

FEDERAL CIRCUIT REVIEW

OBVIOUSNESS

VOLUME ONE | ISSUE TWO
OCTOBER 2008

IN THIS ISSUE:

- The Obviousness Inquiry
- Rulings Invalidating Patents For Obviousness
- Rulings Finding Patents Not Obvious
- Objective Evidence

The Willkie Farr & Gallagher LLP *Federal Circuit Review* is a newsletter from the Intellectual Property Department on recent developments taking place in the Court of Appeals for the Federal Circuit. The *Federal Circuit Review* will present a synopsis of the most recent decisions and what they mean for today's intellectual property-focused businesses. Each issue will present recent developments and highlights concerning a specific area of patent law.

Obviousness is rooted in the concept that the act of "invention" requires a certain degree of skill and ingenuity. Section 103 of the Patent Act states that a patent may not be obtained if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter of the invention pertains." Whether an invention would have been obvious is a legal question underpinned by factual determinations, such as those made by a jury.

In 2007, the Supreme Court revisited the legal principles for determining obviousness in *KSR Int'l Co. v. Teleflex Inc.* The Federal Circuit has issued several recent decisions that illustrate how the court will apply *KSR* to decide whether a patent is obvious.

THE OBVIOUSNESS INQUIRY

In 1966, the Supreme Court in *Graham v. John Deere Co.* observed that obviousness lends itself to four basic factual inquiries, now known as the "Graham factors": (1) the scope and the content of the prior art, (2) the differences between the prior art and the claims at issue, (3) the level of ordinary skill in the pertinent art, and (4) evidence of secondary factors to give light to the circumstances surrounding the origin of the claimed invention. Because the Patent Act requires a determination of what would have been obvious "at the time the invention was made," the Federal Circuit and its predecessor court developed a means of applying the Graham factors that would prevent the tendency toward hindsight bias. For example, in the 1983 case *In re Sernaker* the Federal Circuit held that obviousness involved determining "whether a combination of the teachings of all or any of the references would have suggested (expressly or by implication) the possibility of achieving further improvement by combining such teachings along the line of the invention in suit." Later, in deciding *In re Gordon*, the court held that with regard to a single

FEDERAL CIRCUIT REVIEW

prior art apparatus, “[t]he mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification.” The test for obviousness that emerged from this line of cases became known as the teaching, suggestion or motivation (“TSM”) test.

Under the TSM test, an invention would have been obvious if the prior art explicitly taught, suggested or motivated one of ordinary skill in the art to combine the references, or to modify one reference, to encompass the invention. The explicit satisfaction of the TSM test oftentimes became a prerequisite for proving obviousness at trial, and for rejecting claimed inventions for obviousness at the Patent Office. For example, in *Golight v. Wal-Mart*, the court agreed with the district court’s ruling that *all the elements* of the claimed invention were disclosed by the prior art references. However, the court found the invention to be *not* obvious because no prior art reference provided “explicit motivation” to combine the elements. The net effect was that rigid application of the TSM requirement made it difficult to invalidate a patent.

In *KSR*, the Supreme Court addressed whether the TSM test was contrary to the Patent Act. With Justice Kennedy speaking for the Court, the Court held that while the TSM test can provide “helpful insight” to identify the reason a skilled person would combine references, a rigid application of the TSM test is not acceptable as a substitute for a full obviousness analysis according to the *Graham* factors. Further, the Court held that “[t]o facilitate review [of an obviousness determination], this analysis should be made specific.” The Court then found that the claimed invention, a vehicle pedal and sensor, would have been obvious under this renewed “expansive and flexible” obviousness approach.

In the wake of *KSR*, the Federal Circuit has found obviousness when clear and convincing evidence proves that a person of ordinary skill would have had within her or his technical grasp a finite and small number of identifiable, predictable solutions. The court has reasoned that one of ordinary skill would have the ability to pursue known solutions to problems within the relevant field. In addressing a known problem, one of ordinary skill would also be able to use “ordinary ingenuity” and common sense to combine prior art references. However, as the court emphasized in *Takeda v. Alphapharm*, *KSR* holds that the prior art must still provide one of ordinary skill with specific reasoning to combine references. Accordingly, the court has declined to find inventions obvious when the reasoning for combining prior art references is factually deficient.

Cases referenced

Golight v. Wal-Mart, 355 F.3d 1327 (Fed. Cir. 2004)

Graham v. John Deere Co., 383 U.S. 1 (1966)

In re Gordon, 733 F.2d 900 (Fed. Cir. 1984)

KSR Int’l Co. v. Teleflex Inc., 127 S. Ct. 1727 (2007)

In re Sernaker, 702 F.2d 989 (Fed. Cir. 1983)

Takeda Chem. Indus. v. Alphapharm Pty., Ltd., 492 F.3d 1350 (Fed. Cir. 2007)

RULINGS INVALIDATING PATENTS FOR OBVIOUSNESS

The Federal Circuit’s post-*KSR* rulings invalidating patents for obviousness reveal some notable trends. The court has held several patents invalid for obviousness when evidence has shown that the

claims involve the “combination of known elements according to known methods that do no more than yield predictable results.” The court also has focused on the creativity of one of ordinary skill. In practice, this focus has meant that the sources of motivation for one of ordinary skill to combine prior art references have expanded. In particular, factors motivating one of ordinary skill can include commonly understood commercial benefits such as better reliability, streamlined operation, marketability, and reduced size and cost. In addition, patents for optimizations and new ways of administering known compounds, such as are common in the chemical arts, have notably been held invalid for obviousness.

The first post-KSR obviousness decision was *Leapfrog v. Fisher-Price*. In *Leapfrog*, the court found that a prior art electronic device would have provided a “roadmap” for adding updated electronics to a mechanical device based on the “common sense” of the ordinarily skilled person.

Leapfrog’s invention involved an electronic educational device. The device allowed a child to press a switch associated with a single letter in a word and then hear the sound of the letter as used in that word. Delivering the opinion of the court, Judge Lourie deemphasized the TSM test in this instance, holding that “[a]n obviousness determination is not the result of a rigid formula disassociated from the facts of the case.” In particular, the court found that updating a prior art mechanical device with modern electronics, when the mechanical device accomplishes the goal of the invention “when viewed as a whole,” would have been obvious to one skilled in the art. Further, the known benefit of an electronic update alone was sufficient reasoning for the combination. While the prior art electronic device operated in a “slightly different” mode from the mechanical device (allowing a child to hear the sound associated with only the first letter of a word), the electronic device nonetheless would have provided “a roadmap for one of ordinary skill in the art desiring to produce an electronics-based learning toy for children that allows the use of the [claimed] phonetic-based learning methods.”

In the chemical arts, the court reversed a pre-KSR non-obviousness ruling in *Aventis v. Lupin*. The court held that the structural similarity of chemical compounds can create a *prima facie* case of obviousness. The invention was directed to a pharmaceutical compound called “ramipril” in a purified form. A close structural analogy existed between ramipril and the compound “enalapril”, which was disclosed in a single prior art reference. It was known in the field of art that enalapril exhibited increased potency in certain structural forms. Unlike inquiries which turn on whether it would have been obvious to *combine multiple references* to achieve the claimed invention, the inquiry in this instance turned on whether it would have been obvious for one of ordinary skill to *modify a single reference* for that purpose. The question before the court was whether one skilled in the art would have been motivated to isolate a specific purified stereoisomer of ramipril for increased potency given the increase in potency exhibited by the structurally analogous form of enalapril.

The court held that one of ordinary skill would have expected an isolated ingredient to retain the same properties it exhibited in a mixture. As such, it would have been obvious to one of ordinary skill that those properties would be amplified in purified form. With Judge Linn noting that an explicit teaching was precisely the sort of rigid application of the TSM test criticized in *KSR*, the court’s decision was based on two critical points. First, the court observed that the isolation of compounds that exhibit interesting characteristics is a “mainstay of the chemist’s art,” and thus within the province of the skilled artisan. Second, citing *Takeda*, Judge Linn noted that the criteria for a *prima facie* case of obviousness in the chemical arts had been met:

FEDERAL CIRCUIT REVIEW

In the chemical arts, we have long held that “structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a *prima facie* case of obviousness.”

Further, “[o]nce such a *prima facie* case is established, it falls to the applicant or patentee to rebut it, for example with a showing that the claimed compound has unexpected properties.” The properties of enalapril, being structurally analogous to those of ramipril, created such a *prima facie* case. The court held the finding of increased potency for ramipril to be insufficient to rebut the *prima facie* case, as one of ordinary skill would have been led to the expected results.

In a third case, *Pharmastem v. Viacell*, a claimed invention resulting from routine research was also found to have been obvious in light of prior art references. *Pharmastem* turned on whether the prior art would have given rise to a reasonable expectation of success in creating a hematopoietic treatment based on using cryo-preserved umbilical cord blood. The claimed invention was regarded with “genuine surprise” in the scientific community and was very successful commercially. The prior art revealed no direct evidence of umbilical cord blood containing hematopoietic cells. However, evidence did exist that umbilical cord blood had similar properties to bone marrow, which was known for use in hematopoietic reconstitution. It was also acknowledged in the patent specification that umbilical cord blood contains high numbers of progenitor cells. Progenitor cells were not directly indicative of the presence of hematopoietic cells, but they were known to be produced by hematopoietic cells.

Noting that this was a close case, the court reversed the district court by holding that the inventors merely used routine research methods to prove what was already believed to be true (i.e., that umbilical cord blood contained high concentrations of hematopoietic cells). Judge Bryson, citing *Pfizer v. Apotex*, further noted that the expectation of success need only be reasonable, not absolute. Emphasizing the “admissions” in the specification, the court distinguished this case from one in which the prior art gives either no indication of which parameters are critical or no direction as to which of many possible choices is likely to be successful.

Cases referenced

Aventis Pharma Deutschland GmbH v. Lupin, Ltd., 499 F.3d 1293 (Fed. Cir. 2007)

KSR, 127 S. Ct. 1727

Leapfrog Enters. v. Fisher-Price, Inc., 485 F.3d 1157 (Fed. Cir. 2007)

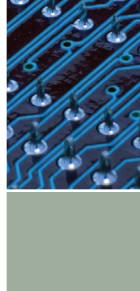
Pharmastem Therapeutics, Inc. v. Viacell, Inc., 491 F.3d 1342 (Fed. Cir. 2007)

Pfizer, Inc. v. Apotex, Inc., 488 F.3d 1377 (Fed. Cir. 2007)

Takeda Chem. Indus. v. Alphapharm Pty., Ltd., 492 F.3d 1350 (Fed. Cir. 2007)

RULINGS FINDING PATENTS NOT OBVIOUS

Trends also have emerged from the court’s post-KSR rulings finding patents not obvious. While invalidations for obviousness appear to have increased somewhat, several patents have been found not obvious. In those cases, the court has been careful to avoid hindsight reconstruction of the claimed inventions by focusing on the universe of prior art teachings that one of ordinary skill would have at hand.



Prior to *KSR*, being “obvious to try” was not generally a sound basis to find that a claimed invention was obvious. While *KSR* overturned this line of cases, the court has been conservative in applying its “obvious to try” reasoning. In particular, the court has held that one cannot discount the number and complexity of alternatives when considering whether a combination or modification would have been obvious to try.

Illustrating recent trends, *Takeda and Eisai v. Dr. Reddy’s Labs., Ltd.* are examples where the court found that new chemical compounds would not have been obvious. In both cases, the prior art provided no clear roadmap that would have led one of ordinary skill to select these new compounds for drug treatments.

Takeda involved a new anti-diabetic drug. The court’s decision reinforced that the TSM test is consistent with *KSR*. In particular, Judge Lourie explained that the TSM test is still useful for identifying the reasoning used to establish *prima facie* obviousness 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 the *prima facie* obviousness of a new claimed compound.

The case turned on two points: The first was whether the prior art references would have led one of ordinary skill to select a known compound, compound “b”, as a lead compound. The second was whether, after selecting compound “b”, one of ordinary skill would have performed the necessary scientific steps of homologation and “ring-walking” to reach the claimed compounds. Alphapharm relied on *KSR* and *Pfizer* to argue that compound “b” was “obvious to try” and that one of ordinary skill would have had a reasonable expectation of success in performing the necessary scientific steps.

Citing *KSR*, the *Takeda* 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.” In such circumstances, “the fact that a combination was obvious to try might show that it was obvious under § 103.” However, the court found that compound “b” was not obvious to try in this instance. Rather, the evidence showed that the prior art disclosed “millions of compounds” with, notably, none showing compound “b” as an anti-diabetic candidate. Further, the closest prior art compound to compound “b” was singled out as the cause of adverse side effects, thus teaching away from using compound “b” as a lead compound.

The court found that nothing in the prior art would have narrowed the field of possible compounds to try to include compound “b”. Unlike *Pfizer*, where the disclosed genus of possible lead compound candidates was narrowed to a few possibilities, any of the millions of compounds could have been selected as a lead compound candidate in this instance. Therefore, one of ordinary skill did not have a clear roadmap to try compound “b” with any reasonable expectation of success.

In *Eisai*, the court found the new compound “rabeprazole” non-obvious over three prior art references. The court held that a *prima facie* case of obviousness for a new chemical compound begins with the reasoned identification of a lead compound. In reference to the TSM test, Judge Rader

noted that a *prima facie* case based on structural similarity can be proved by the identification of some motivation that would have led one of ordinary skill to select and modify a known compound to achieve the claimed compound. In accordance with *KSR*, that motivation need not be explicit. Rather, the court interpreted *KSR* as presupposing (1) a starting reference point before the invention for identifying a problem and potential solutions, (2) that the record up to the time of the invention would give reason to one of ordinary skill to make particular modifications to achieve the claimed compound, and (3) that the record would supply some reason for narrowing the prior art universe down to a “finite number of identified, predictable solutions.” In this instance, however, no evidence showed a motivation to modify the prior art to achieve the new compound.

Unlike *Takeda* and *Eisai*, *Ortho-McNeil v. Mylan* did not involve a lead chemical compound. However, the court affirmed a non-obviousness ruling due to the unexpected discovery of anticonvulsive properties in the compound “topiramate”. The compound was produced as an intermediate during a search for new anti-diabetic drugs. Mylan argued that a finite number of options would have led one of ordinary skill faced with finding an anti-diabetic drug to necessarily discover the invention. Mylan also relied on the following passage of *KSR*: “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.”

In *Ortho-McNeil*, Judge Rader noted, however, that one of ordinary skill would not have chosen topiramate as a lead compound for diabetes research. According to the court, one of ordinary skill also would not have had a reason to select among the vast number of alternatives the exact route that produced topiramate as an intermediate. Moreover, one would then have had to further test the intermediate, without any clue as to its utility, for properties “far afield” from the purpose of developing an anti-diabetic drug to ultimately discover the invention. The court distinguished *KSR* as “posit[ing] 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.” That was not the case here. In addition, the court renewed its warning against hindsight bias by noting that the circumstances surrounding the invention must be taken into account:

In retrospect, [the inventor’s] pathway to the invention, of course, seems to follow the logical steps to produce these properties, but at the time of the invention, the inventor’s insights, willingness to confront and overcome obstacles, and yes, even serendipity, cannot be discounted.

In this light, the court noted that “a flexible TSM test remains the primary guarantor against a non-statutory hindsight analysis.”

Cases referenced

Eisai Co. Ltd. v. Dr. Reddy’s Labs., Ltd., 253 F.3d 1353 (Fed. Cir. 2008)

KSR, 127 S. Ct. 1727

Leapfrog, 485 F.3d 1157

Ortho-McNeil Pharma., Inc. v. Mylan Labs., Inc., 520 F.3d 1358 (Fed. Cir. 2008)

Pfizer, 488 F.3d 1377

Takeda, 492 F.3d 1350

OBJECTIVE EVIDENCE

Ortho-McNeil is also notable for the weight that was given to objective evidence (sometimes referred to as “secondary considerations” or “secondary factors”). The Supreme Court described objective evidence in *Graham* as evidence that “might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” Examples of such evidence include commercial success, long-felt but unsolved needs, failure of others to solve the problem solved by the inventor, skepticism of experts, and copying of the invention by others. Like the TSM test, objective evidence can help prevent hindsight reconstruction of the claimed invention. As the court noted in *Stratoflex v. Aeroquip* (1983), objective evidence can establish that an invention appearing to have been obvious in light of the prior art is not.

In holding the invention to be not obvious, the *Ortho-McNeil* court noted the powerful objective evidence of unexpected results, skepticism of experts, copying and commercial success. The court held that objective evidence “may often be the most probative and cogent evidence of nonobviousness in the record.” Significantly, the court reaffirmed that objective evidence “is not just a cumulative or confirmatory part of the obviousness calculus but constitutes independent evidence of non-obviousness.” (quoting *Catalina Lighting v. Lamps Plus*)

Ortho-McNeil, however, contrasts with the court’s treatment of objective evidence in *Pharmastem* and *Aventis*. In *Pharmastem*, in the dissenting opinion Judge Newman criticized the limited weight accorded to the objective evidence, which included surprise in the scientific community and widespread commercial success. *Aventis* did not even mention objective evidence in its obviousness analysis. In addition, strong objective evidence failed to carry the day in *Agrizap v. Woodstream*, *Muniauction v. Thomson* and *Asyst v. Emtrak*.

Agrizap involved an electronic rodent-killing device. The objective evidence of non-obviousness included the “commercial success of the Rat Zapper, copying by [the defendant], and a long felt need in the market for electronic rat traps.” Although the court noted that it must afford a “high level” of deference to a jury’s factual findings, including findings relating to objective evidence, the objective evidence could not overcome what the court held to be “overwhelming” primary evidence in this instance. In particular, the court held that the only difference between the claims and *Agrizap*’s own prior art commercial product was the substitution of a mechanical activation switch for an electrical one. While not explicitly addressing the TSM test in the decision, Judge Moore cited *KSR* in concluding that “[t]his is 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.”

In *Muniauction*, which involved an online auction system, the court also reversed a jury’s non-obviousness verdict. Although *Muniauction* presented evidence of praise, copying and commercial success supporting the jury’s verdict, the court concluded that this objective evidence could not be attributed to the invention because the commercial product did not sufficiently embody the claimed features. This lack of a “nexus” between the claims and the commercial product meant that the objective evidence could not be weighed as a factor. The court then held that the claimed invention would have been obvious based on the prior art.

Asyst involved a system for tracking the status of articles, such as semiconductor wafers, in the course of the manufacturing process. The court discounted evidence of commercial success, long-felt need and industry praise because the patentee failed to prove a nexus between that evidence and “the features of its invention that were not disclosed” in the prior art. Interestingly, the court focused on whether there was a nexus to a particular claimed feature rather than a nexus to the claimed invention as a whole. The court then held the asserted claims invalid for obviousness.

Cases referenced

Agrizap, Inc. v. Woodstream Corp., 520 F.3d 1337 (Fed. Cir. 2008)

Asyst Techs., Inc. v. Emtrak, Inc., ___ F.3d ___ (Fed. Cir. 2008)

Aventis, 499 F.3d 1293

Catalina Lighting, Inc. v. Lamps Plus, Inc., 295 F.3d 1277 (Fed. Cir. 2002)

Graham, 383 U.S. 1

KSR, 127 S. Ct. 1727

Muniauction, Inc. v. Thomson Corp., 532 F.3d 1318 (Fed. Cir. 2008)

Ortho-McNeil, 520 F.3d 1358

Pharmastem, 491 F.3d 1342

Stratoflex v. Aeroquip, 713 F.2d 1530 (Fed. Cir. 1983)

CONTACT INFORMATION

If you have any questions, please contact the authors of this newsletter listed below or the Willkie attorney with whom you regularly work.

Kelsey I. Nix

(212) 728-8256

knix@willkie.com

Michael W. Johnson

(212) 728-8137

mjohnson1@willkie.com

Andrew A. Noble

(212) 728-8165

anoble@willkie.com

ABOUT WILLKIE FARR & GALLAGHER LLP

Established in 1888, Willkie comprises more than 700 lawyers in offices in New York, Washington, Paris, London, Milan, Rome, Frankfurt, and Brussels. Our diverse areas of expertise and pragmatic approach to the practice of law make our firm uniquely qualified to comprehensively serve the needs of our clients around the world.

WILLKIE FARR & GALLAGHER LLP

787 Seventh Avenue

New York, NY 10019-6099

Tel (212) 728-8000

Fax (212) 728-8111

Copyright © 2008 by Willkie Farr & Gallagher LLP.

All Rights Reserved. This newsletter may not be reproduced or disseminated in any form without the express permission of Willkie Farr & Gallagher LLP. This newsletter is provided for news and information purposes only and does not constitute legal advice or an invitation to an attorney-client relationship. While every effort has been made to ensure the accuracy of the information contained herein, Willkie Farr & Gallagher LLP does not guarantee such accuracy and cannot be held liable for any errors in or any reliance upon this information. Under New York’s Code of Professional Responsibility, this material may constitute attorney advertising. Prior results do not guarantee a similar outcome.

WILLKIE FARR & GALLAGHER LLP

www.willkie.com | NEW YORK WASHINGTON PARIS LONDON MILAN ROME FRANKFURT BRUSSELS