CAFC Invalidates Claims Covering Specified Dose Range as Obvious

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On June 22, 2011, the Court of Appeals for the Federal Circuit (CAFC) upheld a summary judgment invalidating two claims of U.S. Patent No. 5,211,954 ("the '954 patent"), which covers a pharmaceutical formulation comprising particular doses of a sleep-inducing agent. The case is *Tyco Healthcare v. Mutual Pharma.*

The '954 patent is directed toward the compound temazepam, which has been marketed as a sleep-aid since the 1970s under the trade name Restoril®. The first claim at issue in this case specified a hard gelatin capsule comprising 6-8 mg of crystalline temazepam, wherein the temazepam has a particular surface area and particle size. The second claim is identical to the first, but specifies 7.5 mg of temazepam.

According to the court, the only difference between the claims and the prior art were the claimed dosages. In its analysis, the court relied on the medical reference British National Formulary ("BNF"), which taught the use of 5-15 mg of temazepam for the treatment of insomnia in the elderly. In view of this reference, as well as what was known to one of skill at the time of filing the '954 patent, the court held that it would have been obvious to pursue a temazepam formulation comprising the claimed dosages. ("[W]here there is a range disclosed in the prior art, and the claimed invention falls within that range, there is a presumption of obviousness.")

In an attempt to demonstrate nonobviousness, Tyco, the patent holder, submitted an expert declaration arguing that the BNF reference did not teach that the claimed doses of 6-8 mg and 7.5 mg were effective for the treatment of insomnia. Tyco also noted that the BNF reference cited commercially available formulations having 10 mg and 20 mg doses of temazepam. In response, the court noted that none of these arguments "undermine the teaching of the BNF reference that a person of ordinary skill in the art could consider temazepam dosages between 5 mg and 15 mg to treat insomnia."

In addition, Tyco argued that certain references taught away from the claimed ranges. For example, one of the references disclosed that a 10 mg dose of temazepam reduced the amount of time it took for a user to fall asleep ("sleep latency"), but did not increase total sleep time. The court was not convinced by these arguments, noting that there was no evidence "that a sleeping pill must achieve improvement on both [sleep latency and total sleep time] in order to be considered effective." The court also disagreed with how Tyco

characterized data and statements disclosed in other references that were alleged to teach away from the invention.

Tyco also submitted that the claimed dosages displayed unexpected results, and that there was skepticism among experts that the claimed low doses would actually work. The court, however, found no evidence in the record of any unexpected results. ("Unsupported statements in the specification, however, cannot support a finding of unexpected results.") Furthermore, any skepticism among experts about the claimed dosages was specific to *transient* insomnia, which was not specified in the claims.

Finally, Tyco argued that the commercial success associated with the claimed invention ($30 million in annual sales) supported a finding of nonobviousness. The court disagreed, noting "the evidence as a whole did not overcome Mutual's strong *prima facie* case of obviousness."

Since the Supreme Court's decision *KSR v. Teleflex* (2007), a number of patents directed toward new dosages and/or formulations of known compounds have been invalidated as obvious by the CAFC. The *Tyco* case is yet another example of the Federal Circuit demanding appropriate evidence against obviousness to justify extending the patent life of a drug. See, *e.g.*, *Bayer Schering Pharma AG v. Barr Laboratories* (CAFC 2009) and *Purdue Pharma v. Par Pharmaceutical* (CAFC 2010) (claims invalid as obvious), as well as *Abbott v. Sandoz* (CAFC 2009) and *Eli Lilly v. Teva* (CAFC 2010) (claims upheld as nonobvious).

It is also interesting to draw parallels between the *Tyco* case and *Pfizer v. Apotex* (CAFC 2007), which was directed toward a new salt form of a known drug. In both instances, the court noted submissions to the FDA by the patentees arguing bioequivalence of the formulation or drug at issue with a previously known drug form. It is clear that such submissions influenced the court in making its determinations of obviousness.

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.