

PHARMA IP AND THE U.S. SUPREME COURT

(2006 - 2008)

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Four recent U.S. Supreme Court cases will affect how patents are procured, licensed and litigated in the United States.

These cases are, in chronological order, eBay v. MercExchange, Genentech v. Medimmune, KSR International v. Teleflex and Quanta Computer, Inc. v LG Electronics (argued on January 16, 2008).

The Medimmune case (subject of an article published in the April/May 2007 edition of Pharma Patent Bulletin) changed the law as to when a Declaratory Judgment (D/J) action could be brought to have a patent declared invalid and/or non-infringed. Medimmune, a licensee in full compliance with all the provisions of the license, was permitted to contest via, a D/J action, the validity and/or infringement issues of the licensed patent while operating under the security of the license, with only the risk of having to pay the agreed-upon royalty if the D/J action were unsuccessful.

Prior to Medimmune a licensee had to renounce (breach) the license so that it was at risk of suit by the patentee/licensor for infringement and potential injunction before a D/J action could be brought. However, the Supreme Court reasoned that since Medimmune's net income was almost wholly dependent upon the licensed product, Medimmune should not have to risk the possibility of an injunction against it as a "non-licensed" infringer in order to contest a patent it alleged was either not infringed and/or invalid. Thus, the Supreme Court sanctioned "a free bite at the apple" for patent licensees.

In the aforementioned article, suggestions were offered for licensors and licensees in existing or prospective license arrangements to ameliorate problems raised by the Medimmune decision.

The eBay case was decided before Medimmune clarified existing law. In that case, the Supreme Court held that a prevailing patentee is not entitled, as a matter of right, to an injunction against an infringer.

In the eBay case it was held that a patentee succeeding in litigation had to meet the same tests for injunctive relief as any other prevailing litigant. These tests being: 1) that plaintiff has suffered irreparable harm; 2) that there is no adequate remedy at law to compensate for the injury; 3) that considering the balance of hardships between the plaintiff and the defendant, a remedy in equity is warranted; and 4) that the public interest would not be disserved by a permanent injunction.

While the elements of such a test may be met in litigation by a successful patentee, the likelihood of a debilitating injunction issuing against an adjudicated infringer is much diminished in many cases.

The jurisprudence exercised by the Supreme Court in eBay is sound. The court faulted the District Court in refusing the prevailing Patentee-Plaintiff (MercExchange) an injunction because it had licensed others. The CAFC reversed, categorically, finding in favor of an injunction based upon long-standing precedent that a prevailing patentee is so entitled other than “in exceptional cases.”

The Supreme Court chastised both courts for failing to apply each element of the equitable test for injunctive relief. Thus, in future cases each party to a patent suit should be prepared to produce evidence and rational argument on each element as to why or why not a permanent injunction should issue.

For example, in the Medimmune case, the lynchpin of the Court’s reasoning was the disastrous effect (potential bankruptcy), of an injunction possibly issuing against Medimmune if it breached. Under the eBay rationale, however, no “automatic injunction” would have issued against Medimmune, and it can be rationally argued that none would have issued because there was an adequate remedy at law, namely, a monetary award based upon the previously negotiated royalty between the parties. Such a royalty could hardly be argued as inadequate. Even in such a circumstance, eBay stands for the proposition that the four elements cited above must be addressed by the court and the parties.

Although the logic of Medimmune can be argued to be internally inconsistent (see previous article) and, perhaps, at odds with the holding in eBay, both cases indicate a strong interest by the U.S. Supreme Court in the philosophy of IP law in the U.S.

The third case, KSR v. Teleflex, further shows the Supreme Court’s intention to leave its imprimatur on the patent landscape. In KSR, the court addressed the issue of patentability under 35 USC §103 which requires the “invention as a whole” not to be obvious to one of ordinary skill in the art at the time the invention was made.

In KSR, the Supreme Court addressed the “obviousness standard” as enunciated in the “teaching/suggestion/motivation” (TSM) test historically followed by the CAFC and the USPTO. The TSM test was generally employed as an objective test to require that the prior art set forth a “teaching” of the invention at issue in a combination of references, a “suggestion” therein to combine such references, and a “motivation” to combine same.

The TSM test had been adopted as rational analysis to preclude inventions being adjudged “obvious” by subjective “hindsight” reasoning.

The Supreme Court reversed the CAFC’s holding of patentability in KSR and condemned the rigid application of the TSM test. The court stated “The

combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”

A further quote from KSR indicates the Supreme Court’s attitude, “Where 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 known options within his or her grasp. If this leads to the anticipated success, it is likely the product is 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).

Although warning against hindsight analysis and urging the testing of inventions by the template of long felt need and failure of others, unexpected results or commercial success, the KSR decision has been viewed with antipathy by many U.S. patent attorneys.

The KSR opinion has resonated within the CAFC. In *Aventis v. Lupin* the “TSM” test was noted as having been too “rigidly” applied in the past and that the prior art does not require “explicit” teaching in order to support a conclusion of obviousness.

The CAFC reversed a holding of “non-obviousness” by the District Court stating, “Obviousness is a question of law reviewed de novo, based upon underlying factual questions which are reviewed for clear error....”

The CAFC then observed that since the District Court’s decision, the Supreme Court had rendered its decision in KSR.

Then citing its own precedence, and that of the prior patent court (the Court of Customs and Patent Appeals, known as the CCPA), the CAFC stated “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.” Then, it states that the “reason or motivation” need not be an explicit teaching - - it is sufficient to show that the claimed and prior art compounds possess a “sufficiently” close relationship - - to create an “expectation” - -that the new compound will have “similar properties” to the old.

The Court then concludes, “one who claims a compound per se, which is structurally similar to a prior art compound must rebut the presumed expectation has similar properties...”

The Court then concluded in the facts before it that the claimed compound was in a racemic mixture, the method of separation was known and that the purified compound had potency expected of such a purified compound, thus holding the patent on SSSSS acampril to be obvious, permitting Lupin to proceed with its ANDA process.

One effect of these cases is that a patent licensor in the United States can have its licensed patent contested by its licensee who still enjoys the sanctuary

of the license and to have the patent's validity challenged under a more stringent test than when the patent was originally allowed by the U.S. Patent Office.

Even if a licensee breaches (renounces the license and discontinues paying royalties) before filing a D/J action, the downside for the licensee, if it is found to infringe and the patent survives, there is a minimal risk of an injunction issuing per the rationale of the eBay decision.

The suggestions set forth in the aforementioned article on Meddimmune for licensors/licensees are even more pertinent following eBay and KSR.

Licensors, especially, need to audit existing licenses and to exercise prudence with respect to future licenses and be prepared to defend the validity of all commercially important patents under the standards enunciated in the KSR case.

The fourth case, Quanta, has yet to be decided, but from the questions and comments of the Supreme Court during oral argument, the result is expected to be adverse to the patentee-licensor. Quanta addresses the principle of patent exhaustion, also referred to as the "first sale doctrine." The facts of the case involved the license and sale of electronic components. The infringement action by the Patentee-licensor was against purchasers of licensed components who then combined them into a structure which infringed licensor's unlicensed system patents.

If the result, as anticipated, is a ruling that the first sale of components exhausts a patentee's rights as to other patents on combinations of those components, the decision can have implications far beyond the electronics industry.

In a pharmaceutical setting, a company may have a patent on Compound A, a physiologically active composition, including claims to its method of manufacture (First Patent) and also a second patent on a combination of Compound A with other materials, to form, for example, a time-release composition. Would the patentee be precluded from suing an infringer of the Second Patent because the putative infringer had bought Compound A from a Licensee of Patentee under the First Patent?

How would the situation affect a company which holds two separate patents; one upon a pharmaceutical and another upon its metabolite?

The Quanta decision apparently means that a patentee who holds a bundle of patents, cannot license certain basic patents, e.g., sub-combination patents within that bundle without an "implied license" being imputed by law to all related patents in that bundle. Thus, commercial arrangements involving the licensing of any such patents becomes much more complex. What does such a concern do to the strategy of patenting precursors, active ingredients and pharmaceutical compositions containing such active ingredients? (None of the courts which addressed the Quanta case found related method patents to have been

“exhausted.” Thus, a word to the wise: file applications on methods of manufacture, methods of use and methods for synthesizing metabolites and methods for testing for effective dosages of a pharmaceutical and its metabolites, etc.).

If the Quanta case rationale cascades over to situations in the pharmaceutical industry, will that result further exacerbate the schism between the electronics industry, as represented by companies such as Intel, and the pharmaceutical industry. Adverse positions between these industries are currently being evidenced in the tension involved in U.S. Congressional legislation on “Patent Reform.”

A revealing insight into the Supreme Court’s concerns about patents is found in a concurring opinion in eBay which views injunctive relief as a strategy by some patentees to “extort exorbitant royalties.” Further, in that opinion it is stated: “An additive injunctive relief may have different consequences for the burgeoning number of patents over business methods which were not of much economic and legal significance in earlier times.” The opinion then notes: “The potential vagueness and suspect validity of some of these patents...”

Thus, the antipathy towards patents as evidenced by the recent Supreme Court decisions appears to have its roots in its misgivings about “business method” patents. However, this skepticism flows over to all patents, including pharmaceutical patents in which the inventions may have required hundreds of millions of dollars in their creation.

A basic question arises from these Supreme Court cases and many aspects of proposed patent reform measures, namely: does a “one size fits all” patent system still foster innovation and the public good?

Does the KSR decision mean that licensed patents may be attacked by licensees demanding that the patents be judged by an *ex post facto* higher standard? Given the Supreme Court’s apparent attitude, could a licensor even adequately protect itself by an agreed upon “Standard of Patentability” clause in a license agreement which addressed potential disagreements between licensor and licensee?

The necessity to have exceptionally able legal counseling in all U.S. Patent matters is more important now than ever.