# Supreme Court Denies Review of Daiichi v. Mylan (Benicar®)

March 23, 2011

On March 21, 2011, the Supreme Court denied a review of the Court of Appeals for the Federal Circuit's (CAFC) decision in *Daiichi Sankyo Company, Ltd. et al. v. Matrix Laboratories, LTD., Mylan Inc. et al.* (Mylan). The case was decided in September, 2010.

In the Federal Circuit case, Mylan alleged that claim 13 of U.S. Patent No. 5,616,599, which covers olmesartan medoxomil, was invalid as obvious under 35 U.S.C. 103. Olmesartan medoxomil, an angiotensin receptor blocker, is the active ingredient in Benicar®, Benicar HCT®, and Azor®, which are used in the treatment of high blood pressure. The CAFC disagreed with Mylan's arguments, and upheld the '599 patent as valid. In their analysis, the court relied on the "lead compound analysis," first introduced in *Yamanouchi Pharm. v. Danbury Pharmacal* (CAFC 2000), which provides a two-step analysis for the determination of small-molecule obviousness: 1) determine whether one of skill in the art would select a particular compound (s) to serve as a starting point for chemical modification (a "lead compound"); 2) consider whether a chemist would have had some reason to modify the known compound in the particular manner necessary to achieve the new compound. The court held that none of the cited prior art compounds (*e.g.,* example 6 of U.S. Patent 5,137,902) represented a lead that one of skill in the art would be motivated to modify; the lack of a lead notwithstanding, the court further held that there was no teaching in the art to make the molecular modifications necessary to arrive at olmesartan medoxomil. Read more ...