

## FEDERAL CIRCUIT PATENT LAW CASE UPDATE

Purdue Pharma v. Endo Pharms., 04-1189 (Fed. Cir. Feb. 1, 2006) (Plager, J.)

In a suit triggered by Endo's ANDA application to sell a generic version of OxyContin<sup>®</sup>, the court vacated the district court's determination that Purdue's three patents related to OxyContin were unenforceable due to inequitable conduct. This determination replaced an earlier opinion affirming the inequitable conduct determination. In this appeal, while there was a low level of materiality in Purdue's description of results as surprising with language that intoned that scientific, clinical tests underpinned that statement when in fact it was insight without scientific proof, the district court incorrectly handled the intent prong of the inequitable conduct interpretation by overly inferring negative intent from the statements, and not realizing that Purdue's admitted inability to prove certain experimental results were primarily results required for FDA approval and labeling and thus less relevant to patenting.

Purdue owns three related U.S. Patents that underlie this suit. They "are directed to controlled release oxycodone medications for the treatment of moderate to severe pain."

In an earlier opinion the court affirmed the district court's determination that Purdue's three patents related to OxyContin were unenforceable due to inequitable conduct, citing a clear pattern over the prosecution of the patents to describe results as surprising with language that intoned that scientific, clinical tests underpinned that statement, when in fact it was insight without scientific proof.

On petition for rehearing, the court determined to withdraw the earlier opinion because the issues needed further development.

In addition to fact-finding regarding materiality and intent, inequitable conduct requires a special kind of balancing, weighing the level of materiality against the weight of the evidence of intent. Our further review has persuaded us that the trial judge may have erred in how he viewed certain of the evidence, and that this may have caused an error in the balancing step. . . .

The current version of PTO Rule 56 applied due to the date of the applications underlying the patents.

The trial court in this case based its materiality finding on Purdue's repeated

and convincing representations to the PTO that it had discovered its controlled release oxycodone formulations controlled pain over a four-fold range of dosages for 90% of patients, compared to an eight-fold range for other opioids. Purdue had no clinical evidence supporting its claim at the time it was made or at any time before the patents issued. . . . In the trial court's view, by representing to the PTO that it had "discovered" that oxycodone acceptably controlled pain over a four-fold dosage range, while withholding from the PTO the fact that the discovery was based on insight without scientific proof, Purdue failed to disclose material information.

During prosecution of the patents, they eventually issued over the examiner's obviousness rejections in light of the applicant's explanations.

Purdue first told the PTO it had "surprisingly discovered" the four-fold dosage range for controlled release oxycodone, compared to the eight-fold range for other opioids, during prosecution of the '331 parent patent in October 1992, prior to the filing date of the '912 patent. In response to an obviousness rejection, under headings containing the phrases "Surprisingly Improved Results" and "Results



Obtained,” Purdue distinguished its oxycodone formulations from other opioids based on the “surprising result” of the four-fold dosage range and its “clinical significance”—a more efficient titration process. Purdue presented this argument even though neither the written description nor the pending claims of the ’331 patent application made reference to the four-fold dosage range. Purdue’s response contained language identical to that which was soon to appear in the written description of the ’912 patent application. . . .

Given this prosecution history, the court affirmed could not “say [that] the trial court’s finding that Purdue failed to disclose material information was clearly erroneous.”

We emphasize that this case is an unusual one. A failure to inform the PTO whether a “surprising discovery” was based on insight or experimental data does not in itself amount to a material omission. In this case, however, Purdue did much more than characterize the four-fold dosage range of the claimed oxycodone formulation as a surprising discovery. Purdue repeatedly relied on that discovery to distinguish its invention from other prior art opioids while using language that suggested the existence of clinical results supporting the reduced dosage range. . . . This omission of information was material, but not as material as an affirmative misrepresentation would have been.

While mostly agreeing with the trial court on the materiality prong, the court found error in the intent prong analysis.

There are two problems with the trial court’s analysis of the intent prong. First, in discounting any evidence of good faith put forth by Purdue, the trial

court relied heavily on internal memoranda and trial testimony regarding Purdue’s admitted inability to prove with experimental results that OxyContin® was the most efficiently titratable analgesic. This evidence, however, relates primarily to Purdue’s attempt to gain FDA approval for a proposed labeling claim rather than its attempt to obtain allowance of its patent claims. . . .

The trial court’s second problem was its failure to properly consider the level of materiality. It appears the trial court perceived the level of materiality to be high and inferred deceptive intent from that high materiality, combined with the court’s erroneous finding that any good faith on the part of Purdue was undercut by its admitted inability to prove the ease of titration claim.

Finally, the court affirmed the infringement judgment in response to Endo’s cross-appeal on that issue.

