reinstitute suspension of liquidation² effective on the date of publication of the ITC's notice of final determination in the **Federal Register**, and to require a cash deposit for each entry of subject

¹ *Narrow Woven Ribbons With Woven Selvedge From the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Countervailing Duty Determination With Final Antidumping Duty Determination*, 74 FR 66090 (December 14, 2009).

² The Department instructed CBP to discontinue the suspension of liquidation on April 13, 2010, in accordance with section 703(d) of the Act. Section 703(d) states that the suspension of liquidation pursuant to a preliminary determination may not remain in effect for more than four months.

merchandise in an amount equal to the net countervailable subsidy rates noted below.

Exporter/manufacturer	Net subsidy rate
Yama Ribbons and Bows Co., Ltd	1.56
Changtai Rongshu Textile Co., Ltd	117.95
All Others	1.56

Termination of the Suspension of Liquidation

The Department will also instruct CBP to terminate the suspension of liquidation for entries of narrow woven ribbons from the PRC entered, or withdrawn from warehouse, for consumption prior to the publication of the ITC's notice of final determination, and refund any cash deposits made and release any bonds posted between December 14, 2009 (*i.e.*, the date of publication of the Department's *Preliminary Determination*) and the date of publication of the ITC's final determination in the **Federal Register**.

This notice constitutes the countervailing duty order with respect to narrow woven ribbons from the PRC, pursuant to section 706(a) of the Act. Interested parties may contact the Department's Central Records Unit, Room 1117 of the main Commerce Building, for copies of an updated list of countervailing duty orders currently in effect.

This order is issued and published in accordance with section 706(a) of the Act and 19 CFR 351.211(b).

Dated: August 30, 2010.

Ronald K. Lorentzen,
Deputy Assistant Secretary for Import Administration.

[FR Doc. 2010-21978 Filed 8-31-10; 8:45 am]

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DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No.: PTO-P-2010-0055]

Examination Guidelines Update: Developments in the Obviousness Inquiry After *KSR v. Teleflex*

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice.

SUMMARY: The United States Patent and Trademark Office (USPTO or Office) is issuing an update (*2010 KSR Guidelines Update*) to its obviousness guidelines for its personnel to be used when applying the law of obviousness under

35 U.S.C. 103. This *2010 KSR Guidelines Update* highlights case law developments on obviousness under 35 U.S.C. 103 since the 2007 decision by the United States Supreme Court (Supreme Court) in *KSR Int'l Co. v. Teleflex Inc.* These guidelines are intended to be used by Office personnel in conjunction with the guidance in the Manual of Patent Examining Procedure when applying the law of obviousness under 35 U.S.C. 103. Members of the public are invited to provide comments on the *2010 KSR Guidelines Update*. The Office is especially interested in receiving suggestions of recent decisional law in the field of obviousness that would have particular value as teaching tools.

DATES: *Effective Date:* This *2010 KSR Guidelines Update* is effective September 1, 2010.

ADDRESSES: Comments concerning this *2010 KSR Guidelines Update* may be sent by electronic mail message over the Internet addressed to KSR_Guidance@uspto.gov, or submitted by mail addressed to: Mail Stop Comments—Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313–1450. Although comments may be submitted by mail, the Office prefers to receive comments via the Internet.

FOR FURTHER INFORMATION CONTACT: Kathleen Kahler Fonda or Pinchus M. Laufer, Legal Advisors, Office of Patent Legal Administration, Office of the Associate Commissioner for Patent Examination Policy, by telephone at (571) 272–7754 or (571) 272–7726; by mail addressed to: Mail Stop Comments Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313–1450; or by facsimile transmission to (571) 273–7754, marked to the attention of Kathleen Kahler Fonda.

SUPPLEMENTARY INFORMATION:

1. *Introduction.* The purpose of this *2010 KSR Guidelines Update* is to remind Office personnel of the principles of obviousness explained by the Supreme Court in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) (*KSR*), and to provide additional guidance in view of decisions by the United States Court of Appeals for the Federal Circuit (Federal Circuit) since *KSR*. This body of case law developed over the past three years provides additional examples that will be useful to Office personnel as well as practitioners during the examination process. Although every question of obviousness must be decided on its own facts, these cases begin to clarify the contours of the obviousness inquiry after *KSR*, and help to show when a rejection on this basis is proper and when it is not.

This *2010 KSR Guidelines Update* does not constitute substantive rule making and hence does not have the force and effect of law. It has been developed as a matter of internal Office management and is not intended to create any right or benefit, substantive or procedural, enforceable by any party against the Office. Rejections will continue to be based upon the substantive law, and it is these rejections that are appealable. Consequently, any failure by Office personnel to follow this *2010 KSR Guidelines Update* is neither appealable nor petitionable.

After a review of the principles of obviousness and Office policy as reflected in the *Manual of Patent Examining Procedure* (MPEP), this *2010 KSR Guidelines Update* addresses a number of issues that arise when Office personnel consider whether or not a claimed invention is obvious. The concepts discussed are grounded in Federal Circuit cases, and correlated with existing Office policy as appropriate. A number of cases which have been selected for their instructional value on the issue of obviousness will be discussed in detail.

The law of obviousness will continue to be refined, and Office personnel are encouraged to maintain an awareness of precedential case law from the Federal Circuit and precedential decisions of the Board of Patent Appeals and Interferences (Board) in this area. The Office will train Office personnel and update the MPEP as necessary to reflect the current state of the law.

2. *Principles of Obviousness and the Guidelines.* In response to the Supreme Court's April 2007 decision in *KSR*, the Office developed guidelines for patent examiners to follow when determining obviousness of a claimed invention and published these guidelines in the **Federal Register** and Official Gazette. See *Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc.*, 72 FR 57526 (Oct. 10, 2007), 1324 *Off. Gaz. Pat. Office* 23 (Nov. 6, 2007) (*2007 KSR Guidelines*). The *2007 KSR Guidelines* have been incorporated in the MPEP. See MPEP § 2141 (8th ed. 2001) (Rev. 6, Sept. 2007). The purpose of the *2007 KSR Guidelines* was to give Office personnel practical guidance on how to evaluate obviousness issues under 35 U.S.C. 103(a) in accordance with the Supreme Court's instruction in *KSR*. The *2007 KSR Guidelines* also alerted Office personnel to the importance of considering rebuttal evidence submitted

by patent applicants in response to obviousness rejections.

The *2007 KSR Guidelines* pointed out, as had the Supreme Court in *KSR*, that the factual inquiries announced in *Graham v. John Deere*, 383 U.S. 1, 17–18 (1966) (scope and content of the prior art; differences between the claimed invention and the prior art; level of ordinary skill in the art; and secondary indicia of nonobviousness), remain the foundation of any determination of obviousness. It remains true that “[t]he determination of obviousness is dependent on the facts of each case.” *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1089 (Fed. Cir. 2008) (citing *Graham*, 383 U.S. at 17–18 (1966)). As for the reasoning required to support an obviousness determination, the *2007 KSR Guidelines* noted that the teaching-suggestion-motivation (TSM) test was but one possible approach. The *2007 KSR Guidelines* identified six other rationales gleaned from the *KSR* decision as examples of appropriate lines of reasoning that could also be used. The six other rationales identified in the *2007 KSR Guidelines* are: (1) Combining prior art elements according to known methods to yield predictable results; (2) simple substitution of one known element for another to obtain predictable results; (3) use of a known technique to improve similar devices, methods, or products in the same way; (4) applying a known technique to a known device, method, or product ready for improvement to yield predictable results; (5) obvious to try—choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and (6) 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. 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 in the *2007 KSR Guidelines*, they are to adhere to the instructions provided in the MPEP regarding the necessary factual findings. However, the *2007 KSR Guidelines* also stressed that while the *Graham* inquiries and the associated reasoning are crucial to a proper obviousness determination, the Supreme Court in *KSR* did not place any limit on the particular approach to be taken to formulate the line of reasoning.

In other words, the *KSR* decision is not to be seen as replacing a single test for obviousness—the TSM test—with the seven rationales listed in the *2007 KSR Guidelines*. See MPEP §§ 2141 and 2143 (8th ed. 2001) (Rev. 8, July 2010) (references to the MPEP are to Revision 8 of the 8th Edition of the MPEP unless otherwise indicated). It remains Office policy that appropriate factual findings are required in order to apply the enumerated rationales properly. If a rejection has been made that omits one of the required factual findings, and in response to the rejection a practitioner or inventor points out the omission, Office personnel must either withdraw the rejection, or repeat the rejection including all required factual findings.

3. *The Impact of the KSR Decision.* *KSR*'s renewed emphasis on the foundational principles of *Graham* coupled with its abrogation of the strict TSM test have clearly impacted the manner in which Office personnel and practitioners carry out the business of prosecuting patent applications with regard to issues of obviousness. However, Office personnel as well as practitioners should also recognize the significant extent to which the obviousness inquiry has remained constant in the aftermath of *KSR*.

In footnote 2 of the *2007 KSR Guidelines*, the Office acknowledged that ongoing developments in the law of obviousness were to be expected in the wake of the *KSR* decision. That footnote also stated that it was “not clear which Federal Circuit decisions will retain their viability” after *KSR*. See *2007 KSR Guidelines*, 72 FR at 57,528 n.2. The edition of the MPEP that was current when the *KSR* decision was handed down had made the following statement in § 2144:

The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law.

MPEP § 2144 (8th ed. 2001) (Rev. 5, Aug. 2006) (citing five pre-*KSR* Federal Circuit opinions and two decisions of the Board). The *KSR* decision has reinforced those earlier decisions that validated a more flexible approach to providing reasons for obviousness. However, the Supreme Court's pronouncement in *KSR* has at the same time clearly undermined the continued viability of cases such as *In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002), insofar as *Lee* appears to require a strict basis in record evidence as a reason to modify the prior art.

The Supreme Court's flexible approach to the obviousness inquiry is reflected in numerous pre-*KSR* decisions, as can be seen in a review of MPEP § 2144. This 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 a part of the patent examination process. See MPEP § 2144.

Although the *KSR* approach is flexible with regard to the line of reasoning to be applied, the *2007 KSR Guidelines* and MPEP § 2143 state: “The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.” MPEP § 2143. In *Ball Aerosol v. Limited Brands*, 555 F.3d 984 (Fed. Cir. 2009), the Federal Circuit offered additional instruction as to the need for an explicit analysis. The Federal Circuit explained, as is consistent with the *2007 KSR Guidelines*, 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. 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 time of the invention. This requirement for explanation remains even in situations in which Office personnel may properly rely on intangible realities such as common sense and ordinary ingenuity.

When considering obviousness, Office personnel are cautioned against treating any line of reasoning as a *per se* rule. MPEP § 2144 discusses supporting a rejection under 35 U.S.C. 103 by reliance on scientific theory and legal precedent. In keeping with the flexible

approach and the requirement for explanation, Office personnel may invoke legal precedent as a source of supporting rationale when warranted and appropriately supported. See MPEP § 2144.04. So, for example, automating a manual activity, making portable, making separable, reversal or duplication of parts, or purifying an old product may form the basis of a rejection. However, such rationales should not be treated as *per se* rules, but rather must be explained and shown to apply to the facts at hand. A similar caveat applies to any obviousness analysis. Simply stating the principle (e.g., “art recognized equivalent,” “structural similarity”) without providing an explanation of its applicability to the facts of the case at hand is generally not sufficient to establish a *prima facie* case of obviousness.

Many basic approaches that a practitioner may use to demonstrate nonobviousness also continue to apply in the post-*KSR* era. Since it is now clear that a strict TSM approach is not the only way to establish a *prima facie* case of obviousness, it is true that practitioners have been required to shift the emphasis of their nonobviousness arguments to a certain degree. However, familiar lines of argument still apply, including teaching away from the claimed invention by the prior art, lack of a reasonable expectation of success, and unexpected results. Indeed, they may have even taken on added importance in view of the recognition in *KSR* of a variety of possible rationales.

At the time the *KSR* decision was handed down, some observers questioned whether the principles discussed were intended by the Supreme Court to apply to all fields of inventive endeavor. Arguments were made that because the technology at issue in *KSR* involved the relatively well-developed and predictable field of vehicle pedal assemblies, the decision was relevant only to such fields. The Federal Circuit has soundly repudiated such a notion, stating that *KSR* applies across technologies:

This court also declines to cabin *KSR* to the “predictable arts” (as opposed to the “unpredictable art” of biotechnology). In fact, this record shows that one of skill in this advanced art would find these claimed “results” profoundly “predictable.”

In re Kubin, 561 F.3d 1351, 1360 (Fed. Cir. 2009). Thus, Office personnel should not withdraw any rejection solely on the basis that the invention lies in a technological area ordinarily considered to be unpredictable.

The decisions of the Federal Circuit discussed in this *2010 KSR Guidelines*

Update provide Office personnel as well as practitioners with additional examples of the law of obviousness. The purpose of the 2007 KSR Guidelines was, as stated above, to help Office personnel to determine when a claimed invention is not obvious, and to provide an appropriate supporting rationale when an obviousness rejection is appropriate. Now that a body of case law is available to guide Office personnel and practitioners as to the boundaries between obviousness and nonobviousness, it is possible in this 2010 KSR Guidelines Update to contrast situations in which the subject matter was found to have been obvious with those in which it was determined not to have been obvious. Thus, Office personnel may use this 2010 KSR Guidelines Update in conjunction with the 2007 KSR Guidelines (incorporated into MPEP §§ 2141 and 2143) to provide a more complete view of the state of the law of obviousness.

This 2010 KSR Guidelines Update provides a “teaching point” for each discussed case. The “teaching point” may be used to quickly determine the relevance of the discussed case, but should not be used as a substitute for reading the remainder of the discussion of the case in this 2010 KSR Guidelines Update. Nor should any case in this 2010 KSR Guidelines Update be applied or cited in an Office action solely on the basis of what is stated in the “teaching point” for the case.

4. *Obviousness Examples from Federal Circuit Cases.* The impact of the Supreme Court’s decision in *KSR* can be more readily understood in the context of factual scenarios. The cases in this 2010 KSR Guidelines Update are broadly grouped according to obviousness concepts in order to provide persons involved with patent prosecution with ready access to the examples that are most pertinent to the issue at hand. The first three groups correspond directly with three of the rationales identified in the 2007 KSR Guidelines. These rationales—combining prior art elements, substituting one known element for another, and obvious to try—have each been the subject of a significant number of post-*KSR* obviousness decisions. The fourth group focuses on issues concerning consideration of evidence during prosecution. Office personnel as well as practitioners are reminded of the technology-specific obviousness examples previously posted on the Office’s Web site at http://www.uspto.gov/web/offices/pac/dapp/opla/ksr/ksr_training_materials.htm.

Although the other rationales discussed in the 2007 KSR Guidelines

are not the focus of separate discussions in this 2010 KSR Guidelines Update, it will be noted that obviousness concepts such as applying known techniques, design choice, and market forces are addressed when they arise in the selected cases. The cases included in this 2010 KSR Guidelines Update reinforce the idea, presented in the 2007 KSR Guidelines, that there may be more than one line of reasoning that can properly be applied to a particular factual scenario. The selected decisions also illustrate the overlapping nature of the lines of reasoning that may be employed to establish a *prima facie* case of obviousness. Although the 2007 KSR Guidelines presented the rationales as discrete, self-contained lines of reasoning, and they may indeed be employed that way, it is useful to recognize that real-world situations may require analyses that may not be so readily pigeon-holed into distinct categories.

A. *Combining Prior Art Elements.* In discussing the obviousness rationale concerning combining prior art elements, identified as Rationale A, the 2007 KSR Guidelines quoted *KSR* and noted that “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *KSR*, 550 U.S. at 401. In view of the cases decided since *KSR*, one situation when it is important to identify a reason to combine known elements in a known manner to obtain predictable results is when the combination requires a greater expenditure of time, effort, or resources than the prior art teachings. Even though the components are known, the combining step is technically feasible, and the result is predictable, the claimed invention may nevertheless be nonobvious when the combining step involves such additional effort that no one of ordinary skill would have undertaken it without a recognized reason to do so. When a combination invention involves additional complexity as compared with the prior art, the invention may be nonobvious unless an examiner can articulate a reason for including the added features or steps. This is so even when the claimed invention could have been readily implemented.

Example 4.1. In re Omeprazole Patent Litigation, 536 F.3d 1361 (Fed. Cir. 2008). *Teaching point:* Even where a general method that could have been applied to make the claimed product was known and within the level of skill of the ordinary artisan, the claim may nevertheless be nonobvious if the

problem which had suggested use of the method had been previously unknown.

The case of *In re Omeprazole Patent Litigation* 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 skill in the art likely would have chosen a different modification even if he or she 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 4.2. Crocs, Inc. v. U.S. International Trade Commission, 598 F.3d 1294 (Fed. Cir. 2010). *Teaching point*: A claimed combination of prior art elements may be nonobvious where the prior art teaches away from the claimed combination and the combination yields more than predictable results.

The case of *Crocs, Inc. v. U.S. International Trade Commission* 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.

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. 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 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 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 4.3. Sundance, Inc. v. DeMonte Fabricating Ltd., 550 F.3d 1356 (Fed. Cir. 2008). *Teaching point*: A claimed invention is likely to be obvious if it is a combination of known prior art elements that would reasonably have been expected to maintain their respective properties or functions after they have been combined.

Sundance 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 4.4. Ecolab, Inc. v. FMC Corp., 569 F.3d 1335 (Fed. Cir. 2009).

Teaching point: A combination of known elements would have been *prima facie* obvious if an ordinarily skilled artisan would have recognized an apparent reason to combine those elements and would have known how to do so.

In the case of *Ecolab, Inc. v. FMC Corp.*, 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. 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 4.5. Wyers v. Master Lock Co., No. 2009–1412, —F.3d—, 2010 WL 2901839 (Fed. Cir. July 22, 2010).

Teaching point: The scope of analogous art is to be construed broadly and includes references that are reasonably pertinent to the problem that the inventor was trying to solve. Common sense may be used to support a legal conclusion of obviousness so long as it is explained with sufficient reasoning.

In the case of *Wyers v. Master Lock Co.*, 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.” *Wyers*, slip. op. at 12. 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.” *Wyers*, slip. op. at 13 (quoting *KSR*, 550 U.S. at 415 and 421). 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 15 (citing *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1329 (Fed. Cir. 2009); *Ball Aerosol*, 555 F.3d at 993).

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. As stated in the MPEP:

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.”

MPEP § 2141 III. Office personnel should continue to provide a reasoned explanation for every obviousness rejection.

Example 4.6. DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 567 F.3d 1314 (Fed. Cir. 2009). *Teaching point:* Predictability as discussed in *KSR* encompasses the expectation that prior art elements are capable of being combined, as well as the expectation that the combination would have worked for its intended purpose. An inference that a claimed combination would not have been obvious is especially strong where the prior art’s teachings undermine the very reason being proffered as to why a person of ordinary skill would have combined the known elements.

The claim in *DePuy Spine* 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. Substituting One Known Element for Another. As explained in the 2007 *KSR Guidelines*, the substitution rationale applies when the claimed invention can be viewed as resulting from substituting a known element for an element of a prior art invention. The rationale applies when one of ordinary skill in the art would have been technologically capable of making the substitution, and the result obtained would have been predictable. See MPEP § 2143(B).

Example 4.7. In re ICON Health & Fitness, Inc., 496 F.3d 1374 (Fed. Cir. 2007). *Teaching point:* When determining whether a reference in a different field of endeavor may be used to support a case of obviousness (*i.e.*, is analogous), it is necessary to consider the problem to be solved.

The claimed invention in *ICON* 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 comes from 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.

Other evidence was considered concerning 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 the 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 “treadmill” concept was too narrow a lens through which to view the art in light of the prior art teachings concerning the problem to be solved. The Teague reference was analogous art because “Teague and the current application both address the need to stably retain a folding mechanism,” *id.* at 1378, and because “nothing about *ICON*’s folding mechanism requires any particular focus on treadmills,” *id.* at 1380.

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.

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.

Example 4.8. *Agrizap, Inc. v. Woodstream Corp.*, 520 F.3d 1337 (Fed. Cir. 2008). *Teaching point:* Analogous art is not limited to references in the field of endeavor of the invention, but also includes references that would have been recognized by those of ordinary skill in the art as useful for applicant’s purpose.

Agrizap 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. 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 applicant’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 4.9. *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318 (Fed. Cir. 2008). *Teaching point:* Because Internet and Web browser technologies had become commonplace for communicating and displaying information, it would have been obvious to adapt existing processes to incorporate them for those functions.

The invention at issue in *Muniauction* 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 Enterprises, Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157 (Fed. Cir. 2007), cited in the *2007 KSR Guidelines*. 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 had 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 4.10. *Aventis Pharma Deutschland v. Lupin Ltd.*, 499 F.3d 1293 (Fed. Cir. 2007). *Teaching point:* A chemical compound would have been obvious over a mixture containing that compound as well as other compounds where it was known or the skilled artisan had reason to believe that some desirable property of the mixture was derived in whole or in part from the claimed compound, and separating the claimed compound from the mixture was routine in the art.

In *Aventis*, 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*. 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. 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 4.11. Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd., 533 F.3d 1353 (Fed. Cir. 2008). *Teaching point:* A claimed compound would not have been obvious where there was no reason to modify the closest prior art lead compound to obtain the claimed

compound and the prior art taught that modifying the lead compound would destroy its advantageous property. Any known compound may serve as a lead compound when there is some reason for starting with that lead compound and modifying it to obtain the claimed compound.

Eisai 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 sufficient 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, *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S.Ct. 1727, 1739, 167 L.Ed.2d 705 (2007), the requisite motivation can come from any number of sources and need not necessarily be explicit in the art. See *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1301 (Fed. Cir. 2007). 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.* (quoting *Dillon*, 919 F.2d at 692).

Eisai, 533 F.3d at 1357. 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; http://www.combichemistry.com/glossary_k.html, accessed January 13, 2010; and <http://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. 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 lead compound other than the mere fact that the “lead compound” merely exists. See *Altana Pharma AG v. Teva Pharmaceuticals USA, Inc.*, 566 F.3d 999, 1007 (Fed. Cir. 2009) (holding that there must be some reason “to select and modify a known compound”); *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Labs, Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008).

Example 4.12. Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc., 566 F.3d 989 (Fed. Cir. 2009). *Teaching point:* It is not necessary to select a single compound as a “lead compound” in order to support an obviousness rejection. However, where there was reason to select and modify the lead compound to obtain the claimed compound, but no reasonable expectation of success, the claimed compound would not have been obvious.

A chemical compound was also found to be nonobvious in *Procter & Gamble*. 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 stated 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, and that the superior properties were unexpected and could not be predicted. 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, 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 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 4.13. Altana Pharma AG v. Teva Pharmaceuticals USA, Inc., 566 F.3d 999 (Fed. Cir. 2009). *Teaching point:* 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 a prior art lead compound in a particular way to produce the claimed compound. It is not necessary for the reasoning to be explicitly found in the prior art of record, nor is it necessary for the prior art to point to only a single lead compound.

Although the decision reached by the Federal Circuit in *Altana* involved a motion for preliminary injunction and did not include a final determination of obviousness, the case is nevertheless 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.

C. *The "Obvious to Try" Rationale.* 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 2007 *KSR Guidelines* explain, in view of the Supreme Court's instruction, that this rationale is only appropriate when there is a recognized problem or need in the art; there are a finite number of identified, predictable solutions to the recognized need or problem; and one of ordinary skill in the art could have pursued these known potential solutions with a reasonable expectation of success. 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.

In a recent Federal Circuit decision, the court 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 (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 4.14. In re Kubin, 561 F.3d 1351 (Fed. Cir. 2009). *Teaching point:* A claimed polynucleotide would have been obvious over the known protein

that it encodes where the skilled artisan would have had a reasonable expectation of success in deriving the claimed polynucleotide using standard biochemical techniques, and the skilled artisan would have had a reason to try to isolate the claimed polynucleotide. *KSR* applies to all technologies, rather than just the "predictable" arts.

The Federal Circuit's decision in *In re Kubin* was an affirmation of the Board's decision in *Ex parte Kubin*, 83 USPQ2d 1410 (Bd. Pat. App. & Interf. 2007), and the Board in turn had affirmed the examiner's determination that the claims in question would have been obvious over the prior art applied. A discussion of *Ex parte Kubin* was included in the 2007 *KSR Guidelines*. See 2007 *KSR Guidelines*, 72 FR at 57532. The claimed invention in *Kubin* was an isolated nucleic acid molecule. 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 (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." 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.” 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. 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. 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 *O’Farrell*, 853 F.2d at 903).

Example 4.15. *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007). **Teaching point:** A claimed compound would not have been obvious where it was not obvious to try to obtain it from a broad range of compounds, any one of which could have been selected as the lead compound for further investigation, and the prior art taught away from using a particular lead compound, and there was no predictability or reasonable expectation of success in making the particular modifications necessary to transform the lead compound into the claimed compound.

Takeda is an example of a chemical case in which the Federal Circuit found that the claim 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 had 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*, 127 S.Ct. at 1732. 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.

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 predictability or 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 4.16. *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Labs, Inc.*, 520 F.3d 1358 (Fed. Cir. 2008). **Teaching point:** Where the claimed anti-convulsant drug had been discovered somewhat serendipitously in the course of research aimed at finding a new anti-diabetic drug, it would not have been obvious to try to obtain a claimed compound where the prior art did not present a finite and easily traversed number of potential starting compounds, and there was no apparent reason for selecting a particular starting compound from among a number of unpredictable alternatives.

The *Ortho-McNeil* case 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. As in *DePuy Spine*, whether the combination would predictably be effective for its intended purpose is part of the obviousness analysis.

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 why 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. 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 4.17. Bayer Schering Pharma A.G. v. Barr Labs., Inc., 575 F.3d 1341 (Fed. Cir. 2009). *Teaching point:* A claimed compound would have been obvious where it was obvious to try to obtain it from a finite and easily traversed number of options that was narrowed down from a larger set of possibilities by the prior art, and the outcome of obtaining the claimed compound was reasonably predictable.

In *Bayer* 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 4.18. Sanofi-Synthelabo v. Apotex, Inc., 550 F.3d 1075 (Fed. Cir. 2008). *Teaching point:* A claimed isolated stereoisomer would not have been obvious where the claimed stereoisomer exhibits unexpectedly strong therapeutic advantages over the prior art racemic mixture without the correspondingly expected toxicity, and the resulting properties of the enantiomers separated from the racemic mixture were unpredictable.

The case of *Sanofi* 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 4.19. Rolls-Royce, PLC v. United Technologies Corp., 603 F.3d 1325 (Fed. Cir. 2010). *Teaching point:* An obvious to try rationale may be proper when the possible options for solving a problem were known and finite. However, if the possible options were not either known or finite, then an obvious to try rationale cannot be used to support a conclusion of obviousness.

In *Rolls-Royce* 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.

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, citing *Abbott*, 544 F.3d at 1351. In this case, there had been no suggestion in the prior art that 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." *Rolls-Royce*, 603 F.3d at 1339. 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 4.20. Perfect Web Technologies, Inc. v. InfoUSA, Inc., 587 F.3d 1324, 1328–29 (Fed. Cir. 2009). *Teaching point:* Where there were a finite number of identified, predictable solutions and there is no evidence of unexpected results, an obvious to try inquiry may properly lead to a legal conclusion of obviousness. Common sense may be used to support a legal conclusion of obviousness so long as it is explained with sufficient reasoning.

The *Perfect Web* case provides an example in which the Federal Circuit held that a claimed method for managing bulk e-mail distribution was obvious on the basis of an obvious to try argument. In *Perfect Web*, the method required selecting the intended recipients, transmitting the e-mails, determining how many of the e-mails had been successfully received, and repeating the first three steps if a predetermined minimum number of intended recipients had not received the e-mail.

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 e-mail recipients was a recognized problem in the field of e-mail marketing. The prior

art had also recognized three potential solutions: Increasing the size of the initial recipient list; resending e-mails to recipients who did not receive them on the first attempt; and selecting a new recipient list and sending e-mails 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 e-mail 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 (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 (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 (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 (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 (Fed. Cir. 2006), and *In re Kahn*, 441 F.3d 977 (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.

5. *Federal Circuit Cases Discussing Consideration of Evidence.* Office personnel should consider all rebuttal evidence that is timely presented by the applicants when reevaluating any obviousness determination. In the case of a claim rendered obvious by a combination of prior art references, applicants may submit evidence or argument to demonstrate that the results of the claimed combination were unexpected.

Another area that has thus far remained consistent with pre-*KSR* precedent is the consideration of rebuttal evidence and secondary considerations in the determination of obviousness. As reflected in the MPEP, such evidence should not be considered simply for its “knockdown” value; rather, all evidence must be reweighed to determine whether the claims are nonobvious.

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.*, 90 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.

MPEP § 2141.

Office personnel should not evaluate rebuttal evidence for its “knockdown” value against the *prima facie* case, *Piasecki*, 745 F.2d at 1473, 223 USPQ at 788, or summarily dismiss it as not compelling or insufficient. If the evidence is deemed insufficient to

rebut the *prima facie* case of obviousness, Office personnel should specifically set forth the facts and reasoning that justify this conclusion.

MPEP § 2145. The following cases exemplify the continued application of these principles both at the Federal Circuit and within the Office. Note that these principles were at issue in some of the cases previously discussed, and have been addressed there in a more cursory fashion.

Example 5.1. PharmaStem Therapeutics, Inc. v. Viacell, Inc., 491 F.3d 1342 (Fed. Cir. 2007). *Teaching point:* Even though all evidence must be considered in an obviousness analysis, evidence of nonobviousness may be outweighed by contradictory evidence in the record or by what is in the specification. Although a reasonable expectation of success is needed to support a case of obviousness, absolute predictability is not required.

The claims at issue in *PharmaStem* were directed to compositions comprising hematopoietic stem cells from umbilical cord or placental blood, and to methods of using such compositions for treatment of blood and immune system disorders. The composition claims required that the stem cells be present in an amount sufficient to effect hematopoietic reconstitution when administered to a human adult. The trial court had found that *PharmaStem*’s patents were infringed and not invalid on obviousness or other grounds. On appeal, the Federal Circuit reversed the district court, determining that the claims were invalid for obviousness.

The Federal Circuit discussed the evidence presented at trial. It pointed out that the patentee, *PharmaStem*, had not invented an entirely new procedure or new composition. Rather, *PharmaStem*’s own specification acknowledged that it was already known in the prior art that umbilical cord and placental blood-based compositions contained hematopoietic stem cells, and that hematopoietic stem cells were useful for the purpose of hematopoietic reconstitution. *PharmaStem*’s contribution was to provide experimental proof that umbilical cord and placental blood could be used to effect hematopoietic reconstitution in mice. By extrapolation, one of ordinary skill in the art would have expected this reconstitution method to work in humans as well.

The court rejected *PharmaStem*’s expert testimony that hematopoietic stem cells had not been proved to exist in cord blood prior to the experiments described in *PharmaStem*’s patents. The court explained that the expert

testimony was contrary to the inventors’ admissions in the specification, as well as prior art teachings that disclosed stem cells in cord blood. In this case, *PharmaStem*’s evidence of nonobviousness was outweighed by contradictory evidence.

Despite *PharmaStem*’s useful experimental validation of hematopoietic reconstitution using hematopoietic stem cells from umbilical cord and placental blood, the Federal Circuit found that the claims at issue would have been obvious. There had been ample suggestion in the prior art that the claimed method would have worked. Absolute predictability is not a necessary prerequisite to a case of obviousness. Rather, a degree of predictability that one of ordinary skill would have found to be reasonable is sufficient. The Federal Circuit concluded that “[g]ood science and useful contributions do not necessarily result in patentability.” *Id.* at 1364.

Example 5.2. In re Sullivan, 498 F.3d 1345 (Fed. Cir. 2007). *Teaching point:* All evidence, including evidence rebutting a *prima facie* case of obviousness, must be considered when properly presented.

It was found to be an error in *Sullivan* for the Board to fail to consider evidence submitted to rebut a *prima facie* case of obviousness.

The claimed invention was directed to an antivenom composition comprising F(ab) fragments used to treat venomous rattlesnake bites. The composition was created from antibody molecules that include three fragments, F(ab)₂, F(ab) and F(c), which have separate properties and utilities. There have been commercially available antivenom products that consisted of whole antibodies and F(ab)₂ fragments, but researchers had not experimented with antivenoms containing only F(ab) fragments because it was believed that their unique properties would prevent them from decreasing the toxicity of snake venom. The inventor, *Sullivan*, discovered that F(ab) fragments are effective at neutralizing the lethality of rattlesnake venom, while reducing the occurrence of adverse immune reactions in humans. On appeal of the examiner’s rejection, the Board held that the claim was obvious because all the elements of the claimed composition were accounted for in the prior art, and that the composition taught by that prior art would have been expected by a person of ordinary skill in the art at the time the invention was made to neutralize the lethality of the venom of a rattlesnake.

Rebuttal evidence had not been considered by the Board because it

considered the evidence to relate to the intended use of the claimed composition as an antivenom, rather than the composition itself. Appellant successfully argued that even if the Board had shown a *prima facie* case of obviousness, the extensive rebuttal evidence must be considered. The evidence included three expert declarations submitted to show that the prior art taught away from the claimed invention, an unexpected property or result from the use of F(ab) fragment antivenom, and why those having ordinary skill in the art expected antivenoms comprising F(ab) fragments to fail. The declarations related to more than the use of the claimed composition. While a statement of intended use may not render a known composition patentable, the claimed composition was not known, and whether it would have been obvious depends upon consideration of the rebuttal evidence. Appellant did not concede that the only distinguishing factor of its composition is the statement of intended use and extensively argued that its claimed composition exhibits the unexpected property of neutralizing the lethality of rattlesnake venom while reducing the occurrence of adverse immune reactions in humans. The Federal Circuit found that such a use and unexpected property cannot be ignored—the unexpected property is relevant and thus the declarations describing it should have been considered.

Nonobviousness can be shown when a person of ordinary skill in the art would not have reasonably predicted the claimed invention based on the prior art, and the resulting invention would not have been expected. All evidence must be considered when properly presented.

Example 5.3. Hearing Components, Inc. v. Shure Inc., 600 F.3d 1357 (Fed. Cir. 2010). *Teaching point:* Evidence that has been properly presented in a timely manner must be considered on the record. Evidence of commercial success is pertinent where a nexus between the success of the product and the claimed invention has been demonstrated.

The case of *Hearing Components* involved a disposable protective covering for the portion of a hearing aid that is inserted into the ear canal. The covering was such that it could be readily replaced by a user as needed.

At the district court, Shure had argued that Hearing Components' patents were obvious over one or more of three different combinations of prior art references. The jury disagreed, and determined that the claims were

nonobvious. The district court upheld the jury verdict, stating that in view of the conflicting evidence presented by the parties as to the teachings of the references, motivation to combine, and secondary considerations, the nonobviousness verdict was sufficiently grounded in the evidence.

Shure appealed to the Federal Circuit, but the Federal Circuit agreed with the district court that the jury's nonobviousness verdict had been supported by substantial evidence. Although Shure had argued before the jury that the Carlisle reference taught an ear piece positioned inside the ear canal, Hearing Components' credible witness countered that only the molded duct and not the ear piece itself was taught by Carlisle as being inside the ear canal. On the issue of combining references, Shure's witness had given testimony described as "rather sparse, and lacking in specific details." *Id.* at 1364. In contradistinction, Hearing Components' witness "described particular reasons why one skilled in the art would not have been motivated to combine the references." *Id.* Finally, as to secondary considerations, the Federal Circuit determined that Hearing Components had shown a nexus between the commercial success of its product and the patent by providing evidence that "the licensing fee for a covered product was more than cut in half immediately upon expiration" of the patent.

Although the *Hearing Components* case involves substantial evidence of nonobviousness in a jury verdict, it is nevertheless instructive for Office personnel on the matter of weighing evidence. Office personnel routinely must consider evidence in the form of prior art references, statements in the specification, or declarations under 37 CFR 1.131 or 1.132. Other forms of evidence may also be presented during prosecution. Office personnel are reminded that evidence that has been presented in a timely manner should not be ignored, but rather should be considered on the record. However, not all evidence need be accorded the same weight. In determining the relative weight to accord to rebuttal evidence, considerations such as whether a nexus exists between the claimed invention and the proffered evidence, and whether the evidence is commensurate in scope with the claimed invention, are appropriate. The mere presence of some credible rebuttal evidence does not dictate that an obviousness rejection must always be withdrawn. *See* MPEP § 2145. Office personnel must consider the appropriate weight to be accorded to each piece of evidence. An obviousness

rejection should be made or maintained only if evidence of obviousness outweighs evidence of nonobviousness. *See* MPEP § 706(I) ("The standard to be applied in all cases is the 'preponderance of the evidence' test. In other words, an examiner should reject a claim if, in view of the prior art and evidence of record, it is more likely than not that the claim is unpatentable."). MPEP § 716.01(d) provides further guidance on weighing evidence in making a determination of patentability.

Example 5.4. Asyst Techs., Inc. v. Emtrak, Inc., 544 F.3d 1310 (Fed. Cir. 2008). *Teaching point:* Evidence of secondary considerations of obviousness such as commercial success and long-felt need may be insufficient to overcome a *prima facie* case of obviousness if the *prima facie* case is strong. An argument for nonobviousness based on commercial success or long-felt need is undermined when there is a failure to link the commercial success or long-felt need to a claimed feature that distinguishes over the prior art.

The claims at issue in *Asyst* concerned a processing system for tracking articles such as silicon wafers which move from one processing station to the next in a manufacturing facility. The claims required that each processing station be in communication with a central control unit. The Federal Circuit agreed with the district court that the only difference between the claimed invention and the prior art to Hesser was that the prior art had taught the use of a bus for this communication, while the claims required a multiplexer. At trial, the jury had concluded that Hesser was not relevant prior art, but the district court overturned that conclusion and issued a judgment as a matter of law (JMOL) that the claims would have been obvious in view of Hesser. Because the evidence showed that persons of ordinary skill in the art would have been familiar with both the bus and the multiplexer, and that they could have readily selected and employed one or the other based on known considerations, the Federal Circuit affirmed the district court's conclusion that the claims were invalid for obviousness.

The Federal Circuit also discussed arguments that the district court had failed to consider the objective evidence of nonobviousness presented by *Asyst*. *Asyst* had offered evidence of commercial success of its invention. However, the Federal Circuit pointed out that *Asyst* had not provided the required nexus between the commercial success and the claimed invention, emphasizing that "*Asyst's* failure to link that commercial success to the features

of its invention that were not disclosed in Hesser undermines the probative force of the evidence * * *.” *Id.* at 1316. Asyst had also offered evidence from others in the field praising the invention as addressing a long-felt need. Once again, the Federal Circuit found the argument to be unavailing in view of the prior art, stating that “[w]hile the evidence shows that the overall system drew praise as a solution to a felt need, there was no evidence that the success * * * was attributable to the substitution of a multiplexer for a bus, which was the only material difference between Hesser and the patented invention.” *Id.* The Federal Circuit also reiterated, citing pre-*KSR* decisions, that “as we have often held, evidence of secondary considerations does not always overcome a strong *prima facie* showing of obviousness.” *Id.* (citing

Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1372 (Fed. Cir. 2007); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 719–20 (Fed. Cir. 1991); *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988)).

When considering obviousness, Office personnel should carefully weigh any properly presented objective evidence of nonobviousness against the strength of the *prima facie* case. If the asserted evidence, such as commercial success or satisfaction of a long-felt need, is attributable to features already in the prior art, the probative value of the evidence is reduced.

6. *Conclusion.* This 2010 *KSR Guidelines Update* is intended to be used by Office personnel in conjunction with the guidance provided in MPEP §§ 2141 and 2143 (which incorporates the 2007 *KSR Guidelines*) to clarify the contours of obviousness after *KSR*. It

addresses a number of issues that arise when Office personnel consider whether or not a claimed invention is obvious. While Office personnel are encouraged to make use of these tools, they are reminded that every question of obviousness must be decided on its own facts. The Office will continue to monitor the developing law of obviousness, and will provide additional guidance and updates as necessary.

Dated: August 20, 2010.

David J. Kappos,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

Appendix

The following table contains the cases set out as examples in this 2010 *KSR Guidelines Update* and the teaching points of the case.

Case	Teaching point
Combining Prior Art Elements	
<i>In re Omeprazole Patent Litigation</i> , 536 F.3d 1361 (Fed. Cir. 2008).	Even where a general method that could have been applied to make the claimed product was known and within the level of skill of the ordinary artisan, the claim may nevertheless be nonobvious if the problem which had suggested use of the method had been previously unknown.
<i>Crocs, Inc. v. U.S. Int'l Trade Comm'n.</i> , 598 F.3d 1294 (Fed. Cir. 2010).	A claimed combination of prior art elements may be nonobvious where the prior art teaches away from the claimed combination and the combination yields more than predictable results.
<i>Sundance, Inc. v. DeMonte Fabricating Ltd.</i> , 550 F.3d 1356 (Fed. Cir. 2008).	A claimed invention is likely to be obvious if it is a combination of known prior art elements that would reasonably have been expected to maintain their respective properties or functions after they have been combined.
<i>Ecolab, Inc. v. FMC Corp.</i> , 569 F.3d 1335 (Fed. Cir. 2009).	A combination of known elements would have been <i>prima facie</i> obvious if an ordinarily skilled artisan would have recognized an apparent reason to combine those elements and would have known how to do so.
<i>Wyers v. Master Lock Co.</i> , No. 2009–1412, —F.3d—, 2010 WL 2901839 (Fed. Cir. July 22, 2010).	The scope of analogous art is to be construed broadly and includes references that are reasonably pertinent to the problem that the inventor was trying to solve. Common sense may be used to support a legal conclusion of obviousness so long as it is explained with sufficient reasoning.
<i>DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.</i> , 567 F.3d 1314 (Fed. Cir. 2009).	Predictability as discussed in <i>KSR</i> encompasses the expectation that prior art elements are capable of being combined, as well as the expectation that the combination would have worked for its intended purpose. An inference that a claimed combination would not have been obvious is especially strong where the prior art's teachings undermine the very reason being proffered as to why a person of ordinary skill would have combined the known elements.
Substituting One Known Element for Another	
<i>In re ICON Health & Fitness, Inc.</i> , 496 F.3d 1374 (Fed. Cir. 2007).	When determining whether a reference in a different field of endeavor may be used to support a case of obviousness (<i>i.e.</i> , is analogous), it is necessary to consider the problem to be solved.
<i>Agrizap, Inc. v. Woodstream Corp.</i> , 520 F.3d 1337 (Fed. Cir. 2008).	Analogous art is not limited to references in the field of endeavor of the invention, but also includes references that would have been recognized by those of ordinary skill in the art as useful for applicant's purpose.
<i>Muniauction, Inc. v. Thomson Corp.</i> , 532 F.3d 1318 (Fed. Cir. 2008).	Because Internet and Web browser technologies had become commonplace for communicating and displaying information, it would have been obvious to adapt existing processes to incorporate them for those functions.
<i>Aventis Pharma Deutschland v. Lupin, Ltd.</i> , 499 F.3d 1293 (Fed. Cir. 2007).	A chemical compound would have been obvious over a mixture containing that compound as well as other compounds where it was known or the skilled artisan had reason to believe that some desirable property of the mixture was derived in whole or in part from the claimed compound, and separating the claimed compound from the mixture was routine in the art.
<i>Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.</i> , 533 F.3d 1353 (Fed. Cir. 2008).	A claimed compound would not have been obvious where there was no reason to modify the closest prior art lead compound to obtain the claimed compound and the prior art taught that modifying the lead compound would destroy its advantageous property. Any known compound may serve as a lead compound when there is some reason for starting with that lead compound and modifying it to obtain the claimed compound.
<i>Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.</i> , 566 F.3d 989 (Fed. Cir. 2009).	It is not necessary to select a single compound as a “lead compound” in order to support an obviousness rejection. However, where there was reason to select and modify the lead compound to obtain the claimed compound, but no reasonable expectation of success, the claimed compound would not have been obvious.

Case	Teaching point
<i>Altana Pharma AG v. Teva Pharms. USA, Inc.</i> , 566 F.3d 999 (Fed. Cir. 2009).	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 a prior art lead compound in a particular way to produce the claimed compound. It is not necessary for the reasoning to be explicitly found in the prior art of record, nor is it necessary for the prior art to point to only a single lead compound.
The Obvious To Try Rationale	
<i>In re Kubin</i> , 561 F.3d 1351 (Fed. Cir. 2009).	A claimed polynucleotide would have been obvious over the known protein that it encodes where the skilled artisan would have had a reasonable expectation of success in deriving the claimed polynucleotide using standard biochemical techniques, and the skilled artisan would have had a reason to try to isolate the claimed polynucleotide. <i>KSR</i> applies to all technologies, rather than just the “predictable” arts.
<i>Takeda Chem. Indus. v. Alphapharm Pty., Ltd.</i> , 492 F.3d 1350 (Fed. Cir. 2007).	A claimed compound would not have been obvious where it was not obvious to try to obtain it from a broad range of compounds, any one of which could have been selected as the lead compound for further investigation, and the prior art taught away from using a particular lead compound, and there was no predictability or reasonable expectation of success in making the particular modifications necessary to transform the lead compound into the claimed compound.
<i>Ortho-McNeil Pharmaceutical, Inc. v. Mylan Labs, Inc.</i> , 520 F.3d 1358 (Fed. Cir. 2008).	Where the claimed anti-convulsant drug had been discovered somewhat serendipitously in the course of research aimed at finding a new anti-diabetic drug, it would not have been obvious to try to obtain a claimed compound where the prior art did not present a finite and easily traversed number of potential starting compounds, and there was no apparent reason for selecting a particular starting compound from among a number of unpredictable alternatives.
<i>Bayer Schering Pharma A.G. v. Barr Labs., Inc.</i> , 575 F.3d 1341 (Fed. Cir. 2009).	A claimed compound would have been obvious where it was obvious to try to obtain it from a finite and easily traversed number of options that was narrowed down from a larger set of possibilities by the prior art, and the outcome of obtaining the claimed compound was reasonably predictable.
<i>Sanofi-Synthelabo v. Apotex, Inc.</i> , 550 F.3d 1075 (Fed. Cir. 2008).	A claimed isolated stereoisomer would not have been obvious where the claimed stereoisomer exhibits unexpectedly strong therapeutic advantages over the prior art racemic mixture without the correspondingly expected toxicity, and the resulting properties of the enantiomers separated from the racemic mixture were unpredictable.
<i>Rolls-Royce, PLC v. United Technologies Corp.</i> , 603 F.3d 1325 (Fed. Cir. 2010).	An obvious to try rationale may be proper when the possible options for solving a problem were known and finite. However, if the possible options were not either known or finite, then an obvious to try rationale cannot be used to support a conclusion of obviousness.
<i>Perfect Web Techs., Inc. v. InfoUSA, Inc.</i> , 587 F.3d 1324 (Fed. Cir. 2009).	Where there were a finite number of identified, predictable solutions and there is no evidence of unexpected results, an obvious to try inquiry may properly lead to a legal conclusion of obviousness. Common sense may be used to support a legal conclusion of obviousness so long as it is explained with sufficient reasoning.
Consideration of Evidence	
<i>PharmaStem Therapeutics, Inc. v. ViaCell, Inc.</i> , 491 F.3d 1342 (Fed. Cir. 2007).	Even though all evidence must be considered in an obviousness analysis, evidence of nonobviousness may be outweighed by contradictory evidence in the record or by what is in the specification. Although a reasonable expectation of success is needed to support a case of obviousness, absolute predictability is not required.
<i>In re Sullivan</i> , 498 F.3d 1345 (Fed. Cir. 2007).	All evidence, including evidence rebutting a <i>prima facie</i> case of obviousness, must be considered when properly presented.
<i>Hearing Components, Inc. v. Shure Inc.</i> , 600 F.3d 1357 (Fed. Cir. 2010).	Evidence that has been properly presented in a timely manner must be considered on the record. Evidence of commercial success is pertinent where a nexus between the success of the product and the claimed invention has been demonstrated.
<i>Asyst Techs., Inc. v. Emtrak, Inc.</i> , 544 F.3d 1310 (Fed. Cir. 2008).	Evidence of secondary considerations of obviousness such as commercial success and long-felt need may be insufficient to overcome a <i>prima facie</i> case of obviousness if the <i>prima facie</i> case is strong. An argument for nonobviousness based on commercial success or long-felt need is undermined when there is a failure to link the commercial success or long-felt need to a claimed feature that distinguishes over the prior art.