PATENTWATCH

Good-faith explanation

The Federal Circuit Appeals Court has upheld the finding of no inequitable conduct during the prosecution of a Warner-Lambert patent covering a formulation of the blockbuster antihypertensive drug quinapril, because of a plausible good-faith explanation.

When Warner-Lambert was issued its patent for quinapril, generics firm Teva filed an Abbreviated New Drug Application seeking FDA approval to market a generic version with magnesium carbonate and lactose excipients, certifying that any patents pertinent to the generic formulation are invalid.

One problem with angiotensin-converting enzyme (ACE) inhibitors is that when mixed with common excipients they become unstable and degrade through cyclization and hydrolysis. Warner-Lambert's patent claimed a formulation that contained magnesium carbonate to prevent cyclization of quinapril and lactose to prevent hydrolysis. Independently, Merck were experimenting with a different ACE inhibitor, enalapril, and found that converting the inhibitor to its sodium salt prevented cyclization. Merck marketed Vasotec on the basis of this discovery, and, because all of the ingredients were already in the public domain, chose to keep the process a trade secret rather than seek a patent.

When Warner-Lambert subsequently sued Teva for infringement for using excipients that inhibited the same kinds of degradation, Teva argued that Warner-Lambert's patent was invalid because the invention was obvious from Merck's discovery of Vasotec, and that Warner-Lambert had engaged in inequitable conduct by failing to bring Vasotec to the US Patent and Trademark Office's attention. A district court ruled that Teva had infringed Warner-Lambert's patent, citing evidence that Teva's magnesium carbonate excipient inhibited cyclization and discoloration, and that its lactose excipient inhibited hydrolysis. The court also dismissed the case of inequitable conduct because evidence failed to show that Warner-Lambert intended to deceive the PTO.

Although Warner-Lambert's scientists had considered Vasotec during their initial experimentation with sodium bicarbonate to alter pH, they did not consider the drug once their research advanced to the core issue of how to inhibit cyclization-based degradation. The Federal Appeals Court reasoned that the patentees had no way of knowing that Merck used the excipient to prevent cyclization rather than to adjust pH levels, because Merck never filed a patent application publicizing its discoveries. So although Vasotec was probably a material reference for the Warner-Lambert patent, the company had good-faith justification for not recognizing its materiality.

The appellate court did, however, reverse the district court's rulings for Warner-Lambert on infringement and enablement, having been unconvinced by Warner-Lambert's argument for Teva's infringement, and stating that the lower court had never addressed the issue of enablement. The case was therefore remanded back to lower court for further hearings.

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Warner-Lambert Co. versus Teva Pharmaceuticals USA, Inc., No. 04-1506 (11 Aug 2005):
http://www.fedcir.gov/opinions/04-1506.pdf