

Obviousness Standard for Patents

Approaches to Withstand USPTO Obviousness Rejections and Attacks on Patent Validity

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**Obviousness Standard for Patents and New USPTO Guidelines
Strategies to Withstand Obviousness Rejections and Attacks on Validity¹**

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I. Obviousness Standard for Patents

A. America Invents Act

The America Invents Act (AIA), enacted on September 16, 2011, sets out a new definition of prior art under §102 that will provide the definition of invalidating prior art under § 103 also. This change will become effective on March 16, 2013.

In particular, AIA SEC. 3(c) states CONDITIONS FOR PATENTABILITY; NONOBVIOUS SUBJECT MATTER.—Section 103 of title 35, United States Code, is amended to read as follows:

§ 103. Conditions for patentability; non-obvious subject matter

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been **obvious before the effective filing date of the claimed invention** to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

125 STAT. 287. “Prior art” as used in new §103 is defined under new §102 as subject matter publicly disclosed or patent filing disclosures that later become public. There are no geographic restrictions, but there are a few exceptions delineated in new §102(b).

A big change from old §103 to new §103 in the AIA is the change in timing. Under the new law, obviousness is judged before the effective filing date of the claimed invention.” Under the old law, obviousness was judged “at the time the invention was made.” The change to “effective filing date” is consistent with the change to first-inventor-to-file, and means that the window is wider for additional prior art in one respect since effective filing date is almost always later than pre-AIA date of invention, but is obviously narrower in another respect since prior inventions of others under pre-AIA §§102 (f) and (g)/103 are no longer prior art under AIA.

Notice that old §103(b) (provision relating to the Biotechnology Process Patent Act of 1995) and old §103(c) (provisions relating to commonly assigned patents and patents developed pursuant to Joint Research Agreements) are not included in new §103. Old §103(b) is repealed, and old §103(c) is now incorporated (and broadened) in new §102(b)(2)(c) as an exception to new §102(a)(2) and new §102(c).

It is also worth noting that the exception under new §102(b)(1) (“disclosures made 1 year or less before the effective filing date of the claimed invention”) may well apply ONLY for the same subject matter earlier disclosed; “related” subject matter could still be used against the patentee under §103.

B. *Graham v. John Deere* factors

The Supreme Court first interpreted § 103 in 1966 and set forth a framework for analyzing obviousness in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966). The Court explained that the obviousness inquiry was a legal question supported by factual findings:

While the ultimate question of patent validity is one of law, [citation omitted] the s [sic] 103 condition, . . . lends itself to several basic factual inquiries.

Id. at 17. Four underlying factual issues were identified:

Under s [sic] 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such objective indicia as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

Id. at 17-18.

1. *Graham* Factor 1: Scope and Content of the Prior Art

In ascertaining *Graham* Factor 1, the scope and content of the prior art, one must first determine what constitutes legally-cognizable prior art. In making this initial determination for claims under the pre-AIA law, one considers the earliest effective date of the publication or patent or the exact date of any alleged prior knowledge, use or sale to see if it "fits" into one or more subparagraphs of 35 U.S.C. § 102. Prior art for § 103 purposes can also be created by the admissions of the parties, and there is no evidence that was overruled in AIA, as noted below.

For claims judged under the AIA law (effective filing dates on or after March 16, 2013 or mixed AIA and pre-AIA claims in the same patent application), new § 102 still establishes what qualifies as prior art for both anticipation and obviousness purposes, and prior art for § 103 purposes can also still be created by the admissions of the parties. There is no indication that the AIA legislatively overrules the *Nomiya* line of cases, wherein admissions can make prior art out of non-prior art. See *In re Nomiya*, 509 F.2d 566, 571 (CCPA 1975). Thus, admissions should remain as non-statutory prior art.

If there is relevant prior art, the analysis of its scope and content (Graham Factor 1) must consider the prior art as a whole; it is not proper to “pick and choose” or isolate portions of references from the whole. As explained by the Federal Circuit in *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561 (Fed. Cir. 1987):

Among legal standards for determining scope and content of the prior art, for example, are: a prior patent must be considered in its entirety, i.e., as a whole, including portions that would lead away from the invention in suit, *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1550, 220 USPQ 303, 311 (Fed. Cir. 1983), cert. denied, 469 U.S. 851, 105 S.Ct. 172, 83 L.Ed.2d 107 (1984); elements of separate prior patents cannot be combined when there is no suggestion of such combination anywhere in those patents, *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984); and a court should avoid hindsight, *W.L. Gore & Assocs., Inc.*, 721 F.2d at 1553, 220 USPQ at 313.

Id. at 1568. The “prior art as a whole” principle corresponds to the statutory requirement, still in new § 103, that the claimed invention subject matter is considered “as a whole”

2. Graham Factor 2: Differences between the Prior Art and the Claimed Invention

Once the scope and content of the prior art is known, a comparison between that prior art and the claimed invention is appropriate to determine any differences. Analysis of Graham Factor 2 involves construing the claims at issue and comparing them to the prior art. As noted above, comparison of the construed claims is performed relative to the prior art as a whole:

[I]n making the assessment of differences between the prior art and the claimed subject matter, section 103 specifically requires consideration of the claimed invention ‘as a whole.’ . . . Without this important requirement, an obviousness assessment might successfully break an invention into its component parts, then find a prior art reference corresponding to each component. . . . This line of reasoning would import hindsight into the obviousness determination by using the invention as a roadmap to find its prior art components. Further, this improper method would discount the value of combining various existing features or principles in a new way to achieve a new result—often the essence of invention.

Princeton Biochemicals, Inc. v. Coulter, Inc., 411 F.3d 1332, 1337 (Fed. Cir. 2005), citing *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1275 (Fed. Cir. 2004).

3. Graham Factor 3: Level of Ordinary Skill in the Art

Determining “[t]he level of ordinary skill in the art” is required by Graham Factor 3. The actual inventor's skill is irrelevant because the inventor does not necessarily represent a worker of ordinary skill. By focusing on the level of skill of the person of ordinary skill in the art rather than the actual inventor, a fact finder maintains an objective perspective and avoids hindsight.

4. **Graham Factor 4: Objective indicia**

In *Graham v. John Deere Co. of Kansas City*, the Supreme Court instructed that “objective indicia,” such as “commercial success, long felt but unsolved needs, failure of others, etc., . . . may also have relevancy; i.e., objective factors that may show that an invention was not obvious from the prior art Post-Graham case law filled in “etc.” with other “objective indicia”: copying, licensing activity, teaching away, and unexpected results. The Courts often refer to Graham Factor 4 “objective indicia” as “objective indicia of nonobviousness.”

Federal Circuit case law has recognized the importance of objective indicia as a check on impermissible hindsight:

In determining the question of obviousness, inquiry should always be made into whatever objective evidence of nonobviousness there may be. *Connell v. Sears Roebuck & Co.*, 722 F.2d 1542, 1549, 220 USPQ 193, 199 (Fed. Cir. 1983). The so-called “secondary considerations” can often prevent a court from slipping into an impermissible hindsight analysis. They should be considered as a fourth factual inquiry under Graham before coming to a conclusion concerning obviousness.

Vandenberg v. Dairy Equipment Co., a Div. of DEC Intern., Inc., 740 F.2d 1560, 1567 (Fed. Cir. 1984) (citing *Connell*, *id.*; *Stratoflex*, 713 F.2d at 1538, 218 USPQ at 879).

According to the Federal Circuit, Graham Factor 4 must be addressed if the evidence is of record. *Geo M. Martin Co. v. Alliance Machine Systems Intern. LLC*, 618 F.3d 1294 (Fed. Cir. 2010). Objective indicia may show that the allegedly invalidating prior art was not suggested by the prior art and the general level of knowledge in the field.

C. **KSR v. Teleflex**

In April 2007, the Supreme Court confirmed the *Graham* Factors as the proper framework for determining obviousness in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007):

In *Graham v. John Deere Co. of Kansas City*, the Court set out a framework for applying the statutory language of § 103... . While the sequence of these questions might be reordered in any particular case, the factors continue to define the inquiry that controls. If a court, or patent examiner, conducts this analysis and concludes the claimed subject matter was obvious, the claim is invalid or unpatentable under § 103.

Id. at 405-07.

1. **TSM Test**

Before *KSR*, the “teaching-suggestion-motivation” (“TSM”) test was commonly applied by the Federal Circuit to determine if an invention was obvious in view of prior art. The TSM test was a judge-made standard by which inventions were only obvious if there was a teaching,

suggestion, or motivation to modify or combine the prior art teachings to achieve the claimed invention.

In *KSR*, the Supreme Court chastised the Federal Circuit for adopting a "rigid approach" in applying the TSM test for obviousness:

[The rigid application of the "TSM" test for obviousness, is] "incompatible with our precedents. The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents . . . There is no necessary inconsistency between the idea underlying the TSM test and the Graham analysis. But when a court transforms the general principle into a rigid rule that limits the obviousness inquiry, as the Court of Appeals did here, it errs.

Id. at 418.

2. Obvious to Try

Prior to *KSR*, it was well-established that "obvious to try" was not the standard for evaluating patentability under 35 U.S.C. § 103. *Ecolchem, Inc. v. Southern California Edison Co.*, 227 F.3d 1361, 1374 (Fed. Cir. 2000)("With hindsight, we could perhaps agree that the Houghton article seems like an obvious place to start . . . But, "obvious to try" is not the standard.").

Yet, the *KSR* court articulated scenarios in which "obvious to try" is enough to defeat patentability under 35 U.S.C. § 103:

When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

KSR, 550 U.S. at 420.

What is considered "obvious to try"? According to the USPTO Guidelines, "obvious to try" may be grounds for obviousness 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." 75 Fed. Reg. 53,643 (Sept. 1, 2010).

The applicability of the "obvious to try" standard of *KSR* to unpredictable technology came before the Federal Circuit in *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007), *cert. denied*, 128 S.Ct. 1739 (U.S., March 31, 2008). Therein, the Federal Circuit dismissed the "obvious to try" argument:

"the fact that a combination was obvious to try might show that it was obvious under § 103." 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.

Id. at 1359.

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

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

Id. at 1359.

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

This court cannot, in the face of KSR, cling to formalistic rules for obviousness, customize its legal tests for specific scientific fields in ways that deem entire classes of prior art teachings irrelevant, or discount the significant abilities of artisans of ordinary skill in an advanced area of art.

Id. at 1360.

The contours of "obvious to try" in U.S. jurisprudence remain to be worked out in the months and years to come.

D. USPTO Examiner Guidelines

Effective Sept. 1, 2010, the USPTO issued an "Examination Guidelines Update: Developments in the Obviousness Inquiry After KSR v. Teleflex," (75 Fed. Reg. 53,643). These Guidelines provide detailed reviews of 24 Federal Circuit cases and the lessons examiners and practitioners should learn from each.

The Guidelines arrange the cases in 4 groups of obviousness rationales:

- combining prior art elements: combinations may be nonobvious “when the combination requires a greater expenditure of time, effort, or resources than the prior art teachings.”
- substituting one known element for another: “applies when the claimed invention can be viewed as resulting from substituting a known element for an element of a prior art invention”
- obvious to try: applies 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.”
- consideration of evidence.

II. Treatment post-KSR

A. In the courts

The first post-KSR case by the Federal Circuit was *Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157 (Fed. Cir. 2007). The Federal Circuit’s analysis has the tone of “common sense” so often mentioned in *KSR* (“An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not.”), and the issue was similar; in *KSR* as in *Leapfrog*, the technology was shifting from mechanical to electronic. “Accommodating a prior art mechanical device that accomplishes that goal to modern electronics would have been reasonably obvious to one of ordinary skill in designing children's learning devices.” *Leapfrog*, 485 F.3d at 1161.

In *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007), *cert. denied*, 128 S.Ct. 1739 (U.S., March 31, 2008), the Federal Circuit addressed whether the presumption of obviousness for structurally similar chemical compounds survived the Supreme Court’s decision in *KSR*:

That test for prima facie obviousness for chemical compounds is consistent with the legal principles enunciated in *KSR*....Thus, in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound.

Id. at 1356-57.

The Federal Circuit also noted its decision in *In re Deuel*, 51 F.3d 1552, 1558 (Fed. Cir. 1995): even in cases of structural similarity, a prima facie case of unpatentability requires a showing that the “prior art would have suggested making the specific molecular modifications necessary

to achieve the claimed invention." *Takeda*, 492 F.3d at 1356. See also, Martens, et al, "Lead Prior Art Methodology: Applying Lead Compound Case Law to Other Disciplines for Enhanced Objectivity," *Santa Clara Computer & High Technology Law Journal*, Feb. 2011; and "A Hindsight-Averse Application of Lead Compound Case Law," *Law360*, Aug. 24, 2011.

In *Takeda*, Alphapharm argued Takeda's claimed compound would have been obvious over the prior art compound TZD ("compound b"). One of ordinary skill in the art would have selected compound b for antidiabetic research and then would have made "two obvious chemical changes[.]" *Id.* at 1357. The district court found, however, that one of ordinary skill in the art would not have selected compound b from the "hundreds of millions" of possible compounds. "[T]he prior art did not suggest to one of ordinary skill in the art that compound b would be the best candidate as the lead compound for antidiabetic research." *Id.* at 1358. The Federal Circuit affirmed.

Other examples of post-*KSR* cases where the patentee has successfully withstood an obviousness challenge by showing a wide range of possible outcomes are:

- *Ortho-McNeil Pharms. Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358 (Fed. Cir. 2008);
- *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341 (Fed. Cir. 2008), *reh'g denied* (2009);
- *In re Omeprazole Patent Litigation*, 536 F.3d 1361 (Fed. Cir. 2008), *cert. denied*, 129 S.Ct. 1593 (U.S. 2009);
- *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989 (Fed. Cir. 2009);
- *Daiichi Sankyo Co., Ltd. v. Matrix Laboratories, Ltd.*, 619 F.3d 1346 (Fed. Cir. 2010), *cert. denied*, 131 S.Ct. 1678 (U.S. 2011);
- *Unigene Laboratories, Inc. v. Apotex, Inc.*, 131 S.Ct. 1678 (Fed. Cir. 2011), *pet. for cert. filed*, Jan. 13, 2012.

Compare *Altana Pharma v. Teva*, 566 F.3d 999 (Fed. Cir. 2009), where the claimed subject matter was held obvious over prior art that included only 18 compounds, and *Bayer Schering Pharma AG v. Barr Laboratories, Inc.*, 575 F.3d 1341 (Fed. Cir. 2009), *cert. denied*, 130 S.Ct. 2404 (U.S. 2010), where the Federal Circuit affirmed the holding of obviousness, focusing on the limited choices facing one of ordinary skill in the art at the time of the invention.

But see also *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, --F.3d__ (Fed. Cir. Jan. 9, 2012), where the Federal Circuit affirmed the district court's grant of preliminary injunction because the court found "no teaching, suggestion, or motivation in the prior art" likely to invalidate Celsis' claims under obviousness. Judge Gajarsa dissented, arguing that the Federal Circuit ignored the Supreme Court's *KSR* decision, which "explicitly rejected the rigid application of the teaching-suggestion-motivation test."

Significant pre-*KSR* case law remains relevant to the post-*KSR* obviousness challenges. It remains best practice to try to attack rather than rebut a prima facie case of obviousness in an attempt to avoid possibly adverse litigation implications. *KSR* has most significantly impacted

cases involving inventions combining known elements yielding predictable results or having a finite number of identified, predictable solutions.

B. In the USPTO

In *Ex Parte Subramanyam*, Appeal No. 2010-002463 (BPAI March 29, 2010), the rejected claim recited a toothpaste with an antibacterial effective amount of compound I. The issue was whether an ordinary artisan would have chosen tetrahydrohonokiol out of all of the polyols found in the plant extracts disclosed by the prior art. The Board reversed the examiner's rejection, with reasoning similar to that of the Federal Circuit in *Takeda*. The Board noted that while the claimed compound was structurally similar to the prior art, it was only one among many other polyols disclosed:

While the analysis under 35 U.S.C. § 103 allows flexibility in determining whether a claimed invention would have been obvious, *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007), it still requires showing that "there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *Id.* "We must still be careful not to allow hindsight reconstruction of references to reach the claimed invention without any explanation as to how or why the references would be combined to produce the claimed invention." *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1374 n.3 (Fed. Cir. 2008).

In order to make a prima facie case of obviousness based on the structural similarity between the claimed compound and the compound disclosed by the prior art, not only must the structural similarity exist, but the prior art must also provide reason or motivation to make the claimed compound. See *In re Dillon*, 919 F.2d 688, 692 (Fed. Cir. 1990) (en banc), *In re Mayne*, 104 F.3d 1339, 1341 (Fed. Cir. 1997); *In re Payne*, 606 F.2d 303, 313 (CCPA 1979). Therefore, in order to establish a prima facie case of obviousness, there need be "a showing that the 'prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention.'" *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356 (Fed. Cir. 2007), quoting *In re Deuel*, 51 F.3d 1552, 1558 (Fed. Cir. 1995).

Id. at *7-8.

III. Patent Prosecution Post-KSR

The substantive law of obviousness has not changed: *Graham* remains the basic test for obviousness and a reasonable expectation of success is still required. It remains best practice to try to attack rather than rebut a prima facie case of obviousness to avoid possible adverse litigation implications. However, the procedures necessary to overcome obviousness challenges may be different (and more difficult).

Look for evidence of unexpected benefit or result (e.g., synergism); look for teachings away or disincentive to make a modification to arrive at claimed invention. Are there signposts that

lead you to selection of a smaller group from a much larger cited art group? Is there a reasoned identification of a lead candidate in the prior art? Or might multiple candidates be possible? Is there any reason a skilled artisan would have considered modification of the prior art and expected the invention as an identifiable, predictable solution? Are there combinatorial prior art possibilities that mean the invention was not obvious to try? The case law suggests that practitioners have a better chance of surviving an obviousness challenge if they can establish that there is no finite number of predictable solutions with anticipated success.

Patentees may wish to review pre-KSR patents BEFORE litigation and/or licensing arises and consider their options such as filing a reissue application or, if available, a continuation application, or a request for reexamination. But corrective action might not be easy or desirable for the patentee to do, since reissue requires a statutory error, and reexamination requires the existence of a substantial new question of patentability and once started, cannot be stopped.

Such situations call for careful consideration. In addition, rolling effective date provisions of the AIA may impact what options are available.

Patentees may also find it beneficial to compile evidence of unpredictability well before litigation is an issue. Often inventors have left a company during the interim between filing their patent application and the litigation over the resulting patent. However, it is often those very inventors who possess critical knowledge of the obstacles they overcame to make their invention and the uncertainty in the art regarding how to solve the problem they addressed. Cataloguing that evidence in a contemporaneous manner could provide beneficial evidence during future patent infringement litigation.

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