

Keywords: Inequitable Conduct; Materiality; Intent; Insight; Theory; Discovery; Scientific Proof; Unenforceable; Misrepresentation

General: Plaintiffs' patents directed to compositions that claim pain control over four-fold dosage range in approximately 90 percent of patients are unenforceable for inequitable conduct during prosecution, since plaintiffs' repeated assertion that inventors' "surprisingly discovered" that pain could be relieved over this claimed reduced dosage range was deliberate decision to represent mere "expectation" or "insight" as precisely quantified "result" or "discovery."

Purdue Pharma L.P. v. Endo Pharmaceuticals Inc.

70 U.S.P.Q.2d 1185 (S.D.N.Y. 2003)

Decided January 5, 2004

I. Facts

Plaintiffs Purdue Pharma, L.P., the Purdue Frederick Company, the P.F. Laboratories, Inc. and the Purdue Pharma Company ("Purdue") bring suit alleging that defendants Endo Pharmaceuticals Inc. and Endo Pharmaceuticals Holdings Inc. ("Endo") infringed Purdue's patents protecting its product OxyContin. OxyContin is a controlled release oxycodone analgesic designed to treat moderate to severe pain. Oxycodone is a drug known as an opioid analgesic and is the active ingredient in OxyContin. Other opioid analgesics include morphine and hydromorphone. These drugs are generally used to treat moderate to severe pain.

Endo counterclaims against Purdue for a declaration of invalidity and unenforceability regarding the patents in suit. Further, Endo counterclaims for a declaration that plaintiffs misused patents in violation of federal antitrust laws. Endo contends that Purdue committed inequitable conduct when it allegedly misrepresented that Purdue had "surprisingly discovered" that its invention reduced the dosage range and eased titration in comparison to other opioid formulations. Purdue does not dispute that no clinical studies existed to support the patents' disclosure of a four-fold range of doses that treat approximately 90% of patients. Instead, Purdue contends that the word "discovery" can include purely mental acts.

II. Issue

Did Purdue commit inequitable conduct by clear and convincing evidence when it asserted that it had "surprisingly discovered" that its invention reduced the dosage range and eased titration in comparison to other opioid formulations without any scientific proof to support the discovery?

III. Discussion

Yes. Inequitable conduct entails a two-step analysis: first, a determination of whether the withheld reference meets the threshold level of materiality and intent to mislead and, second, a weighing of the materiality and intent in light of the circumstances to determine whether the applicant's conduct is so culpable that the patent should be unenforceable. There is clear and convincing evidence that Purdue misrepresented a material fact and intended to mislead. Accordingly, the patents in suit are rendered unenforceable.

There are two interpretations of materiality that courts have relied upon in evaluating a claim of inequitable conduct. Prior to March 16, 1992, the Federal Circuit “held that materiality for purposes of an inequitable conduct determination required a showing that ‘a reasonable examiner would have considered such prior art important in deciding whether to allow the parent application.’” *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1363 (Fed. Cir. 2003). However, in March 1992, the PTO amended its rules to provide for a definition of materiality that was supposedly clearer and more objective. “The rule reiterated the preexisting ‘duty of candor and good faith,’ but more narrowly defined materiality, providing for disclosure where the information establishes either ‘a prima facie case of unpatentability’ or ‘refutes, or is inconsistent with a position the applicant takes.’” *Id.* at 1363-64. “In determining inequitable conduct, a trial court may look beyond the final claims to their antecedents,” including claims of parent patents when such inequitable conduct is material to the claims of the continuation or divisional patents. *Baxter Int’l Inc. v. McGraw, Inc.*, 149 F.3d 1321, 1332 (Fed. Cir. 1998). The allegations of inequitable conduct in the present case relate to occurrences both prior to and subsequent to March 16, 1992. Accordingly, it is not clear which standard should apply.

Regardless of which standard is applied, Purdue misrepresented material facts to the PTO. The Court finds by clear and convincing evidence that a reasonable examiner would have considered the fact that Purdue did not have any “scientific proof” that the claimed invention actually provided pain relief for most people over a four-fold dosage range to be important information. This finding is supported by the fact that Purdue (1) described the surprising discovery in concise, quantified terms, (2) described it as having occurred in the past, (3) considered the discovery critical to the invention, and most importantly (4) used the precisely quantified discovery throughout the prosecution as a prominent argument for patentability. The lack of any “scientific proof” is inconsistent with Purdue’s assertion that it “surprisingly discovered” that its invention exhibited a reduced dosage range. While the word “discovery” has a broad dictionary meaning that can theoretically cover mere “insights,” Purdue’s definitive statements to the PTO would clearly be undercut if the PTO were aware that the statements lacked any support other than an inventor’s “insight.” Further, it should be noted that the Manual of Patent Examining Procedure (M.P.E.P.) states that an “insight or theory should be described in the present tense or in language like ‘can be done,’ ‘could be done,’ something that imports the notion to the reader, to the scientific community, the public at large and particularly the examiner that something has not yet been actually done or actually reduced to practice.”

Additionally, Purdue’s actions satisfy the intent requirement of the two part test for inequitable conduct. The record as a whole reflects a clear pattern of intentional misrepresentation of a material fact. “When balanced against high materiality, the showing of intent can be proportionally less.” *Bristol-Myers Squibb Co. v. Rhone-Poulenc Roher, Inc.*, 326 F.3d 1226, 1233 (Fed. Cir. 2003). As evidenced by the testimony of Purdue’s own scientists and experts, Purdue knew that it did not have scientific proof of its “discovery” and still repeatedly asserted its “discovery” to the PTO in precise, quantified past-tense language. Further, any claim to a good faith belief on the part of Purdue that the inventions provided pain relief for most patients over a reduced four-fold dosage range is undercut by Purdue’s admitted inability to prove titration.

IV. Conclusion

Although the patents at issue were infringed by Endo, clear and convincing evidence of Purdue’s inequitable conduct before the PTO during prosecution of the patents renders them invalid. The patent claims against Endo are dismissed. Further, the patents in suit are declared invalid and Purdue is enjoined from enforcing those patents.