
US Legal and Regulatory Update

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What is obvious?

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INTRODUCTION

The generic industry has strong incentives to challenge innovator patents to clear the way for low-cost competition. While patent challenges are often based on a variety of grounds, the central issue of whether the invention was obvious at its inception has always been a primary and often-litigated issue. If an invention was obvious, the patent should never have issued in the first place, and if asserted in litigation, it should be invalidated thus clearing the way for generic competition.

US patent law has long provided that a patent shall not stand if the claimed invention is obvious. This is expressed in 35 U.S.C. § 103 (a) that states in relevant part:

A patent may not be obtained though the invention is not identically disclosed or described [in the prior art], if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

The statute finds application in a variety of different forums:

- (a) during patent office examination;
- (b) during re-examination proceedings before the PTO (Patent and Trademark Office);
- (c) at the administrative appellate level within the PTO (Board of Patent Appeals and Interferences);
- (d) at the District Court level in both infringement actions and administrative review of Appeals from the PTO; and
- (e) at the Appellate level before the Court of Appeals of the Federal Circuit (the Court

of exclusive jurisdiction for all patent appeals).

But obviousness is in the eye of the beholder. Given that patents are presumed to be valid under 35 U.S.C. § 282, the burden of proving an invention obvious is a heavy and daunting one. Given the recognised reduced predictability in the pharmaceutical field, some very marginal ‘inventions’ benefitted considerably from the extra hurdle that the case law provided, that is, that an invention was not obvious unless it was clearly suggested in writing.

This paper will first summarise the background in layman’s terms and then examine the change in law brought about by the recent Supreme Court decision *KSR Int’l Co. v Teleflex Inc.*¹ I will then speculate on how the decision will filter through the various forums listed above. This paper is not meant to be a probing legal analysis of the minutiae of *KSR*. Rather, this paper is more intended to present what I believe may be the real-world impact of the case.

BACKGROUND

The very subjective nature of the obviousness question has challenged the courts for the longest time. Without tracing its lengthy history, it suffices to note that subsequent to adoption of the 1952 Patent Act that has framed the law to this date, in 1966 the Supreme Court took on the challenge of guiding the Courts and the PTO in *Graham v John Deere Co.*² The case was notable in that it sought to set out guideposts deemed helpful in determining whether an invention was obvious. It was possibly most notable in

setting out the secondary indicia of nonobviousness to be consulted in deciding the issue. These include commercial success, long felt but unsolved needs, failure of other to solve the problem, etc.³

Graham recognised that the question of obviousness is inherently subjective, and that there would not be 'uniformity of thought in every given factual context'.⁴ Nevertheless, the decision provided hope that adherence to the guidelines provided therein would result in a greater measure of uniformity and definiteness.⁵

At about the same time, the PTO was undergoing a shift in its basic practice in order to shorten patent prosecution. Under its new practice, in order to prevent endless back-and-forth between the PTO and patent applicants, patent examiners were required to bring patent prosecution to a close after just an initial and final rejection. Examiners were instructed to carefully heed the teachings of *Graham* and not to rely on their own imaginations to find suggestions of obviousness, but, rather, to heed the written word, and rely upon suggestions in the documents themselves as the basis for obviousness rejections.⁶ By obliging examiners to reference the written word as the basis for their rejections, it was hoped that arbitrary discretion would be minimised, with a reasonable expectation of greater uniformity and predictability.

Graham became the touchstone of almost every brief written on the obviousness issue, and was widely incorporated into jury instructions and published decisions. And so it went for 40 years!

Upon its inception in 1982 and until this year, virtually every decision on obviousness from the Court of Appeals for the Federal Circuit (CAFC)⁷ typically cited to *Graham*, and often with the admonishment that there had to be some teaching in the documents themselves to combine concepts to arrive at the invention, in the absence of which an invention was deemed patentable.⁸ That is, evolving case law implemented a requirement

that there had to be some teaching, motivation, or suggestion to combine the prior art, within the prior art itself. This has come to be known as the TSM test (for teaching, suggestion or motivation).

The obvious justification for this approach was the desire to avoid the impermissible use of hindsight to arrive at the claimed invention. Thus, experts were often expected to point to particular written teachings to support their positions on obviousness, absent which they were subject to attack as having deviated from the written word and having impermissibly relied upon insight. To be fair, language in some cases was more flexible and less tied to specific statements in documents, but by and large these were the exceptions.

In pharmaceutical cases, the inherent unpredictability of certain pharmaceuticals combined with the requirement that there be an actual suggestion to perform the invention posed a tough challenge to every generic challenger seeking to prove an invention obvious. Merely imagining that an invention was 'obvious to try' was simply not enough to establish that an invention was obvious because pharmaceuticals are deemed unpredictable.⁹

Thus, there was a more or less uniform understanding among the PTO, the District Courts, the CAFC and, for that matter, the practising Bar, on how the issue of obviousness was to be addressed.

TIME FOR A CHANGE

Courts do not decide cases in a vacuum. Judges and juries read the newspapers and they observe what goes on around them.¹⁰ The upswing in patent activity in the US can hardly have escaped the notice of even the most disinterested observer. Huge awards for infringement have become frequent, often for what have been criticised as the most marginal of inventions. The high-tech industries have been whipsawed in one case after another, and many a case has been settled rather than risk leaving the question of obviousness to a judge or jury forced to rely

upon an express teaching in prior documents to justify invalidity based upon obviousness.

Congress set about adjusting the rules of the game with little success. But the Supreme Court saw an opportunity. In the short space of a year it issued three landmark patent decisions, which sought to significantly level the playing field and bring balance back to the patent system.¹¹ This paper focusses on the *KSR* case.

THE *KSR* CASE

The case of *KSR v Teleflex* began with a lower court determination that the invention was obvious. Indeed, the judge in the case found the invention obvious on summary judgment (ie, by the judge, even prior to trial) by making his determination based upon the papers filed and expert testimony. To arrive at the claimed invention, the accused infringer pieced together four prior art teachings to arrive at the claimed invention, and the judge concluded that the invention was obvious.

Upon appeal however, the CAFC acted somewhat predictably and reversed the lower court because it had relied upon unsupported testimony, rather than teachings from the documents themselves, in order to justify a finding of obviousness.

The infringer appealed and in a rare show of interest the Supreme Court granted a Writ of Certiorari — it would hear the case. Change was coming. Oral argument was heard on 28th November, 2006, and a transcript of the oral argument is available online.¹² From the nature and tone of questions from the Justices, it was immediately clear that a new pronouncement would be forthcoming.

For its part, the CAFC did not wait to find out. In some notable decisions rendered after the Supreme Court oral argument in *KSR*, apparently anticipating what it considered unjustified criticism, the CAFC made a point of explaining that indeed it had not been wed to a strict formula for analysing obviousness. In one case, the CAFC wrote that the TSM test 'is in actuality quite flexible and not only permits, but *requires*, consideration of common

knowledge and common sense'.¹³ In another case, the CAFC wrote '[t]here is flexibility in our obviousness jurisprudence because a motivation may be found *implicitly* in the prior art. We do not have a rigid test that requires an actual teaching to combine ...'.¹⁴

KSR was decided on 30th April, 2007. In a 24-page decision, the Court reversed the decision of the CAFC. The decision explained that the precedential case of *Graham* had been misapplied for over 40 years and that the Supreme Court would once again explain that there was no single formula for evaluating obviousness. It recognised that TSM (teaching, suggestion and motive) was one approach,¹⁵ but that it was not the only one. They said:

In the years since the Court of Customs and Patent Appeals set forth the essence of the TSM test, the Court of Appeals no doubt has applied the test in accord with these principles in many cases. 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.¹⁶

The Court duly noted the intervening 'clarifying' decisions of the CAFC¹⁷ but then took the bull by the horns and proceeded to leave no doubt about its view. The Court opened the door to reliance on an expert's opinion whether backed with a written document or not. The Court stated that indeed that there was no categorical reason for dismissing a particular approach as presumptively insufficient to render an invention nonobvious because it is merely 'obvious to try'.

The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was 'obvious to try'. The Supreme Court observed that 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 §103.¹⁸

On this point, too, the CAFC may have anticipated what the Supreme Court ruling was to have been. On 22nd March, 2007 (after *KSR* oral argument, but before decision), the CAFC handed down its decision in the case of *Pfizer v Apotex*.¹⁹ That case involved amlodipine, and whether or not selection of the besylate salt of that drug was obvious. The CAFC noted that relatively few salt forms were accepted in the pharmaceutical industry. In an apparent attempt to finesse the issue, the CAFC stated that it is still true that ‘obvious to try’ is not obvious. Nevertheless, the case held that where there is a small group of candidates to choose from, and testing procedures are routine, then each candidate is obvious, and not merely obvious to try.²⁰

The Supreme Court promoted yet a new concept, the difference between ‘inventions’ and ‘patentable inventions’. In discussing this two-tiered paradigm, the Court indicated that patenting minor inventions might actually be contrary to the very purpose behind the patent system:

We build and create by bringing to the tangible and palpable reality around us new works based on instinct, simple logic, ordinary inferences, extraordinary ideas, and sometimes even genius. These advances, once part of our shared knowledge, define a new threshold from which innovation starts once more. And as progress beginning from higher levels of achievement is expected in the normal course, the results of ordinary innovation are not the subject of exclusive rights under the patent laws. Were it otherwise patents might stifle, rather than promote,

the progress of useful arts. See US Const., Art. I, §8, cl. 8. These premises led to the bar on patents claiming obvious subject matter established in *Hotchkiss* and codified in §103. Application of the bar must not be confined within a test or formulation too constrained to serve its purpose.²¹

To be fair, the Court did not completely reject the previous TSM approach, but took pains to point out that the TSM approach was not exclusive and that other methodologies for establishing obvious were possible as well.²² Bear in mind that the Court had no difficulty in these determinations being made on summary judgment, before a final trial on the merits.

IMMEDIATE REACTION

KSR can be expected to have a long-term effect in patent litigation. Its immediate impact might be less clear. As of this writing, the Federal Circuit has not yet released a precedential opinion that discusses *KSR* or its ramifications in detail.

In one case, the Federal Circuit invalidated a patent for obviousness, and cited the *KSR* decision for the well-settled proposition that a ‘combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results’.²³

In another case, involving the drug amlodipine, a divided Federal Circuit declined to permit the full panel of the court to review and reconsider the three-judge panel’s invalidation of a patent covering the billion-dollar-plus drug.²⁴ Employing an ‘obvious to try’ standard, a divided (6–3) opinion maintained the obviousness rejection based at least in part on an ‘obvious to try’ standard.

The USPTO for its part, plagued with a multitude of patent applications awaiting disposal reacted predictably with a pronouncement that there was no need to alter its practice in light of the decision. In a Memorandum dated 3rd May, 2007, the US

PTO noted a number of points about the *KSR* decision, and concluded by stating:

[I]n formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed.

It is quite possible that the PTO simply could not bear the thought of applying heightened obviousness criteria that would only have served to increase its already massive backlog of pending patent applications.²⁵

KSR will undoubtedly play a significant role in re-examination proceedings where examiners will have an additional tool at their disposal should they deem an invention obvious, knowing that their chances of withstanding an appeal may be improved.

District Courts, too, have reacted at least initially in several cases, although a representative number of cases will not be available for some time. In one noteworthy example, the patent on Pepcid[®] Complete was found invalid as being obvious.²⁶ The invention was directed to a bead combination tablet that solved instability problems by coating one of the pellet components. The District Court chose to find the invention obvious because the coating also served to mask unpleasant taste of one of the components, a reason having nothing to do with stability.

Bearing in mind that *KSR* condones obviousness determinations prior to trial, we are likely to see an increased number of invalidation motions being filed early on to give judges the opportunity to avoid lengthy and unnecessary discovery and trials.

It would be wrong to assume that reaction in the courts will be uniform. For example, in an order rendered after the *KSR* decision, a District Court found a patent relating to clopidogrel (Plavix) to be valid and unobvious, without any mention of *KSR* at all.²⁷

Although very difficult to quantify, it is reasonable to expect as well that *KSR* will inject an additional element into settlement considerations, thus increasing the likelihood of settlements prior to trial.

CONCLUSION

The *KSR* case opened up and expanded the obviousness inquiry, and has given judges and examiners additional room for consideration. It is unlikely that reaction will be immediate, or, for that matter, uniform. The next year or two will tell the story, and with the vast number of pharmaceutical cases now pending, there are likely to be numerous attempts by generics to apply *KSR* in the particular framework of pharmaceutical inventions.

ADDENDUM

After this article was submitted for publication, a recently decided case from the Patent Office Board of Patent Appeals and Interferences was published.²⁸ *Ex parte Kubin*, Westlaw (PTO Bd. App. 31st, May 2007), is a preliminary indication of how the Board of Appeals and Interferences is applying *KSR*. In this case, before an enlarged panel of administrative law judges, the Board issued a precedential decision in which it found that the prior CAFC decision on obviousness (*In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995)) had been effectively overruled by the *KSR* case. In a biotechnology context the Board said:

To the extent *Deuel* is considered relevant to this case, we note the Supreme Court recently cast doubt on the viability of *Deuel* to the extent the Federal Circuit rejected an ‘obvious to try’ test. *See KSR Int’l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, ___, 82 USPQ2d 1385, 1394, 1396 (2007) (citing *Deuel*, 51 F.3d at 1559). Under *KSR*, it’s now apparent ‘obvious to try’ may be an appropriate test in more situations than we previously contemplated.

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. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.’ *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, ___, 82 USPQ2d 1385, 1397 (2007).

Based upon this and other considerations, the Board found the claims at issue unpatentable for obviousness. Because the area of biotechnology has traditionally been one of the most difficult areas for proving obviousness (due to inherent unpredictability), this Board decision may be one early indication of how *KSR* may be applied.

References and Notes

1. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. ____ (case 04-1350) (2007).
2. *Graham v John Deere Co.*, 383 U.S. 1 (1966).
3. *Id.* at 17–18.
4. *Id.* at 18.
5. *Id.*
6. This is currently codified in the Manual of Patent Examining Procedure at MPEP § 2144.
7. The Court of Appeals for the Federal Circuit (or CAFC) is the court designated to hear all appeals in patent cases in the US.
8. See, for example, *Medichem S.A. v Rolabo, S.L.*, 437 F.3d 1157, 1164 (Fed. Cir. 2006); *Tec Air, Inc. v Denso Mfg. Michigan Inc.*, 192 F.3d 1353, 1359 (Fed. Cir. 1999).
9. See, for example, *Merck & Co., Inc. v Biocraft Laboratories, Inc.*, 874 F.2d 804, 806 (Fed. Cir. 1989). See, also, *Medichem*, 437 F.3d at 1165.
10. This is not to impugn the impartiality of the judge or jury. Judges and juries are members of society, and have to be members of society in order to perform their roles. Naturally, this means that to a greater or lesser extent, judges and juries are aware of current events, and can be expected to place a litigation into that context.
11. In addition to *KSR*, the Supreme Court decided *eBay, Inc. v Mercexchange, L.L.C.*, 547 U.S. ____ (2006) (holding that an injunction is not an automatic right when a patent owner wins an infringement case); and *Medimmune, Inc. v Genentech, Inc.*, 549 U.S. ____ (2007) (holding that a patent licensee paying royalties has the right to sue for a declaratory judgment of patent invalidity).
12. http://www.supremecourt.us/oral_arguments/argument_transcripts/04-1350.pdf.
13. *DyStar Textilfarben GmbH & Co. v C. H. Patrick Co.*, 464 F.3d 1356, 1367 (2006).
14. *Alza Corp. v Mylan Labs, Inc.*, 464 F.3d 1286, 1291 (2006).
15. *KSR*, slip op. at 14–15.
16. *KSR*, slip op. at 15.
17. *KSR*, slip op. at 16–17.
18. *KSR*, slip op. at 17 (internal citation omitted).
19. *Pfizer, Inc. v Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007), *pet. for reh’g en banc denied* ____ (2007).
20. *Pfizer*, 480 F.3d at 1365–67.
21. *KSR*, slip op. at 23–24.
22. *KSR*, slip op. at 14–15.
23. *Leapfrog Enterprises, Inc. v Fisher-Price, Inc.*, Fed. Cir. No. 06-1402, slip op. at 7 (9th May, 2007).
24. *Pfizer v Apotex*, Fed. Cir. No. 06-1261 (21st May, 2007).
25. However, subsequent to the latest three Board of Appeals decisions (see footnote 28) the PTO will be issuing new guidelines to Examiners and will be conducting dedicated tutorials to all Examiners on how *KSR* is to be applied.
26. *McNeil-PPC Inc. v Perrigo Co.*, S.D.N.Y., No. 05 Civ. 01321 (5th June, 2007).
27. *Sanofi-Synthelabo v Apotex, Inc.*, S.D.N.Y., No. 02 Civ. 2255 (19th June, 2007).
28. Two other decisions issued at the same time in the mechanical and electrical technologies separately applied *KSR* in those technological areas as well, but are not discussed here.