



INTELLECTUAL PROPERTY | ANDA

Edwards Angell Palmer & Dodge LLP, Boston, MA

## Takeda v. Mylan

### Takeda Counsel EAPD Enlists CaseSight to Fight Off ANDA Claims

#### THE MATTER

##### Actos Market Under Threat by Generic Drug Makers

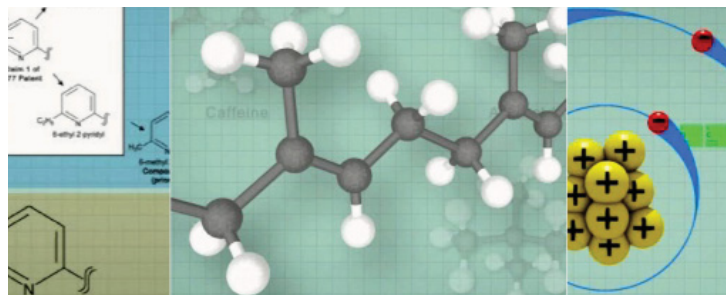
In 2005 Mylan Inc. sought to launch a generic version of Takeda Chemical Industries' successful Type 2 diabetes drug ACTOS® (pioglitazone hydrochloride). In their Abbreviated New Drug Application (ANDA) filings to the FDA, Mylan and three others argued Takeda's Actos patent was invalid due to obviousness and inequitable conduct. Takeda hired Edwards Angell Palmer & Dodge (EAPD) to bring suit in the Southern District of New York against Mylan and the others to roll back the ANDA bid, assert the validity of the patent, and reassert the profitable ACTOS market.

EAPD called on CaseSight to design case presentation assets that would clarify and simplify to the judge the complex nature of the chemical patent under dispute, and clearly demonstrate Takeda's novelty and good conduct in developing and patenting ACTOS.

#### THE CASESIGHT EFFECT

##### DVD Tutorials Effectively Teach, Convince Judge of Patent Validity

Due to the sheer complexity of the compounds under dispute and the difficult legal arguments employed by the defendants, Judge Denise Cote of the U.S. District Court for the Southern District of New York asked EAPD before the trial for two DVDs that she could review on a standard home DVD player: one, an organic chemistry tutorial on the background and development of pioglitazone hydrochloride, and the other, a synopsis of the patent validity arguments. Using engaging 3D animation imagery, CaseSight's Presentation Consultant and expert designers worked with the EAPD team to create two clear, convincing programs



that effectively gave Judge Cote the background and facts she needed to render in Takeda's favor.

CaseSight's tutorials helped EAPD convincingly fight off the claim of obviousness by showing to the judge the complex nature of the lead compound in question in the prior art, and its millions of potential variations. The tutorials also demonstrated abundant evidence of Takeda's good faith before the PTO, rendering the defendants' arguments regarding disclosures before the PTO immaterial.

#### THE OUTCOME

##### Actos Validity Upheld, Takeda's Market and Brand Enhanced

Judge Cote ruled that the Takeda patent covering pioglitazone hydrochloride, the active ingredient in its diabetes drug ACTOS, was valid and enforceable against generic challengers.

Cote wrote in her February 21, 2005 ruling, "the [ACTOS] Patent discloses a remarkable invention. After decades of work to develop an anti-diabetic treatment, Takeda discovered a pharmaceutical agent that was both effective and nontoxic. This represented a significant advance over compounds disclosed in the prior art. Faced with the task of proving their cases by clear and convincing evidence, both Alphapharm and Mylan have failed to make even a rudimentary showing that the invention was obvious or that Takeda engaged in inequitable conduct. Their challenges to the [ACTOS] Patent are rejected."