CAFC Upholds Validity of Method of Treatment Claim (Strattera®)

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On July 27, 2011, the Court of Appeals for the Federal Circuit (CAFC) determined that a claim directed toward a method of treating a new indication using a previously known drug was both non-obvious and properly enabled. The court also held that the patentees established proper utility for the claimed method. The case is *Eli Lilly and Company v. Actavis Elizabeth LLC, et al.*

The case focused on the following method claim from U.S. Patent No. 5,658,590 (the '590 patent):

1. A method of treating attention-deficit/hyperactivity disorder (ADHD) comprising administering to a patient in need of such treatment an effective amount of tomoxetine.

Tomoxetine had been previously studied for the treatment of urinary incontinence, and was a known norepinephrine inhibitor. The applicants envisaged that this compound could be useful in the treatment of ADHD, and filed the '590 patent after submitting an Investigational New Drug application to the FDA. Tomoxetine is now marketed in the U.S. as the ADHD drug Strattera®.

In response to the infringement suit, the defendants argued that the method claim should have been held as obvious, submitting that the inventors simply "substituted one potent selective norepinephrine reuptake inhibitor (tomoxetine) for another (desipramine) known to be effective in treating ADHD." The court disagreed, noting significant side effects associated with desipramine, as well as a lack of teaching in the art to solely target norepinephrine reuptake inhibition to treat the claimed condition. The court also observed tomoxetine's failure to treat depression "was contrary to the likelihood that tomoxetine would be effective to treat ADHD."

The defendants also argued that the specification of the '590 patent did not enable "administering to a patient…an effective amount of tomoxetine," as specified in the claim. According to the defendant, this claim language was much broader than the immediate release formulations and dosages specifically exemplified in the specification. The defendants also submitted expert testimony that determining formulations and dosages for treatment of ADHD was not routine experimentation. However, in view of the general description of dosage forms and amounts in the application, the court held that "[e]nablement is not negated if a reasonable amount of experimentation is required to establish dosages and formulation of an active

ingredient." See also *Enzo Biochem, Inc. v. Calgene Inc.* (CAFC 1999).

Finally, the defendants argued that the utility of the new method had not been established because the '590 patent lacked a showing of any experimental treatment of ADHD. The court also disagreed with this allegation, observing that "the norepinephrine relationship was known, safety for antidepressant activity had been established, the specification contained a full description of the utility, experimental verification had been obtained before the patent was granted, and the examiner had not requested additional information." In view of this litany of factors, the court ruled that utility for the method had been established. The court appeared to be especially persuaded by the initiation of human trials soon after the filing of the '590 patent, even in view of testimony in which one of the inventors described doubts as to whether, at the time of filing the patent, tomoxetine would treat ADHD.

In recent years, the CAFC has reviewed a number of patents directed toward new administration profiles, formulations, and dosages of previously known drugs. A tally of these cases shows that the court holds the majority of these patents as invalid. One explanation for the high invalidity rate may be a hesitancy by the court to extend the patent coverage of a previously protected drug product. In the *Eli Lilly* case, however, the court may not have viewed the claiming of a new method of treatment using an old drug as an attempt to gain additional patent term. See also *Eli Lilly v. Teva* (CAFC 2010), in which methods of treating osteoporosis using raloxifene were held to be non-obvious, even in view of the previous disclosure of this compound to treat autoimmune diseases.

This case also emphasizes the importance of carefully considering written description, enablement and utility requirements when preparing a patent application, especially when the filing is made prior to the acquisition of comprehensive experimental data. For example, the court at least partially relied on general descriptions of dosages, formulations, and mode of action when considering the enablement and utility of the '590 patent.

If you have any questions about this case, or any other aspect of chemical/pharmaceutical patent law, please contact Brian C. Trinque or Giulio A. DeConti of Lathrop Gage's Boston office.