



TSM –ALIVE AND WELL AT THE FEDERAL CIRCUIT

A Survey of Post KSR CAFC Cases

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KSR International Co., v. Teleflex, Inc., 127 S.Ct. 1727 (2007) was decided on April 30, 2007.

Leapfrog Enterprises, Inc. v. Fisher-Price, Inc., 425 F.3d 1157 (decided May 9, 2007) was the first Federal Circuit case to substantially rely on **KSR** in its obviousness analysis. In affirming a trial Court ruling of invalidity for obviousness, the Court stated that an obviousness determination is not the result of a rigid formula, noting the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not, relying on this quote from **KSR**: “The combination of familiar elements according to known method is likely to be obvious when it does no more than yield predictable results.” **KSR**, 127 S.Ct. at 1739. The Court further noted that the defendant did not present any evidence that the combination of prior art references was uniquely challenging or difficult for one of ordinary skill in the art, citing **KSR**, 127 S.Ct. 1741.

In **Takeda Chemical Industries, Ltd. v. Alphapharma Pty., Ltd.**, 492 F.3d 1350, (decided June 28, 2007) the Court addressed the issue of obviousness in the context of structurally similar chemical compounds. The Court affirmed the decision of the District Court after a bench trial that the patent was not invalid. Judge Lourie, in rendering the decision, made clear that the TSM test is not dead, but only a rigid application of the test. The Federal Circuit noted that the Supreme Court acknowledged the importance of identifying “a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in a way the claimed new invention does.” Citing **KSR**, 127 S.Ct. at 1741. Judge Lourie further noted that the Supreme Court indicated “there is no inconsistency between the idea underlying the TSM test and the Graham analysis.” **KSR**, 127 S.Ct. at 1731. Judge Lourie stated: “[t]hus, 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.” **Takeda**, 492 F.3d at 1357. The Court held that that a person of ordinary skill in the art would not have selected the claimed compound because a prior art reference taught away due to negative effects. The Court also held the modification of the compound was not obvious because of unexpected results.

The Court distinguished **Pfizer, Inc. v. Apotex, Inc.**, 480 F.3d 1348. The Court discussed the “obvious to try” argument relied upon in the Pfizer decision and addressed the statement

in **KSR** stated that when “there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options.... In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.” **KSR**, 127 S.Ct. at 1742. The Federal Circuit stated that the Pfizer’s decision was based on particularized facts of the case. In Pfizer, the prior art provided ample motivation to narrow the genus of 53 anions known in the prior art to the claimed compound. However, there must be a balancing of evidence of a reason to combine versus a reason not to combine. The Court distinguished Takeda because of the evidence that taught away from the claimed compound. It is interesting to note that three judges dissented from the order denying rehearing *en banc* of the **Pfizer v. Apotex** case. **Pfizer, Inc. v. Apotex, Inc.**, 488 F.3d 1377. Even though the original CAFC decision was pre-**KSR** (March 22, 2007), the Court’s opinion presaged **KSR** by relying on a flexible application of the TSM test and obvious to try in analyzing the evidence of obviousness.

In **Omegaflex, Inc. v. Parker-Hannifin Corporation**, 243 Fed.Appx. 592 (decided on June 18, 2007) (non-precedential) Chief Judge Michel spoke for the first time in an opinion on the **KSR** decision. In this case, summary judgment of infringement and validity was reversed and remanded for trial. The District Court had held that there was no motivation to combine the prior art because the prior art patent taught the element might be problematic, i.e., teaches away. The District Court also held that there was no reasonable expectation of success because defendant’s own engineers decided the element would be problematic. However, the defendant later included the problematic element because of customer complaints that its product did not have the element. In addition, the District Court found evidence of the solving of a long felt need. The Federal Circuit held that the District Court’s analysis was too narrow and failed to account for evidence regarding knowledge of a skilled artisan by giving no probative weight to the defendant’s expert. In discussing the law on motivation to combine, Judge Michel was careful to follow citations to **KSR** with citations to Federal Circuit decisions that paralleled the quote from **KSR**, citing **DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.**, 464 F.3d 1356, 1366 (Fed.Cir.2006) (“[W]e have stated explicitly that evidence of a motivation to combine need not be found in the prior art themselves,” citing **In re Dembiczak**, 175 F.3d 994, 999 (Fed.Cir. 1999)) (emphasis in original).

This was a clear message that the Federal Circuit believed its TSM test was consistent with the Supreme Court precedents. However, based on the evidence described in the opinion, it appears that this may have been an overreaction to **KSR**.

In **Pharmastem Therapeutics, Inc. v. Viacell, Inc.**, 491 F.3d 1342 (decided July 9, 2007) a jury verdict that the patent was not invalid and JMOL was denied. The Federal Circuit reversed and directed a JMOL that the patent was invalid. Judge Newman dissented. The obviousness issue was whether there was reasonable expectation of a success. This case dealt with the apparent pioneer discovery of stem cells in umbilical cord blood. The facts show that no prior art reference established in positive proof that umbilical cord blood contains stem cells and the inventors were the first to make that discovery. The scientific community widely recognized the inventors are being the pioneers of this science. However, the Federal Circuit determined that because several prior art references suggested that it could be possible that umbilical cord blood contained stem cells, that it was an obvious

invention. Quoting from **KSR** that “a combination of elements must do more than yield predictable results” and granting a patent “to advances that would occur in the ordinary course without real innovation retards progress”, (**KSR**, 127 S.Ct. 15 1732, 1740) the Court determined that the inventor merely used routine methods to prove what was already believed to be true, observing that “scientific confirmation of what was already believed to be true, may be a valuable contribution, but it does not give rise to a patentable invention.”

In Judge Newman’s dissent, she noted that after a three-week trial in which the jury sustained validity, after the District Court’s thorough opinion upholding the verdict and after validity was confirmed in three separate reexaminations, the Federal Circuit still reversed. In her opinion there was ample evidence upon which a reasonable jury could have made the decision it did and, therefore, the verdict and JMOL should not have been reversed. This case also appears to be a severe overreaction to **KSR**.

In **In Re Icon Health and Fitness, Inc.**, 496 F.3d 1374 (decided August 1, 2007) the Federal Circuit affirmed a reexamination Board decision holding the claims unpatentable. The patent was directed to a treadmill with a holding base and gas springs to maintain the base in an upright position. Relying on **KSR**’s statement that familiar items may have obvious uses beyond their primary purposes (**KSR**, 127 S.Ct. at 1742) the Court held that any art addressing a folding mechanism and gas springs is analogous. The Court found the combination obvious relying on the statement in **KSR** that “any need or problem known in the field ... and addressed by the patent can provide a reason for combining the elements in the manner claimed”(**KSR**, 127 S.Ct. at 1742) the Court made clear that not just the problem being solved by the claimed invention. Citing the Supreme Court’s statement that “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results (**KSR**, 127 S.Ct. at 1739) the Court rejected teaches away and inoperability arguments.

In **In re Trans Texas Holdings Corp.**, 498 F.3d 1290 (Fed.Cir.2007) (decided) August 22, 2007) the Federal Circuit again affirmed a Board’s decision in a reexamination that upheld the rejection of the claims as obvious. The Court citing the Supreme Court’s statement that “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results (**KSR**, 127 S.Ct. at 1739), held that claims to a capital investment system were unpatentable because it would have been obvious to combine indexed loan accounts disclosed in a prior art reference with the well-known practice of offering loans secured by mortgaged real estate.

In re John B. Sullivan, 489 F.3d 1345, (Fed.Cir. 2007) (decided August 29, 2007) was yet another appeal from a Board decision upholding claim rejections in which the Court agreed there was a *prima facie* obviousness case. The Court cited **KSR** for the proposition that “if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.” **KSR**, 127 S.Ct. at 1740-41. However, what is significant here is that the Federal Circuit vacated and remanded because the Board failed to consider declarations providing evidence of secondary considerations of non-obviousness, including, teaches away, unexpected results and long-felt need.

In **Aventis Pharma Deutschland GmbH v. Lupin, Ltd.**, 499 F.3d 1293, (decided September 11, 2007), The Federal Circuit reversed a summary judgment decision that the patent to the drug Ramipril was infringed and not invalid. Judge Linn characterized **KSR** as “counsel[ing]” against applying the TSM test in a rigid manner. The inventor knew the active ingredient of the compound and the prior art suggested that the claimed compound was an active ingredient of a known mixture. There was no evidence that separating the active ingredient was outside the capacity of the ordinary skilled artisan. The Court held that an explicit teaching of purification was no longer required in view of **KSR**’s rejection of the rigid TSM tests. The Court rejected the unexpected results argument indicating that the potency of this active ingredient was expected.

In **Verizon Services Corp. v. Vonage Holdings Corp.**, 503 F.3d 1995, (decided September 26, 2007), the Federal Circuit affirmed a jury verdict of non-obviousness of two of three patents but remanded on a third patent due to claim construction. One issue on appeal was whether the jury was instructed to apply the TSM test too rigidly regarding the need to find a suggestion in the prior art to combine elements. On remand, the District Court will reconsider the jury instruction in view of **KSR**. In a dissenting opinion, Chief Judge Michel stated that he would hold that the jury’s instruction on obviousness was based on the Federal Circuit’s flexible test set forth in pre-**KSR** cases and therefore was a correct instruction. This is another signal that the Federal Circuit believes its current TSM test as articulated in **DyStar** is consistent with Supreme Court precedents.

In **In Re Translogic Technology, Inc.**, 504 F.3d 1249 (decided October 12, 2007) the Federal Circuit affirmed a Board decision upholding an obviousness rejection in a Reexamination. The Court explained the error it made in **KSR** was relying too strictly on solving a different problem as a distinction. The Court reiterated that “obvious variants of prior art references are themselves part of the public domain,” and that these obvious variants must be considered even though the reference is solving a different problem. Judge Rader noted that while the Supreme Court rejected the rigid application of the TSM test in **KSR**, the Supreme Court also observed that the Federal Circuit had expressed a flexible TSM test in later cases citing **DyStar**, 464 F.3d 1356, 1367 which would be more consistent with the Supreme Court’s precedents. The Court affirmed the Board’s decision of obviousness holding that the patentee pursued known options within his/her technical grasp.

In **Cordis Corporation v. Medtronic Ave, Inc.**, 511 F.3d 1157 (decided on January 7, 2008), one issue on appeal was a challenge to a jury instruction on obviousness. The instruction at issue was:

“If the prior art references as a whole do not teach, suggest or motivate that combination, then they may not be combined. The mere fact that the prior art can be modified does not make the modification obvious unless the prior art suggests the desirability of the modification.” “A suggestion to combine references may also flow from the nature of the problem or from the ordinary knowledge of those skilled in the art that certain references are of special importance.”

In upholding the instruction as proper, Judge Bryson **rebuffed the argument that KSR resulted in a significant change in the law to warrant a new trial**. The Court noted that **KSR** made clear that the TSM test cannot be rigidly applied so as to limit the obviousness inquiry. Judge Bryson noted that the Supreme Court stated there no inconsistency between the idea underlying the TSM test and the *Graham v. John Deere* and that the TSM test can provide helpful insight to an obviousness inquiry. **Cordis**, 511 F.3d at 1172. The Court held no new trial on obviousness was warranted.

In **Innogenetics, N.V. v. Abbott Laboratories**, 512 F.3d 1363, (decided on January 17, 2008) one aspect of the appeal was the exclusion of an expert report. The issue on appeal was whether the expert opinion on obviousness which made mere conclusory statements after listing several prior art references, was sufficient under FRCP 26. The Federal Circuit, in an opinion by Judge Moore, affirmed the decision to exclude the expert testimony. The basis for the opinion was the statement in **KSR** that the analysis to determine whether there was an apparent reason to combine the known elements in the fashion claimed must be explicit, citing **In re Kahn**:

“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”. **KSR**, 127 S.Ct. at 1741.

The expert stated that a prior art reference provided the motivation to find a method of genotyping. However, Judge Moore stated: “knowledge of a problem and motivation to solve it are entirely different from motivation to combine particular references to teach the particular claimed method.” The Court observed that while the Supreme Court made it clear in **KSR** that the TSM test cannot be a rigid rule that limits the obviousness inquiry but noted that “We must 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 considered to produce the claimed invention.”

In **Erico International Corporation v. Vutec Corporation**, 516 F.3d 1350 (decided on February 19, 2008), Judge Rader rendered the opinion for the majority with a dissenting opinion by Judge Newman. A preliminary injunction was granted by the District Court, but the Federal Circuit vacated it, holding there was a substantial question regarding obviousness. The asserted claims had survived reexamination. The District Court held that because the prior art was already considered by the PTO, and in view of evidence of commercial success and actual copying, the patent was likely to be found not invalid at trial. The Federal Circuit reversed holding there was an implicit motivation to combine based on the prior art references and common sense and common knowledge based on testimony of the inventor. In the majority’s view, the evidence raised a severe challenge to validity sufficient to negate likelihood of success. In Judge Newman’s dissenting view the majority ignored the factors of commercial success and copying. She accused the majority of using hindsight. In her opinion, the preliminary injunction was not an abuse of discretion. Judge Newman believed the majority was influenced by fact it was a simple invention. **Enrico**, 516 F.3d 1359, 1360.

In **Agrizap, Inc. v. Woodstream Corporation**, 2008 WL 819757 (Fed.Cir.(Pa.)) (decided March 28, 2008), the jury held the patent not invalid and JMOL was denied as to invalidity. The Federal Circuit reversed on invalidity and found the patent invalid. Judge Moore started by quoting **KSR** that “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” **KSR**, 127 S.Ct. at 1739. Federal Circuit held that this was a classic case of predictable results. Prior art product had all claimed elements except it had a mechanical pressure switch instead of a resistive switch. The Court found that evidence of commercial success, copying and long-felt need was not enough to overcome the strong *prima facie* case of obviousness.

Ortho-McNeil Pharmaceutical, Inc., v. Mylan Laboratories, Inc., 2008 WL 834402 (Fed. Cir. (N.J.)) (decided March 31, 2008), the Federal Circuit, by Rader, affirmed the denial of summary judgment of invalidity. Judge Rader addressed the issue of a finite number of predictable solutions in the context of a patent for the drug Topiramate. In **KSR**, the Supreme Court stated:

“[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. If this lead 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.” (emphasis added). **KSR**, 127 S.Ct. at 1742.

The Court interpreted this statement in **KSR** as follows:

The passage above in **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.

In the context of this case, the Court held that there must be some reason to select, among several unpredictable alternatives, the exact route to arrive at the same compound and then have a reason to stop and test it for properties far afield from its known use. The Court also held that there was evidence of objective criteria of non-obviousness such as powerful, unexpected results, skepticism of experts, copying, and commercial success. Judge Rader noted that the Federal Circuit’s flexible TSM test remains the primary guarantor against hindsight. A flexible TSM test assumes that obviousness is determined on the basis of evidence which is consistent with the requirements in **KSR** that the teaching need not be written, but within knowledge and creativity of the ordinary skilled artisan.

The Federal Circuit has given notice that as far as it is concerned, the law on motivation to combine has not changed. Whether that actually turns out to be true, we will have to wait and see.