

Wiley Rein Files *Amicus* Brief in Generic Patent Case

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On January 10, 2011, Wiley Rein filed an *amicus* brief in the United States Supreme Court on behalf of the Generic Pharmaceutical Association (GPhA) in support of a petition for certiorari in a case of national importance involving the nation's quarter-of-a-trillion-dollar prescription drug market and the standards for patentability under the federal patent laws. Mylan Inc.'s cert petition in *Mylan, Inc. v. Daiichi Sankyo Co.*, No. 10-770 (filed Dec. 8, 2010), presents the question whether the Federal Circuit's so-called "lead compound" test for determining obviousness of a chemical compound conflicts with the Supreme Court's decision in *KSR International Co. v. Teleflex Inc.* Nonobviousness is one of the statutory prerequisites for federal patent protection. In *KSR*, the Supreme Court expressly rejected a "rigid approach" to obviousness in favor of the "expansive and flexible approach" the Court had applied for decades and reversed a decision of the Federal Circuit that utilized a "teaching-suggestion-motivation" test as the exclusive means of determining obviousness. Contrary to the teaching of *KSR*, the Federal Circuit has employed its "lead compound" test as the sole means of determining obviousness in the arena of chemical compounds.

Wiley Rein's *amicus* brief on behalf of GPhA highlights the importance of this case, explaining how conferring patent monopolies on "obvious" advancements in the field of medicinal chemistry will significantly delay market entry of generic drugs, which will lessen competition and harm the public in multiple respects. In particular, the use of generics instead of brand-name prescriptions saves the national health care system more than \$1 billion dollars every three days, but when generic drugs are improperly foreclosed from the market, prescription drug prices soar and consumers suffer. Individual

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consumers not only suffer serious financial harm, but even worse, high prices for brand-name prescription drugs often cause those afflicted to skip needed doses or forgo obtaining expensive prescription drugs altogether. Moreover, delaying generic drugs from entering the market causes serious harm to the public fisc—and thus to American taxpayers—because the federal government is the largest purchaser of pharmaceutical drugs.

Attorneys from Wiley Rein's nationally recognized Patent (James H. Wallace and John B. Wyss) and Appellate Practices (Helgi C. Walker and Thomas R. McCarthy) combined forces on this important *amicus* brief on behalf of GPhA. A decision by the Supreme Court on certiorari is expected by some time in March of this year.