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## Legal Updates & News

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#### The Resurgence of Inequitable Conduct as a Defense to Patent Infringement (The Special Care Required When Submitting Affidavits to the PTO)

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For over a decade, the inequitable conduct defense to patent infringement has been regarded as a somewhat disfavored defense. Indeed, nearly 20 years ago, the Federal Circuit expressed its distaste for the assertion of the defense in nearly every patent infringement suit, and issued an opinion that served to curtail a district court's discretion to find inequitable conduct. Where the basis of an inequitable conduct allegation was false statements or omissions made in affidavits submitted to the United States Patent and Trademark Office ("PTO"), however, district courts were afforded somewhat broader discretion to find that inequitable conduct had occurred.

Recent developments in Federal Circuit case law have confirmed the vitality of the inequitable conduct defense, particularly where the basis for the defense is misstatements or omissions made in affidavits submitted to the PTO. In cases involving affidavits, recent Federal Circuit opinions have established that district courts have broad discretion to find inequitable conduct, and, in particular, "intent to deceive the PTO." Patent applicants thus must exercise special caution when submitting affidavits to the PTO.

Every patent applicant (and their attorney) "has a duty of candor and good faith" in dealing with the PTO.<sup>[fn1]</sup> The "inequitable conduct" defense to patent infringement has its roots in this duty of candor. <sup>[fn2]</sup> "Inequitable conduct" is an equitable defense which, if proven, may render a patent unenforceable. "To hold a patent unenforceable due to inequitable conduct, there must be clear and convincing evidence that the applicant (1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information [to the PTO], and (2) intended to deceive the [PTO]." <sup>[fn3]</sup>

"If a district court finds that the requirements of materiality and intent have been established by clear and convincing evidence, it must then 'balance the equities to determine whether the patentee has committed inequitable conduct that warrants holding the patent unenforceable.'" <sup>[fn4]</sup> "Under the balancing test, '[t]he more material the omission or the misrepresentation, the lower the level of intent required to establish inequitable conduct, and vice versa.'" <sup>[fn5]</sup> The determination of whether a patentee committed inequitable conduct is "committed to the discretion of the trial court," and the trial court's decision is reviewed by the Federal Circuit "under an abuse of discretion standard." <sup>[fn6]</sup>

In 1988, the late Judge Philip Nichols, writing for a panel of the U.S. Court of Appeals for the Federal Circuit, lamented the rise of inequitable conduct allegations in patent suits, denouncing the "habit of charging inequitable conduct in almost every major patent case" as "an absolute plague." <sup>[fn7]</sup> Subsequently, Federal Circuit decisions and changes in PTO rules served to rein in the defense.

First, in 1988, the Federal Circuit sitting *en banc* issued its opinion in *Kingsdown Medical Consultants*, <sup>[fn8]</sup> which significantly curtailed a district court's discretion to find inequitable conduct. In particular, the Federal Circuit overturned prior precedent<sup>[fn9]</sup> that held that a showing of "gross negligence" was sufficient to meet the "intent to deceive" prong of the defense. <sup>[fn10]</sup> Instead, the Federal Circuit held "the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to

deceive.” [fn11] Second, in 1992, the PTO amended its rules to limit its definition of what constitutes material information. Prior to 1992, the PTO’s rules stated that information “is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.” [fn12] In 1992, the PTO replaced the “reasonable examiner” standard with a standard which states that information is material if it (1) establishes “a *prima facie* case of unpatentability of a claim;” or (2) “refutes, or is inconsistent with” positions taken by the applicant during patent prosecution. [fn13]

In the wake of the *Kingsdown* decision and the PTO’s changes to its definition of what constitutes material information, “inequitable conduct” came to be viewed as a disfavored defense that is difficult to prove.

Despite the changes in Federal Circuit law and in PTO rules, the Federal Circuit appeared willing to afford district courts somewhat broader discretion to hold a patent unenforceable for inequitable conduct where the involved conduct consisted of false statements or omissions made in affidavits submitted to the PTO. This is because in the Federal Circuit’s view “[a]ffidavits are inherently material,” even if cumulative to other affidavits of record, and “[t]he affirmative act of submitting an affidavit must be construed as being intended to be relied upon.” [fn14] Moreover, the PTO examiner often has no ability to investigate the facts recited in an affidavit and must rely entirely upon the candor of the affiant and the party submitting an affidavit. [fn15]

Indeed, patents were held unenforceable for inequitable conduct based on misstatements and omissions in affidavits, even where the statements or omissions were not directly related to patentability. For example, the Federal Circuit affirmed judgments of unenforceability where applicants failed to disclose an affiant’s relationship to the patentee, [fn16] and where the affiant made misstatements in connection with a petition to obtain expedited examination of a patent application. [fn17]

Recently, the inequitable conduct defense has gained new vitality through Federal Circuit decisions that seemingly relax the standards for both materiality and intent. Significantly, inequitable conduct based on false statements and material omissions made in connection with affidavits submitted to the PTO was at the center of these Federal Circuit decisions. First, in February 2006, in *Digital Control Inc.*, [fn18] the Federal Circuit addressed the standard of materiality to be used in an inequitable conduct analysis, and confirmed the vitality of the “reasonable examiner” test. In *Digital Control*, the district court, applying the “reasonable examiner” standard of materiality, had granted summary judgment that, among other things, misstatements in an inventor’s affidavit concerning his reduction to practice of the claimed invention were material. [fn19] The district court applied the “reasonable examiner” standard even though the conduct giving rise to the inequitable conduct allegations occurred in connection with patent applications filed *after* the PTO’s 1992 change to its definition of materiality. [fn20] The Federal Circuit held that the PTO’s adoption of its 1992 materiality standard did not “supplant or replace” the “reasonable examiner” standard, but rather “provide[d] an additional test of materiality.” In so doing, the Federal Circuit emphasized that information which meets the “reasonable examiner” test is material for purposes of an inequitable conduct analysis. [fn21]

One week later, in *Ferring B.V.*, [fn22] the Federal Circuit also considered the circumstances under which “intent to mislead” can be inferred from an applicant’s withholding of material information in an affidavit submitted to the PTO. In *Ferring B.V.*, the applicant failed to disclose the relationships of third-party affiants to a named inventor and the patent assignee, and, based on those omissions, the district court granted summary judgment of unenforceability due to inequitable conduct. [fn23] Over the sharp dissent of Judge Pauline Newman, the Federal Circuit affirmed the district court’s grant of summary judgment. In addressing the “intent to mislead” prong the Federal Circuit held that where omitted information is “highly material” and “the applicant knew of the information,” intent to mislead can be inferred where: (1) the applicant “knew or *should have known*” of the materiality of the withheld information, and (2) the applicant failed to provide a “credible explanation” for withholding the information. [fn24] The Federal Circuit thus revived a “should have known” standard for assessing intent thought to have been laid to rest by the *Kingsdown* opinion.

Very recently, in *Espeed, Inc.*, [fn25] the Federal Circuit again addressed inequitable conduct in the context of false statements made in affidavits submitted to the PTO. In so doing, the Federal Circuit seemingly collapsed the materiality and intent prongs into a single inquiry, approving a district court’s drawing of an inference of intent to mislead by virtue of the patentee’s submission of false affidavits to the PTO. Although acknowledging the *Kingsdown* standard of intent, the Federal Circuit concluded that “[a]n inference of intent may arise where material false statements are proffered in a declaration or other sworn statement submitted to the PTO.” [fn26] The Federal Circuit explained “[t]

he district court was free to draw an inference that these declarations were ‘the chosen instrument of an intentional scheme to deceive the PTO’ . . . because ‘the affirmative act of submitting an affidavit must be construed as being intended to be relied upon.’” [fn27]

In summary, recent developments in Federal Circuit case law confirm that the inequitable conduct defense to patent infringement is alive and well. In assessing materiality, courts are free to use the “reasonable examiner” standard once thought to be superseded (for patent applications filed after January 1992) by changes in the PTO’s rules. Moreover, it appears that district courts have broader discretion to infer “intent to mislead” than the *Kingsdown* decision suggested, at least where an inequitable conduct charge is based upon false statements or omissions made in an affidavit.

Patentees should be particularly vigilant when submitting affidavits to the PTO. Patent applicants should carefully review relevant documents and publications to ensure that any affidavit submitted to the PTO is complete and accurate. [fn28] Any doubts about whether information should be disclosed probably should be resolved in favor of disclosure. A third-party affidavit should completely disclose any conceivable connection between the affiant and the applicants or the assignee.

For defendants in patent infringement suits, misstatements and omissions in affidavits submitted to the PTO are fertile ground for an inequitable conduct defense.

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## Footnotes

1 37 C.F.R. § 1.56 (2005).

2 *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1186 (Fed. Cir. 2006)

3 *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1363-64 (Fed. Cir. 2007) (citation omitted).

4 *Id.* at 1364 (citation omitted).

5 *Id.* (citation omitted).

6 *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc).

7 *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).

8 *Kingsdown*, 863 F.2d at 876-77.

9 *See, e.g., Driscoll v. Cebalo*, 731 F.2d 878, 885 (Fed. Cir. 1984).

10 *Kingsdown*, 863 F.2d at 876.

11 *Id.*

12 37 C.F.R. § 1.56(a) (1991).

13 37 C.F.R. § 1.56(b) (1992).

14 *Refac Int'l, Ltd. v. Lotus Development Corp.*, 81 F.3d 1576, 1583 (Fed. Cir. 1996).

15 *Paragon Podiatry Labs., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1191 (Fed. Cir. 1993) (“The inference [of intent to mislead] arises not simply from the materiality of the affidavits, but from the affirmative acts of submitting them, their misleading character, and the inability of the examiner to investigate the facts.”).

16 *Refac*, 81 F.3d at 1578-1585 (judgment of inequitable conduct affirmed where applicants failed to disclose that affiant (who averred that the patent application was enabling) had been employed for

eight weeks by the inventors' company, and had some prior knowledge of the claimed invention); *Paragon*, 984 F.2d at 1190-92 (affirming summary judgment of inequitable conduct where applicants failed to disclose that affiants were not disinterested third parties, but rather were stockholders in the company to which the application was assigned, and at least one affiant had consulted for the assignee).

17 *General Electro Music Corp. v. Samick Music Corp.*, 19 F.3d 1405 (Fed. Cir. 1994) (affirming judgment of unenforceability due to inequitable conduct where applicant's attorney submitted a declaration in support of a petition for expedited examination of a patent application in which he falsely stated that he had conducted a "careful and thorough" search of the prior art).

18 *Digital Control Inc. v. The Charles Machine Works*, 437 F.3d 1309 (Fed. Cir. 2006).

19 *Id.* at 1314-18.

20 *Id.* at 1310-11.

21 *Id.* at 1316.

22 437 F.3d at 1191.

23 *Id.* at 1183-86.

24 *Id.* at 1191 (emphasis added).

25 *Espeed, Inc. v. Brokertec USA, L.L.C.*, 480 F.3d 1129 (Fed. Cir. 2007).

26 *Id.* at 1138.

27 *Id.* (citations omitted).

28 *See, e.g., Pharmacia Corp. v. Par Pharmaceutical, Inc.*, 417 F.3d 1369 (Fed. Cir. 2005) (affirming inequitable conduct judgment where statements made by affiant conflicted with statements appearing in an article co-authored by the affiant).