

**U.S. IP LAW - POST KSR
Re: Pharmaceutical Inventions**

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This article examines the current disposition of the U.S. Courts towards patents, with especial attention to pharmaceutical patents and inventions.

Prior editions of this journal contained two articles on recent U.S. Supreme Court cases. The first article discussed the *Medimmune* case (See Vol. 10, No. 2 April-May 2007) while the second one dealt with *KSR*, *eBay* and *Quanta* cases (See Vol. 11, No. 1 Feb-Mar. 2008). Both articles discussed future licensing situations in the U.S. In summary, as a result of these decisions, it is now easier for licensees to challenge licensed patents and have the patents tested under a standard of patentability more strict, arguably, than that in effect at the time the licensed patents were issued by the USPTO. These articles contained suggestions for both licensors and licensees as to ways to deal with the changing patent landscape in the United States.

This article will address the progeny of the Supreme Court's *KSR* decision at the Court of Appeals for the Federal Circuit (CAFC), with comments as to how to defend and procure patents under current conditions and recommendations on improved preparation of patent applications in the first instance.

There is, by most credible accounts, an anti-patent sentiment extant within the United States. The reasons for this apparent bias are manifold: 1) An expensive health-care system with patents on pharmaceuticals often blamed; 2) Business method patents held by companies characterized as "patent trolls," i.e., "ambushers," by those being sued; and 3) The dominant size of companies such as Intel, Microsoft and similar large IT companies where a strong patent portfolio may be of lesser importance now to the continuation of their success.

This anti-patent sentiment is of recent origin and can be (will be?) very detrimental to entrepreneurs in any technological area since venture capitalists typically require a defensible patent portfolio before any investment is made. The pharmaceutical industry regardless of size, in particular, may also be adversely affected for obvious reasons. Those knowledgeable of the U.S. situation are aware that in proposed legislation for patent "reform," there are opposing sides; the large IT companies led by Intel on one side and the

pharmaceutical industry on the other. Even the USPTO recently proposed what many regarded as anti-patent rules, which rules will not be enacted currently since it was held in *Tafas and SmithKline Beecham v. Dudas* that the rules were substantive in nature and beyond the authority of the Commissioner of Patents to effectuate.

Legislative action may not occur until 2009, given the current diverse opinions being urged on legislators and the pending presidential and congressional elections. In the meantime, how do companies dependent upon strong patent portfolios successfully navigate these turbulent waters?

The conditions for patentability of an invention in the United States are several, namely: 1) It must fit within the statutory definition (35 USC § 101) - which until recent decades was interpreted to exclude "business methods;" 2) It must be novel (35 USC § 102), i.e., not exactly the same as some prior invention; and 3) That the invention as a whole be not obvious (35 USC § 103) to one ordinarily skilled in the relevant art. It is this third test which, in the view of most patent law commentators, has now been altered to be more strict in view of the Supreme Court's decision in *KSR*.

Recent cases at the CAFC indicate that it has been chastened by the Supreme Court's *KSR* decision wherein one Supreme Court justice referred to the CAFC's long-employed TSM test (teaching-suggestion-motivation test) – an ostensibly objective test for determining obviousness - as "gobbledy-gook," thus deprecating two-decades plus of law understood by the USPTO, the patent bar and the courts.

Does that leave us with the philosophical notion that an invention, like beauty, is "in the eye of the beholder?" The CAFC at this moment, appears to say "no." Its view is that *KSR* condemned only sole reliance on the "TSM" test as the standard for patentability under §103. In *Takeda Chemical Industries Ltd. v. Alphapharm Pty, Ltd* (June 2007) the CAFC stated that the TSM test is still relevant, indicating that the Supreme Court in *KSR*, held that reference also should be made to the patentability tests set up in the *Graham v. John Deere* Supreme Court case (383 U.S. 1 (1966)) wherein it is first to be determined whether there is a prima facie case of "obviousness," i.e., non-patentability, which then may be overcome by secondary factors such as unexpected results, commercial success, long-felt need, failure of others and similar factors.

In *Takeda*, *supra*, the CAFC, insisting that its test for *prima facie* obviousness was consistent with *KSR*, rejected defendants' contention that a *prima facie* case of obviousness had been established. The court stated: "[I]n 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 chemical compound" (emphasis added). On March 31, 2008 the Supreme Court denied a Petition for a Writ of Certiorari by Alphapharm, thus the CAFC's decision on the validity of *Takeda's* patent stands.

Since KSR, the Supreme Court has not decided to review any further decisions of the CAFC on the “obviousness” question, regardless of whether a patent’s validity or invalidity was the holding.

In contrast to Takeda, the CAFC in *Aventis Pharma Deutschland GmbH v. Lupim, Ltd.* (Sept. 2007) reversed a trial court’s finding of validity, with Judge Linn observing: “Since the date of that decision (the trial court’s decision), the Supreme Court (in KSR) --- counsels against applying the --- TSM test as a ‘rigid’ formula.” It remains necessary to show some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness --- but such reasoning need not seek out precise teaching directed to the specific subject matter of the challenged claim” (emphasis added).

As to the particulars of the Aventis case, the court noted that one expects a concentrated or purified ingredient to retain the same properties it exhibited in a mixture and for those properties to be amplified in concentrated or purified form, thus it rejected Aventis’ attempt to establish unexpected results.

In a more recent case, *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.* (CAFC, March 31, 2008), the court found a patent claiming a treatment for epilepsy to be not invalid because the opuamate compound showed unexpected anticonvulsant properties. The chemical had first been directed as a diabetes cure so that its properties for epilepsy were not anticipated.

While, since KSR, the CAFC has paid close attention to KSR, it has not been invalidating patents wholesale on the basis of obviousness.

Given the current situation, holders of patents and patent applicants are well advised to prepare to defend their existing patents and prosecute pending applications with the understanding that a stronger showing of non-obviousness probably will be required.

With respect to holders of pharmaceutical patents, be prepared to show, should litigation occur:

1. That initially there were failed experiments (by others and by inventors), before the invention was ultimately perfected;
2. That others had failed to achieve success or had failed to perceive the unique pharmacological characteristics of the invention;
3. That prior publications, patents, etc., taught away from the invention; i.e., analogs, homologs, isomers, including stereo isomers, were not indicative of the desirable properties of the invention. (This is especially true if there are few options to be tried);
4. That prior publications, patents, etc. recognized a need for further research in the area that the invention addresses;
5. That results were unexpected, synergistic or some similar important technical achievement resulted;
6. That the invention has achieved commercial success;

7. That others have copied the invention; and
8. That others have taken licenses to the invention, thus recognizing its significance.

Every holder of an important U.S. Patent should anticipate adverse litigation and archive important early experimental information and obtain affidavits from experimenters as to the conditions and the state of the art at the time the invention was made. This procedure should be done under the direction of, preferably, a U.S. attorney in “anticipation” of litigation so that to the extent desired, such information could be protected under the attorney-client privilege or the attorney’s work-product doctrine when litigation occurs later.

It may be advisable to compile contemporaneously such information early in the experimentation phase in the event the experimenters are not available at a later date. Such information and preparation may include the preparation of Declarations (such as under 37 C.F.R. § 1.132) from the inventors or others skilled in the art noting the aspects of patentability listed above. For example, Declarations interpreting the results as unexpected given the state of the prior art. This avenue may be of particular importance in light of statements by the Supreme Court in *KSR* that a patentable invention must function in a manner that would not be predicted by one of skill in the art at the time the invention was made.

While the use of Declarations in patent cases may expose the Declarant to rigorous interrogation during any later litigation, an unequivocal Declaration is strong evidence in the eyes of the USPTO that may be difficult for an examiner to overcome in continuing to reject the application on the grounds of obviousness (see, e.g., *In re Sang Su Lee*, 277 F.3d 1338 (CAFC 2002) and *In re Zurko*, 258 F.3d 1379 (CAFC 2001) (together noting that obviousness is a factual determination that must be based on the material evidence of record and that a Declaration constitutes such material evidence).

For inventors and the agents/attorneys representing them, it may be prudent at every stage from conception, to reduction to practice of the invention, to the preparation and prosecution of patent applications, to be mindful of the evolving criteria of patentability in the U.S. Also, it may be important to look for data which supports synergism or unexpected results as well as identifying earlier or contemporary publications which “teach away” from the invention.

Patent applications filed in Europe/United Kingdom jurisdictions present a challenge in that these are first-to-file jurisdictions, which compels filing at the earliest opportunity. Such a filing, however, may be before the availability of later data which would show synergism or unexpected results. Such an early-filed priority document, for U.S. filing purposes, may present difficulties later in prosecution of the U.S. application.

Part of the problem during prosecution of such a companion application in the USPTO is that commercialization, especially of pharmaceuticals requiring FDA approval may not have occurred. Thus, secondary factors such as

commercial success, copying by others, recognition of the invention's value via licensing by others etc. may not have occurred and any information of synergism, unexpected results etc. not found in the priority document may not be subsequently incorporatable in the companion U.S. application but admitted as a Declaration, as indicated hereinabove.

In summary, the expertise and experience of the patent attorneys and patent agents representing inventors becomes ever more important.