

FEBRUARY 24, 2006

## The Federal Circuit's New Trio Of Inequitable Conduct Patent Cases: Clarification Or Confusion?

February 2006 brought a flurry of new decisions from the U.S. Court of Appeals for the Federal Circuit on a key affirmative defense to patent infringement: inequitable conduct. But while the court's recent pronouncements may have tried to clarify the legal standards for inequitable conduct, in fact the case law may be just as confused as ever.

In this TIP Alert, Nixon Peabody's Technology and Intellectual Property Group reviews these new cases, and provides a roadmap to our clients and friends through the newest twists and turns in the maze of Federal Circuit precedent. Both for patent holders who want to protect their hard-won intellectual property rights, and for patent infringement defendants who are litigating against what they believe are unenforceable patents, understanding and anticipating the inequitable conduct affirmative defense is a major battleground in patent litigation.

Robert Fletcher and Jeffrey Lindeman of Nixon Peabody LLP will discuss these Federal Circuit decisions in a live Webinar Thursday, March 2, 2006 at 11:30 AM EST. Webinar information below.

### Inequitable Conduct

Inequitable conduct is a serious concern to patent holders. Unlike invalidity, which may strike a single patent claim but leave others, inequitable conduct takes out the entire patent and, quite possibly, later continuations and divisional applications. Following on three important cases from 2003, the Federal Circuit has recently been exploring the boundaries of materiality and intent underlying inequitable conduct.

This emphasis on the legitimacy of the invention process unfortunately is not out of step with events in research science. *Nature* magazine recently reported the results of a survey of scientists, where 6% admitted to failing to present data that contradict their own previous research, and 13.5% reported that they used inappropriate or inadequate research designs. Martinson, Anderson and de Vries, "Scientists Behaving Badly," *Nature*, June 2005. Even widely publicized scientific "discoveries" can be tainted by fraud, as shown by the recent revelations of falsification by South Korean researchers regarding the results of cloning experiments.



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For those scientists and inventors who make their way successfully through the patent process, patents are, of course, presumed valid and enforceable. Yet defendants in patent infringement litigation almost always seek to have the patents declared unenforceable due to alleged inequitable conduct by the patentee during the patent prosecution process. To find a patent unenforceable due to inequitable conduct, an alleged infringer bears a significant burden of showing inequitable conduct in the patent process through a failure to disclose material information, or submission of false material information, with intent to deceive. What information is “material,” however, is the source of endless legal wrangling. And although intent to deceive is typically inferred from the surrounding circumstances, it cannot be found solely from the fact that information was not disclosed. There must be a factual basis for finding deceptive intent. Moreover, those two elements, materiality and intent, must be proven by clear and convincing evidence. Finally, if the threshold levels of materiality and intent are proven, the court must still balance the materiality with intent to determine if the conduct as a whole was inequitable.

The Federal Circuit, in conjunction with the rules of the Patent and Trademark Office (PTO), has defined information to be material only if it is not cumulative to information already of record or being made of record in the application, and if it (1) establishes by itself or in combination with other information a prima facie case of unpatentability of a claim, or (2) is inconsistent with a position the patent applicant took during prosecution. The latter point is the area the recent cases are exploring.

## The Recent Federal Circuit Decisions

On February 1, 2006, the Federal Circuit issued the latest in a series of decisions in the long-running battle over patents on a controlled release version of the widely used painkiller OxyContin®. On rehearing and in a surprising withdrawal of its initial affirmance, the court vacated the trial court’s finding of inequitable conduct and remanded the case to the district court for further proceedings. *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*, Nos. 04-1189, 04-1347 and 04-1357, 2006 U.S. App. LEXIS 2887 (Fed. Cir. Feb. 1, 2006), *withdrawing prior opinion at* 410 F.3d 690 (Fed. Cir. 2005). In its prior opinion, the same Federal Circuit panel had affirmed the trial court’s findings on materiality and intent and upheld its finding of inequitable conduct.

The trial court found inequitable conduct because, while the patentee told the PTO that it had made a “surprising discovery” about the effective dosage range of OxyContin®, the patentee failed to disclose that its discovery of a lower dose OxyContin® formula was based only on a single inventor’s insight. Moreover, the language of arguments made during the prosecution of the patent suggested that the discovery was based on the results of clinical studies when none had in fact been conducted. Although it called the case an “unusual one,” the Federal Circuit agreed with the trial court’s finding that Purdue failed to disclose material information to the PTO:

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.

2006 U.S. App. LEXIS 2887, at \*25. The Federal Circuit emphasized that the context in which the dosage statements were made – not as a claimed general benefit of the drug formulations but rather as distinguishing features over the prior art “in precise, quantitative terms” – was key to the finding of materiality. The court also upheld the finding of materiality even if the examiner did not necessarily rely on the discovery statements, thereby reaffirming its rejection of a “but-for” standard of materiality.

Upon its “further review” in response to a petition for rehearing, the Federal Circuit, nevertheless, departed from its decision in *Purdue I* and overturned the district court’s finding of inequitable conduct, holding that the trial court may have erred by finding the omission to have a high level of materiality. Because the omission was material, but “not as material as an affirmative misrepresentation would have been,” the Federal Circuit directed the trial court to “rethink” its evaluation of the evidence on intent. Where the materiality of the omission was low, a “proportionally” higher level of intent is required. According to the court, “Our further review has persuaded us that the trial judge may have erred in the way he viewed certain of the evidence, and this may have caused an error in the balancing step.” Specifically, the trial court was directed to consider whether the patentee intentionally withheld material information on the source of the “surprising discovery.”

Next, the Federal Circuit announced its decision in *Digital Control, Inc. v. The Charles Machine Works*, No. 05-1128, 2006 U.S. App. LEXIS 2991 (Fed. Cir. Feb. 8, 2006). In *Digital Control*, it looked like the court would clarify the legal standard for materiality. Whether it succeeded is still to be determined.

The patents in suit in *Digital Control* involved devices and methods for horizontal directional drilling, in which the precise underground location of a horizontal boring tool can be tracked from the surface as it moves through the ground. The trial court held on summary judgment that the inventor-applicant made material misstatements in a declaration filed with the PTO designed to establish a reduction to practice date that preceded relevant prior art. The declaration stated that the sensor arrangement was “within the boring tool,” when it was not, and implied that the invention had been demonstrated “underground,” when it had not. In addition, the court found that the applicant had failed to disclose other non-cumulative prior art.

The Federal Circuit used this case as the occasion to address the long-standing question of whether the PTO’s 1992 adoption of a new Rule 56 materiality standard altered the legal standards in inequitable conduct cases. For more than a decade, the Federal Circuit had repeatedly declined to address the issue of whether the amended PTO procedural rules on the duty of candor and good faith had changed the legal interpretation of materiality in patent litigation.

In the years prior to 1992, the Federal Circuit held that materiality for purposes of inequitable conduct required a showing that a “reasonable examiner” would have considered the information or prior art “important” in deciding whether to allow the application, based on the PTO’s pre-1992 duty of disclosure rule. The 1992 amendment to Rule 56 restated the standard of materiality. In its present formulation, the standard provides that information is material to patentability, and therefore must be disclosed, when it is not cumulative, and when it by itself or

in combination with other information establishes a prima facie case of unpatentability, or it refutes or is inconsistent with a position taken by the applicant before the PTO regarding patentability. Although the court had affirmed findings of materiality under the new standard, it had declined to address whether the new PTO rule replaced the former “reasonable examiner” standard. In *Digital Control*, the court announced that it would finally take that question head on, an answer eagerly awaited by patent practitioners and litigators.

The result was less than a model of clarity. The court held that *both* standards are still relevant and applicable. It found that the amendments to Rule 56 were not intended to supplant or replace case law precedent that led to the “reasonable examiner” standard. Rather, the new Rule 56 provisions “merely provide[] an additional test of materiality.” Therefore, the court held that if a misstatement or omission meets *either* the current Rule 56 standard *or* the “reasonable examiner” standard, it is material.

The court in *Digital Control* again affirmed its distaste for any kind of affirmative misrepresentation made to the PTO. The patentee, however, temporarily escaped a final judgment of inequitable conduct. The court affirmed the summary judgment of materiality for the misstatements in the declaration, using the “reasonable examiner” standard. The court nevertheless vacated the summary judgment of inequitable conduct because whether the prior art omissions were merely cumulative of other information considered by the examiner is a question of fact. That led to vacating the trial court’s intent finding because it had not explained how much of the intent determination depended on misstatements or omissions, or both.

Finally, the court in *Ferring B.V. v. Barr Laboratories, Inc.*, No. 05-1284, 2006 U.S. App. LEXIS 3554 (Fed. Cir. Feb. 15, 2006), affirmed a finding of inequitable conduct in patents for a new solid dosage anti-diuretic drug used in the treatment of diabetes. The new medicine was designed to be swallowed and absorbed through the intestinal tract, rather than the more cumbersome and less effective prior art treatment of a nasal spray or absorption in the mouth through a dissolving tablet.

During prosecution, the examiner repeatedly rejected the application, finding that prior art taught oral administration of the drug’s key peptide for gastrointestinal absorption. In response, the applicant submitted numerous declarations from “non-inventors” to support an interpretation of the prior art as limited to non-gastrointestinal modes. The declarations failed, however, to attach the CVs of several of the declarants. Disclosure of the declarants’ complete histories would have revealed that several of them had prior, although rather tenuous, connections with the applicant, such as receiving consulting or research funds in situations unrelated to the patents-in-suit. Because the examiners were not made aware of these connections with the applicant, the court in a 2-to-1 decision upheld a finding of inequitable conduct.

In *Ferring*, the relevant standard of materiality was not at issue, since all the patents in suit issued prior to the 1992 amendment, so the “reasonable examiner” standard applied. The court summarized its intent to deceive standard on summary judgment as requiring that (1) the applicant knew of the undisclosed information; (2) the applicant knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the non-disclosure.

While the nature of the applicant’s omissions seemed minor in contrast to the heavy penalty of unenforceability – as pointed out by Judge Newman in a scathing dissent in which she called the

majority's materiality finding as based on nothing but "innuendo" and a "travesty" – the majority upheld the inequitable conduct mainly because of the apparent repeated nature of the omissions. In other words, while the court may have been more lenient on a single minor omission of the declarants' connections, evidence that all or nearly all of them had undisclosed connections was too much for the court to accept.

## Have These Decisions Clarified the Inequitable Conduct Defense?

What has become clear from recent Federal Circuit decisions is that the court is willing to examine a wider range of activities when determining materiality and intent. *Purdue Pharma* suggests that the court will look at statements in the patent specification and inquire as to whether or not the statements themselves, and more importantly, the context in which the arguments made on them are based, are credibly supported by facts not known or disclosed to the examiner. The recent *Purdue Pharma* decision, however displays a retreat from the Federal Circuit's decision in *Purdue I. Digital Control* highlights the Federal Circuit's continued unwillingness to commit to a single materiality standard or to delineate the difference, if any, between the old and the new. *Ferring* continues the recent trend of looking for truthfulness and complete candor in dealings with the PTO, even in what appear to be minor or tangential elements of statements or declarations made during the prosecution process.

What, at the end of February 2006, is the standard for materiality in inequitable conduct? The boundaries remain unclear. The safest course for patent applicants is to be as wide-ranging as possible in disclosures to the PTO in order to protect the validity of their patents if issued. For the patent infringement defendant, rather than focusing the legal standards or narrowing the type of conduct that is material to patentability, these decisions leave the field wide open for alleged infringers to explore every aspect of the prosecution process. In the end, if questionable behavior occurred during patent prosecution, one can be sure that it will become the subject of an inequitable conduct challenge to the enforceability of the patent. That, at least, is certain.

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For further information about this article, or patent infringement claims or defenses, please contact Bob Fletcher at 202-585-8323 or by e-mail at [rfletcher@nixonpeabody.com](mailto:rfletcher@nixonpeabody.com), or Jeff Lindeman at 202-585-8350 or by e-mail at [jlindeman@nixonpeabody.com](mailto:jlindeman@nixonpeabody.com).

## **Conference Call Details**

Please join Nixon Peabody attorneys, Robert Fletcher and Jeffrey Lindeman, for a live discussion and PowerPoint presentation about the newest twists and turns in the Federal Circuit's interpretation of the inequitable conduct defense. The call will be conducted on **Thursday, March 2 at 11:30 A.M. EST** (10:30 AM Central, 9:30 AM Mountain, 8:30 AM Pacific , 4:30 PM GMT )

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