

IP Developments in the USA and the Impact on Business Strategies for Generic Companies

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Recent Developments in US IP Law

- Obviousness
- Declaratory Judgment
- Licensee Estoppel
- Injunctive Standard is Changing

Obviousness – 35 U.S.C. §103

- Courts consider a number of factors (*Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966))
 - Scope and content of prior art;
 - Level of skill of person of ordinary skill in the art;
 - Differences between the claimed invention and the teachings of the prior art; and
 - Extent of any objective indicia of non-obviousness.
- Old Test: Teaching/suggestion/motivation to combine.
 - *KSR International v. Teleflex* (Argued before the Supreme Court on November 28, 2006)
 - KSR asks the Supreme Court to review the “teaching-suggestion-motivation test” for obviousness

Obviousness

The Federal Circuit indicates a shift in the obviousness analysis

- *Alza Corp. v. Mylan Laboratories*, 464 F.3d 1286, 1290-91 (Fed. Cir. 2006), citing *In re Kahn*, 441 F.3d 977, 987-88 (Fed. Cir. 2006)
 - “[A] suggestion, teaching, or motivation to combine . . . does not have to be found explicitly in the prior art.”
 - “The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.”
- *DyStar Textilfarben v. C.H. Patrick*, 464 F.3d 1356 (Fed. Cir. 2006)
 - “Our suggestion test is in actuality quite flexible and not only permits, but requires, consideration of **common knowledge** and **common sense**.”

Obviousness

- Federal Circuit uses obviousness to invalidate patent covering the blockbuster drug “Norvasc.”
- Pfizer, Inc. v. Apotex, Inc. (Fed. Cir. March 22, 2007).
 - On appeal, the Federal Circuit overturned the district court’s decision that the patent was not invalid.
 - The Federal Circuit ruled the patent was obvious in view of the prior art.
 - “Only a reasonable expectation of success, not a guarantee, is needed.”
 - Petition for rehearing and rehearing *en banc* denied by Federal Circuit (May 21, 2007).

Obviousness – 35 U.S.C. §103

- New test: *KSR International v. Teleflex*, 550 U.S. ____ (April 30, 2007)
 - No rigid rule: the rigid “*teaching-suggestion-motivation test*” for obviousness overruled.
 - “[A] court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.”
 - What Courts should review:
 - “interrelated teachings of multiple patents;”
 - “the effects of demands known to the design community or present in the marketplace; and
 - “the background knowledge possessed by a person having ordinary skill in the art.”
 - “To facilitate review, this analysis should be made explicit.”
 - Opens the door to “obvious-to-try.”

Obviousness – 35 U.S.C. §103

- Obviousness now a stronger defense

Declaratory Judgment

- **UNITED STATES CONSTITUTION, ARTICLE III, Section 2**
 - The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, . . . --to all Cases . . . to Controversies
- **Declaratory Judgment Act, 28 U.S.C. § 2201(a)**
 - “In a case of actual controversy . . . any court of the United States. . . may declare the rights and other legal relations of any interested party seeking such declaration. . . .”

Declaratory Judgment

- Recent US Supreme Court Case: *MedImmune v. Genentech*
 - A footnote suggested that the Federal Circuit's test for declaratory judgment (DJ) jurisdiction ("reasonable apprehension of suit") would be modified.
- Federal Circuit's Response:
 - *Sandisk Corp. v. STMicroelectronics, Inc.* (March 26, 2007)
 - Discarded the "reasonable apprehension" criterion
 - Holding that this element was no longer a requirement in view of *MedImmune*.
 - *Teva Pharmaceuticals USA Inc. v. Novartis Pharmaceuticals Corp.* (Apr. 6, 2007)
 - Novartis lists 5 patents in Orange Book
 - Teva files ANDA and certifies to all 5 patents
 - Novartis sues on only 1 patent
 - Teva adds DJ counterclaim for invalidity of the other 4 patents
 - Federal Circuit holds that district court has DJ jurisdiction
- By removing the "reasonable apprehension" test and establishing a much broader basis for jurisdiction, *Sandisk* and *Teva*, generics may once again try to file declaratory judgment actions against Orange Book listed patents.

Licensee Estoppel

- A Licensee May Challenge The Validity Of The Licensed Patent
 - A patent licensee is not estopped from attacking validity of patent; and
 - Patent licensee is entitled to avoid payment of all royalties accruing after patent issued if licensee could prove invalidity of patent.
 - *Lear, Inc. v. Adkins*, 395 U.S. 653, 671 (1969)
- Must the Licensee Breach The License Agreement To Create An “Actual Controversy” In Order To Request A Declaratory Judgment Of Invalidity?
 - *Medimmune, Inc. v. Genentech, Inc.*, -- U.S. --, 127 S.Ct. 764, 777 (2007).
 - “We hold that petitioner was not required, insofar as Article III is concerned, to break or terminate its 1997 license agreement before seeking a declaratory judgment in federal court that the underlying patent is invalid, unenforceable, or not infringed.”

Injunctive Standard Is Changing

- *eBay v. MercExchange*, 126 S.Ct. 1837 (2006)
 - No automatic permanent injunction upon finding of infringement
 - Before issuing the permanent injunction, the courts must weigh the four factors traditionally used to determine if an injunction should issue:
 - Plaintiff has suffered an irreparable injury;
 - Remedies available at law are inadequate to compensate for that injury;
 - Balance of the hardships favors plaintiff; and
 - Public interest would not be disserved by a permanent injunction.
- How does this affect generics?
 - At end of 30 month exclusivity, while case is pending, Brands often file for preliminary injunction, which tend to be routinely granted.
 - Since injunctions at the end of the case are no longer automatic, preliminary injunctions may no longer be routine.

QUESTIONS?