Legal Opinion Letter

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2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302

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"INEQUITABLE CONDUCT" STANDARD FOR PATENT SUITS IS HEIGHTENED

by
Peter A. Jackman

When sued in a patent infringement suit, the defendant will frequently assert that the patent is unenforceable because the plaintiff engaged in inequitable conduct before the U.S. Patent and Trademark Office ("PTO") in violation of its duty of "candor, good faith and honesty." In order to prove inequitable conduct, a party must demonstrate by clear and convincing evidence a misrepresentation or omission of a material fact during prosecution as well as an intent to deceive the PTO. *See Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1362 (Fed. Cir. 2003). Once demonstrated, the court must then weigh the materiality and intent in light of all the circumstances to determine whether or not the conduct was so culpable that the patent should be held unenforceable and the patentee stripped of its intellectual property. *Id.* at 1363.

Unfortunately for patentees, the assertion of inequitable conduct has resulted in an increasing number of patents being held unenforceable in recent years. This increase has been attributed at least in part to a lowered standard for finding deceptive intent on the part of the patentee in which intent is inferred based merely on some modicum of materiality. A lowered standard of inequitable conduct can result in increased unpredictability and decreased public confidence in the patent system as well as deter investment in innovation. In the recent decision *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*, 438 F.3d 1123 (Fed. Cir. 2006), the Federal Circuit reversed its previous finding of inequitable conduct and clarified the high standard that should be applied before such a severe sanction is warranted.

The dispute began in September of 2000, when Endo Pharmaceuticals filed an Abbreviated New Drug Application ("ANDA") seeking FDA approval of a generic version of Purdue Pharma's highly successful OxyContin tablets, a controlled release oxycodone analgesic designed to treat moderate to severe pain. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Endo certified that Purdue's relevant U.S. patents for the FDA-approved drug would either not be infringed by Endo's generic tablets or were invalid and provided the requisite notice to Purdue of its intent and certification. Purdue timely filed suit against Endo in October 2000 for patent infringement under 35 U.S.C. § 271(e)(2) in the United States District Court for the Southern District of New York on the basis of Endo's ANDA filing. *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*, 70 U.S.P.Q.2d 1185 (S.D.N.Y. 2004). Purdue alleged that Endo's proposed drug would infringe claims 1-4 of U.S. Patent No. 5,549,912, claims 1 and 2 of U.S. Patent No. 5,508,042 and claims 1-4 and 6-10 of U.S. Patent No. 5,656,295. In response, Endo filed counterclaims against Purdue seeking a declaration that the patents at issue were invalid and unenforceable, that Purdue's misuse of the patents violated federal antitrust laws, as well as injunctive relief and monetary damages.

After an eleven day bench trial, the district court found Purdue had proven that Endo infringed the asserted patents. However, the court also found that the patents were unenforceable due to Purdue's inequitable conduct before the PTO during prosecution of the patents in suit. In particular, the court agreed with Endo that Purdue committed inequitable conduct when it asserted in the patent specifications, as well as repeatedly during prosecution of the patents

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Peter A. Jackman is a director with the law firm Sterne, Kessler, Goldstein & Fox P.L.L.C. *This publication reflects the present thoughts of the author, and should not be attributed to Sterne, Kessler, Goldstein & Fox P.L.L.C. or any of its former, current or future clients. The content is for purposes of discussion and should not be considered legal advice. This publication should not be construed as an attempt to aid or hinder the passage of legislation.*

in suit, that it had "surprisingly discovered" that the claimed invention reduced the dosage range and eased titration in comparison to other opioid formulations, when in fact the surprising discovery was based not on actual clinical experiments performed by Purdue, but rather on "insight" from an inventor without any supporting documentary evidence. According to the court, notwithstanding Purdue's belief that it discovered a novel result, the record as a whole reflected a clear pattern of intentional misrepresentation of a highly material fact – "Purdue knew it did not have 'scientific proof' of its 'discovery,' yet repeatedly asserted its 'discovery' to the PTO in precise, quantified, past-tense language."

Purdue appealed the inequitable conduct judgment and Endo appealed the infringement judgment to the U.S. Court of Appeals for the Federal Circuit. The three-member panel of Judges Gajarsa, Plager and Linn held that the trial court did not err in its inequitable conduct determination and therefore did not address the infringement issues. *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*, 410 F.3d 690 (Fed. Cir. 2005). Using a clearly erroneous standard of review, the panel affirmed the trial court's finding of materiality "because Purdue repeatedly argued to the PTO that the four-fold dosage range distinguished the invention over the prior art and, while using language that implied, if not suggested, experimental results had been obtained, failed to tell the PTO its discovery was based only on . . . insight." *Id.* 699-700. Regarding the intent element, the panel found that "[t]he consistent and repetitive nature of Purdue's communications with the PTO fully supports the trial court's conclusion that Purdue made a deliberate decision to withhold and thus misrepresent the origin of its 'discovery' to the PTO." *Id.* at 701. Based on the record before it, the panel did not find that the trial court abused its discretion in weighing the findings of intent and materiality to conclude that the patents were unenforceable due to Purdue's inequitable conduct.

The Federal Circuit's decision prompted much criticism as well as the filing of a combined petition for panel rehearing and rehearing *en banc* by Purdue. The petition in turn provoked numerous *amicus* briefs in support of Purdue urging the Federal Circuit to clarify the law of inequitable conduct. *Amicus curiae* briefs in support of Purdue's petition were filed by the Biotechnology Industry Organization, Richard L. Edelson, M.D., the International Intellectual Property Institute, Congressman Darrell Issa, Law Professors John F. Duffy *et al.*, the Pharmaceutical Research and Manufacturers of America, and the Washington Legal Foundation. The Federal Circuit granted the petition for panel rehearing since further review "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 same three-member panel then vacated the inequitable conduct judgment and remanded the case back to the trial court. *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*, 438 F.3d 1123 (Fed. Cir. 2006).

The Federal Circuit acknowledged that a failure to inform the PTO on whether a "surprising discovery" is based on insight or experimental data does not *in itself* amount to a material omission. Nevertheless, the court affirmed the trial court's finding of a threshold level of materiality in view of "Purdue's consistent representations of the four-fold dosage range for controlled release oxycodone as a 'surprising discovery' and the context in which that statement was repeatedly made." However, the Federal Circuit stressed that the level of materiality was "not especially high" since Purdue did not expressly misrepresent to the PTO it had obtained experimental results but merely made statements implying the existence of an empirical basis for the surprising discovery.

When balanced against high materiality, the showing of intent can be proportionately less. *Brasseler U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1381 (Fed. Cir. 1999). When the materiality of the undisclosed information is relatively low, however, the panel indicated that there is less basis for inferring intent from materiality alone. Since it appeared that the trial court "perceived the level of materiality to be high and inferred deceptive intent from that high materiality," the Federal Circuit vacated the inequitable conduct judgment and remanded the case "to give the trial court an opportunity to reconsider its intent finding" keeping in mind that "when the level of materiality is relatively low, the showing of intent must be proportionally higher."

While the second panel's holding was favorable for Purdue, it nevertheless suffered significant consequences as a result of the same panel's holding less than eight months earlier. Though the litigation is yet to be resolved, the Federal Circuit's decision in *Purdue* importantly clarified the inequitable conduct standard. By confirming that misleading omissions are less material than affirmative misrepresentations and emphasizing that "materiality does not presume intent, which is a separate and essential component of inequitable conduct," it appears the Federal Circuit has reaffirmed the heightened evidentiary standard required for the fatal finding of unenforceability.

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