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Patent Litigation and Inequitable Conduct Defenses

Asserting and Defending Inequitable Conduct Challenges Amid Inconsistent Federal Circuit Standards

A Live 90-Minute Audio Conference with Interactive Q&A

Today's panel features:

John L. North, Partner, **Sutherland Asbill & Brennan**, Atlanta

Eric J. Lobenfeld, Partner, **Hogan & Hartson**, New York

K.T. (Sunny) Cherian, Partner, **Howrey**, San Francisco

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The conference begins at:

1 pm Eastern

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Patent Litigation and Inequitable Conduct Defenses: Asserting and Defending Inequitable Conduct Challenges Amid Arguably Inconsistent Federal Circuit Standards

K.T. (Sunny) Cherian, Howrey LLP

Eric J. Lobenfeld, Hogan & Hartson LLP

John L. North, Sutherland Asbill & Brennan LLP

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HOWREY^{LLP}

HOGAN &
HARTSON

SUTHERLAND

K.T. (Sunny) Cherian



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- Represents numerous global technology companies in patent litigation with a focus on memory and CMOS imaging chip technology, power converter technology and networking patents.
 - Formerly a program manager with the U.S. Department of Energy, specializing in renewable energy conversion.
 - Earned his J.D. from University of California, Davis School of Law, his M.S. from George Washington University and his ISC from Cambridge University.
 - Has been named a Northern California Super Lawyer by the *San Francisco Daily Journal* since its inception.

Eric J. Lobenfeld

- Practice Group Director for Hogan's Intellectual Property Litigation Group.
- Represents numerous global technology companies, entertainment companies and pharmaceutical companies.
- Has first-chaired more than 20 intellectual property jury trials, bench trials and arbitrations.
- Earned his B.A. from Binghamton University, S.U.N.Y. and his J.D. magna cum laude from Brooklyn Law School.

- Chair of Sutherland's Intellectual Property Practice Group.
- Focuses his practice on patent litigation and related antitrust controversies.
- Has represented one of the world's largest pharmaceutical corporations, a cutting-edge minerals technologies company and a major entertainment company.
- Has been recognized in *Chambers USA*, *The Best Lawyers in America* and Georgia Super Lawyers®.
- From 2004-2007, served as co-editor of the *Scientific Evidence Review*, a publication of the American Bar Association Section of Science and Technology Law.
- Earned his B.A., *magna cum laude* from Duke University and his J.D., *cum laude*, from Emory University School of Law.

OVERVIEW

I. Inequitable Conduct Defense

- History of the Defense
- Law of Inequitable Conduct
- Examples of Inequitable Conduct

II. Litigation Strategies

- Asserting the Defense
- Defending Against Inequitable Conduct Claims

III. Current Trends and Patent Reform Efforts

- Recent Judicial Developments
- Recent Legislative Developments
- Possible Future Developments

IV. Questions

Historical Development

- The inequitable conduct doctrine evolved from three Supreme Court cases:
 - Keystone Driller Co. v. General Excavator Co., 290 U.S. 240 (1933)
 - Hazel-Atlas Glass Co. v. Hartford-Empire Co., 322 U.S. 238 (1944)
 - Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co., 324 U.S. 806 (1945).
- In these cases the Court held that fraud and inequitable conduct are a defense to patent infringement under the equitable doctrine of unclean hands.
- Each of these cases involved misconduct such as the manufacture or suppression of evidence. The Supreme Court had no need to refine the scope of the doctrine given the nature of the misconduct.
- The PTO disbarred the attorneys who committed fraud in Hazel-Atlas. Upholding the disbarment, the Supreme Court stated that “[b]y reason of the nature of an application for patent, the relationship of attorneys to the Patent Office requires the highest degree of candor and good faith.” Kingsland v. Dorsey, 338 U.S. 318, 319 (1949).

Duty to Disclose

- The doctrine of inequitable conduct arises from the duties of candor, good faith, and honesty of applicants for patents and their legal representatives in their dealings with the PTO.
- The duties of candor, good faith, and honesty include the duty to submit truthful information and the duty to disclose to the PTO information known to applicants or their attorneys which is material to the examination of a patent application.
- Inequitable conduct constitutes a breach of this duty, and a violation results in unenforceability of all claims in the patent, not only the claims that were the subject of the inequitable conduct.

Elements of the Defense

- Inequitable conduct requires a material misrepresentation or omission coupled with an intent to deceive the PTO.
- To establish inequitable conduct, a defendant must establish by “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, and
 - (2) intended to deceive the [PTO].”

Praxair, Inc. v. ATMI, Inc., 543 F.3d 1306 (Fed. Cir. 2008).

Two-Step Analysis

A determination of inequitable conduct follows a two-step analysis.

1) Threshold showing of materiality and intent:

- The accused infringer must prove by clear and convincing evidence at least a threshold level of both materiality and intent to deceive.

2) Balancing of materiality and intent:

- If threshold levels of both materiality and intent are found, the Court then must determine, as a matter of law, whether the questioned conduct amounts to inequitable conduct by balancing the levels of materiality and intent, with a greater showing of one factor permitting a lesser showing of the other.

Inequitable conduct is “an equitable determination” and thus “is committed to the discretion of the trial court.” Monon Corp. v. Stoughton Trailers, Inc., 239 F.3d 1253, 1261 (Fed. Cir. 2001).

Standards for Materiality

- Information is material if a reasonable examiner would have considered such information important in deciding whether to allow the application. Monsanto Co. v. Bayer Bioscience N.V., 514 F.3d 1229, 1237 (Fed. Cir. 2008).
- Materiality only requires that a misrepresentation or omission be within a reasonable examiner's realm of consideration. It is not necessary that the patent would not have issued but for the misrepresentation or omission. Merck & Co., Inc. v. Danbury Pharmacal, Inc., 873 F.2d 1418, 1421 (Fed. Cir. 1989).
- PTO Rule 56(b) also defines material information as information that "is not cumulative to information already of record or being made of record in the application, and [that]
 - (1) . . . establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
 - (2) . . . refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

37 C.F.R. § 1.56(b)

Inference of Intent

- To establish an intent to deceive the PTO, there must be clear and convincing evidence of “culpable” conduct. Ariad Pharms., Inc. v. Eli Lilly and Co., 560 F.3d 1366, 1380 (Fed. Cir. 2009).
- Usually, however, there is no “smoking gun” evidence of intent.
- Direct evidence of intent is not necessary, and intent can be inferred from the surrounding facts and circumstances. Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd., 394 F.3d 1348, 1354 (Fed. Cir. 2005).

Sliding Scale of Materiality and Intent

- A district court, upon finding threshold levels of materiality and intent, must “balance the equities to determine whether the patentee has committed inequitable conduct that warrants holding the patent unenforceable.” Monsanto Co. v. Bayer Bioscience N.V., 363 F.3d 1235, 1239 (Fed. Cir. 2004).
- “The more material the omission or misrepresentation, the less intent that must be shown to elicit a finding of inequitable conduct.” Impax Labs., Inc. v. Aventis Pharmaceuticals Inc., 468 F.3d 1366, 1375 (Fed. Cir. 2006).
- “[W]hen balanced against high materiality, the showing of intent can be proportionally less. Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 326 F.3d 1226, 1234 (Fed. Cir. 2003).

Examples of Inequitable Conduct

- Failure to Cite Material Prior Art
- Misrepresentation of Data in a Declaration
- Failure to Submit Material Testing Data
- Failure to Cite Related, Copending Applications

Example 1:

Failure to Cite Material Prior Art

Merck & Co., Inc. v. Danbury Pharmacal, Inc., 873 F.2d 1418 (Fed. Cir. 1989).

- The patents-in-suit claim methods of using cyclobenzaprine to treat certain types of skeletal muscle disorders.
- During prosecution, the patentee failed to disclose prior art suggesting that a related compound, amitriptyline, had muscle relaxant properties.
- The Court found that the failure to disclose the material prior art, in combination with a pattern of other misrepresentations, gave rise to an inference of deceptive intent.

Example 2: Misrepresentation of Data in a Declaration

Aventis Pharma SA v. Amphastar Pharmaceuticals Inc., 525 F.3d 1334 (Fed. Cir. 2008).

- Patentee asserted infringement of patents relating to heparins used to prevent blood clotting while minimizing the risk of hemorrhaging.
- During prosecution, the patentee responded to a claim rejection by submitting a declaration showing data that the half-life of the claimed formulation was different from the half-life of the prior art formulations on which the examiner relied.
- Patentee failed to disclose that the half-life studies comparing the patented composition to the prior art compound were done at different doses.
- Despite providing several explanations for why the comparison at different doses was reasonable, the Federal Circuit affirmed the District Court's finding of deceptive intent.
- J. Rader dissented, arguing that a finding of deceptive intent was impermissible because other reasonable explanations were given for the omission.

Example 3: Failure to Submit Material Testing Data

Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359 (Fed. Cir. 2007).

- Patentee asserted infringement of patents relating to a non-hydrogenated canola oil that possessed superior oxidative stability and fry stability.
- During prosecution, the patentee failed to disclose test data demonstrating that the oxidative stability of the patentee's oil was similar to that of one of the parent lines.
- The Federal Circuit found that test data demonstrating the similarity of the oxidative stability was material, given that a crucial issue during prosecution was the superiority of the oxidative stability properties of patentee's oil.
- The failure to disclose the test data despite the examiner repeatedly raising an issue to which the information relates gave rise to the inference of intent to deceive.

Example 4: Failure to Cite Related, Copending Applications

McKesson Information Solutions, Inc. v. Bridge Medical, Inc., 487 F.3d 897 (Fed. Cir. 2007).

- Patentee sued competitor for infringement of patent related to patient identification system.
- The examiner in a copending application rejected “substantially similar” claims.
- During prosecution, the patentee failed to disclose the claim rejections in the copending application although the patentee did disclose prior art cited in the copending application.
- The Federal Circuit found that the Applicant intended to deceive the PTO by failing to disclose the adverse decisions in the copending application and making statements to the examiner inconsistent with the other examiner’s decisions.

Litigation Strategies: Asserting Inequitable Conduct

Whether to Assert?

- Cost considerations
- Burden of proof
 - The accused infringer has the burden of proving inequitable conduct by clear and convincing evidence. Kingsdown Medical Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 872 (Fed. Cir. 1988).
- Current judicial trend

When to Assert?

- When answering complaint or after discovery?
- Consider the Rule 9(b) heightened pleading requirement for asserting inequitable conduct.

Litigation Strategies: Defending Inequitable Conduct

- Whether to provide discovery if inequitable conduct is not pled?
- How to answer inequitable conduct counterclaims
- Rule 12 motion to dismiss?
- Motion for summary judgment?
- Defending inequitable conduct at trial

Recent Judicial Developments

Inference of Deceptive Intent

- Recent cases follow arguably divergent lines of authority with regard to inference of deceptive intent.
 - See Larson Mfg. Co. v. Aluminart Products Ltd., 559 F.3d 1317 (Fed. Cir. 2009) (Linn, J., concurring) (stating that “the test for inferring deceptive intent, as it currently exists, falls short of the [Star Scientific] standard” and “the time has come for the court to review the issue en banc”).
- A first line of cases holds that deceptive intent must be the single most reasonable inference able to be drawn from the evidence.
 - See Star Scientific
- A second line of cases follows the sliding scale balancing approach in which the more material the omission or misrepresentation, the less intent that must be shown to elicit a finding of inequitable conduct.
 - See Aventis Pharma

Recent Judicial Developments, continued

Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357 (Fed. Cir. 2008).

- Exclusive licensee asserted infringement of patent for tobacco curing process.
- During prosecution, patentee did not disclose test data or a letter from an expert to the prosecuting attorney regarding flue-curing techniques.
- Shortly after the application was filed, the patentee replaced the attorney who received the letter.
- Held that “an inference of deceptive intent based on indirect and circumstantial evidence must not only be based on sufficient evidence and be reasonable in light of that evidence, but it also must be the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard.”
- Reversed the finding of inequitable conduct because the defendants did not provide clear and convincing evidence of intent.

Recent Judicial Developments, continued

Larson Mfg. Co. v. Aluminart Products Ltd., 559 F.3d 1317 (Fed. Cir. 2009).

- Patentee asserted infringement of patent claiming a door with a moving glass insert.
- During reexamination of the patent, the patentee did not cite two office actions in a copending application or a prior art reference cited by the examiner in the uncited office actions.
- Cites favorably the Star Scientific holding that an inference of intent must be the single most reasonable inference able to be drawn.
- An “accused infringer cannot carry its threshold burden simply by pointing to the absence of a credible good faith explanation.”
- Remands to district court for further proceedings to determine whether the patentee acted with deceptive intent.
- J. Linn’s concurrence strongly argues for en banc review in order to clarify the test for inferring deceptive intent.

Recent Judicial Developments, continued

Dickson Industries v. Patent Enforcement Team LLC, 2009 WL 1393862 (Fed. Cir. May 20, 2009).

- Plaintiffs filed for declaratory judgment of unenforceability of a method of cutting rumble strips in the surface of a road.
- The Court found that the district court provided inadequate opportunity to develop fully the record on inequitable conduct and remanded to the district court.
- The Federal Circuit cautioned the district court that the “charging of inequitable conduct in almost every major patent case has become an absolute plague.”
- Cites the Star Scientific holding that “in a case involving nondisclosure of information, clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference.”
- “The materiality prong and the intent prong are separate components of the inequitable conduct and must be independently satisfied.”

Recent Judicial Developments, continued

Aventis Pharma SA v. Amphastar Pharmaceuticals Inc., 525 F.3d 1334 (Fed. Cir. 2008).

- Patentee asserted infringement of patents relating to heparins used to prevent blood clotting while minimizing the risk of hemorrhaging.
- During prosecution, the patentee responded to a claim rejection by submitting a declaration showing data that the half-life of the claimed formulation was different from the half-life of the prior art formulations on which the examiner relied.
- Patentee failed to disclose that the half-life studies comparing the patented composition to the prior art compound were done at different doses.
- Despite providing several explanations for why the comparison at different doses was reasonable, the Federal Circuit affirmed the District Court's finding of deceptive intent.
- J. Rader dissented, arguing that “the judicial process has too often emphasized materiality almost to the exclusion of any analysis of the lofty intent requirement for inequitable conduct.”

Recent Judicial Developments, continued

Praxair, Inc. v. ATMI, Inc., 543 F.3d 1306 (Fed. Cir. 2008).

- Patentee asserted infringement of patents relating to pressurized storage containers for limiting accidental discharge of hazardous gases.
- During prosecution, the patentee failed to disclose prior art relating to restricted flow orifices (RFOs) and made statements inconsistent with the prior art use of RFOs.
- Given the lack of testimony explaining the failure to disclose RFOs, the district court held that “the level of materiality of the RFO art is sufficiently high so as to support an ultimate finding of inequitable conduct.”
- The Federal Circuit approved of the inference of intent from findings (1) that the RFO art was highly material, (2) that the applicant knew or should have known of the materiality, and (3) the failure of the patentee to provide a good faith explanation for the failure to disclose.
- J. Lourie dissented, arguing that there was no evidence of deceptive intent and that the Court incorrectly conflated intent with materiality.

Recent Judicial Developments, continued

Heightened Pleading Standard

Exergen Corp. v. Wal-Mart Stores, Inc., 2009 WL 2366535 (Fed. Cir. Aug. 4, 2009).

- Striking down inequitable conduct pleading for failing to plead “with particularity” under Rule 9(b).
- The “pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission” and “include sufficient allegations of underlying facts from which a court may reasonably infer” intent.
- High pleading standard for intent given Rule 9(b), which states that intent “may be alleged generally.”

Recent Legislative Developments

- Current patent reform pending in Congress does not include an inequitable conduct provision. The Senate Judiciary Committee has reported S. 515, which omits inequitable conduct.
- Past patent reform efforts have sought to codify inequitable conduct
 - In the last Congress, the Patent Reform Act of 2007 (H.R. 1908) passed the House but not the Senate.
 - The bill provided three elements for the inequitable conduct defense:
 - (1) The applicant (or another with the duty to disclose) had “the intent to mislead or deceive the patent examiner;”
 - (2) in furtherance of such intent, the applicant “misrepresented or failed to disclose material information” to the Office; and
 - (3) in the absence of the misrepresentation or nondisclosure, the Office would have made a prima facie finding of unpatentability.
 - The provision was crafted to avoid the inference of intent solely from the materiality of the withheld or misrepresented information. Facts independent of the materiality of the information would have been required in order to support an inference of intent.

What Future Developments Can We Expect?

- Currently there are divergent standards in the doctrine of inequitable conduct.
 - Star Scientific and its progeny versus cases inferring intent from a high degree of materiality
- Need for reconciliation of this authority has been noted by Judge Linn and others.
- Codification of inequitable conduct is unlikely in the near future.
- Without en banc review by the Federal Circuit or Supreme Court guidance, uncertainty in the law of inequitable conduct will remain.

Questions?

Contact Information

K.T. (Sunny) Cherian

Howrey LLP
525 Market Street
Suite 3600
San Francisco, CA 94105-2708
(415) 848-4930
CherianK@howrey.com

Eric J. Lobenfeld

Hogan & Hartson LLP
875 Third Avenue
New York, NY 10022
(212) 918-8202
ejlobenfeld@hhlaw.com

John L. North

Sutherland
999 Peachtree Street, NE
Atlanta, GA 30309-3996
(404) 853-8358
john.north@sutherland.com

HOWREY^{LLP}

HOGAN &
HARTSON

SUTHERLAND