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Client Alert

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WHEN IS A PHARMACEUTICAL INVENTION OBVIOUS?

The monopoly provided by patent protection for a pharmaceutical drives the price a drug manufacturer can charge for the pharmaceutical. In April of 2007 the Supreme Court decided KSR v. Teleflex, 127 S. Ct. 1727, 1739 (2007), in which the Supreme Court distinctly decreased the standard as to whether the prior art invalidates a patent for obviousness. This decision, across the board, decreased the value of existing patents and pending applications because it became harder to show that a patent or pending application extended that which was already publicly known. The technology at issue in KSR had to do with adjustable height gas pedals. Because facts often control how a court views the obviousness of an invention, the pharmaceutical industry awaited cases applying the new KSR standard having to do with small molecules and related inventions.

The Federal Circuit recently decided two cases, Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc., --- F.3d ----, 2008 WL 834402 (C.A.Fed. (N.J.)), 86 U.S.P.Q.2d 1196 and Aventis Pharma Deutschland GmbH v. Lupin, Ltd., 499 F.3d 1293, 84 U.S.P.Q.2d 1197 both of which shine a ray of light on how the Federal Circuit, the main court in the United States that rules on patent cases, views small molecule patents under the new Supreme Court obviousness standard.

In Aventis v. Lupin, Lupin Ltd., a generic drug producer, challenged the validity of the Aventis patent (United States Patent No. 5,061,722, the '722 patent) covering the branded drug, Altace®, (active ingredient, rampiril) Altace® is an ACE inhibitor used for treating high blood pressure. The '722 patent claimed compounds, including specific stereoisomers (rampiril), that were "substantially free of other isomers." The Federal Circuit overturned the district court's finding that the 722 patent was not invalid for obviousness holding that public information showing the immediate precursor to rampiril, enalapril (Merck, 1980), its active stereoisomers and how to isolate them, made a patent covering the active stereoisomers of the related molecule rampiril having similar active stereoisomers . . . obvious. The take home message: purification of an active stereoisomer, when the public knows how to purify the isomer and when related molecules having similar active isomers are known will be difficult to patent. Not a positive message for patentees.

Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc. provides a more positive result for patentees. The drug manufacturer, Mylan, challenged the Ortho-McNeil patent covering Topomax®, the blockbuster epilepsy drug. The

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patent, United States Patent No. 4,513,006, (the '006 patent) had composition claims covering the active ingredient, topiramate. Topiramate actually was invented during a drug development program related to anti-diabetic drugs. Unexpectedly, the inventor discovered the particular intermediate, topiramate, had anticonvulsant properties. The Federal Circuit determined that, while the KSR standard did not require a rigid showing of a teaching, suggestion or motivation (TSM standard) in the art for a finding of obviousness, a flexible use of the TSM standard could be helpful to prevent hindsight analysis of obviousness. The court concluded that the evidence showed that a skilled artisan would not have arrived at the claimed compounds because there were so many alternative choices of which compound to pick. In addition, evidence of objective criteria showing non-obviousness, such as unexpected results like the anticonvulsive activity for topiramate, skepticism among experts about the ease of copying the results, and commercial success played a significant part in the courts decision.

In conclusion, two recent decisions by the Federal Circuit on obviousness of small molecule related inventions post KSR, provide guidance that the Federal Circuit will continue to use a flexible teaching suggestion or motivation test in chemical cases. While this is good for patentees, the finding of invalidity of the patent covering the active compound for Altace® shows that the new standard under KSR will likely still cause patentees some pain.