

*San Diego Intellectual Property Law Association Panel Discussion:  
Therasense and Inequitable Conduct  
September 23, 2010*

Tonight’s panel includes four attorneys who have filed *amicus* briefs in *Therasense, Inc. et al. v. Becton, Dickinson and Co. et al.* The subject matter of this *en banc* Federal Circuit case – inequitable conduct – has sparked a great deal of interest among those with a stake in patent litigation; 31 *amicus* briefs have been filed so far. Oral argument is scheduled for early November.

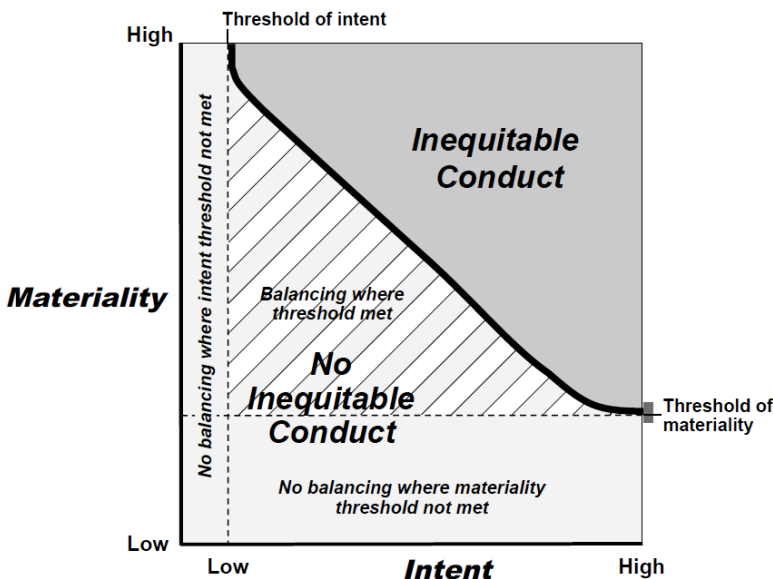
The following briefly describes the evolution of the inequitable conduct doctrine over the past 22 years, sets forth the issues the Court will be addressing in *Therasense*, and includes summaries of the arguments made in each panelist’s *amicus* brief.

*Evolution of the materiality/intent to deceive balancing framework*

In the 1988 *Kingsdown case*,\* the *en banc* Federal Circuit held that inequitable conduct may only be found if a person with a duty of candor makes (with a specific intent to deceive the PTO) a material misrepresentation or omission. Negligence – even gross negligence – is not enough to support a holding of unenforceability.

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

In the years since *Kingsdown*, the Federal Circuit has mandated the use of a test for inequitable conduct in which the fact finder must balance the relative degrees of materiality and intent to deceive after “threshold” levels of both have been found. A graphical representation of this balancing test is shown here:



A graphical representation of the materiality/intent to deceive balancing test.

If threshold levels of either materiality or intent to deceive are not found, no balancing is performed and inequitable conduct cannot be proven.

A relatively high level of materiality will support a finding of inequitable conduct even with a relatively low level of intent to deceive, and vice versa.

Because intent is often difficult to prove, the Federal Circuit allows findings of intent to be inferred from circumstantial evidence. Some have argued that the *Kingsdown* standard has been eroded by a series of cases in which intent was inferred mainly from the materiality of the alleged misrepresentation or omission; once a certain level of materiality has been found, a finding of inequitable conduct is inevitable.†

Defining the types of omissions or misrepresentations that rise to the level of “material” information is therefore critical to the analysis. The Federal Circuit has adopted at least five definitions since *Kingsdown*, any one of which may be used by a finder of fact; these were listed by the panel opinion in *Digital Control*: ‡

- Objective “but for” – “the misrepresentation was so material that the patent should not have issued”;
- Subjective “but for” – “the misrepresentation actually caused the examiner to approve the patent application when he would not otherwise have done so”;
- “But it may have” – “the misrepresentation may have influenced the patent examiner during prosecution”;
- 1992 Rule 56 – information is material if: 1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or 2) It refutes, or is inconsistent with, a position the applicant takes in: (i) opposing [a PTO] argument of unpatentability, or (ii) asserting an argument of patentability;
- 1977 Rule 56 – 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.”

The Court in *Digital Control* made clear that a practitioner who follows the PTO’s current (1992) version of Rule 56 may still be found to have committed inequitable conduct if he or she has violated the broader “reasonable examiner” (1977) version of Rule 56, regardless of when the prosecution took place.

†See, for example, Judge Newman’s dissent in *Ferring B.V. v. Barr Labs, Inc.*, 437 F.3d 1181, 1195 *et seq.* (Fed. Cir. 2006), *cert. denied*, 549 US 1015 (2006). See also, Chief Judge Rader’s article *Always at the Margin: Inequitable Conduct in Flux*, *American University Law Review*, Vol. 59, 777-786 (2010).

‡ *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1314-1316 (Fed. Cir. 2006).

### *Charges of inequitable conduct have become more common*

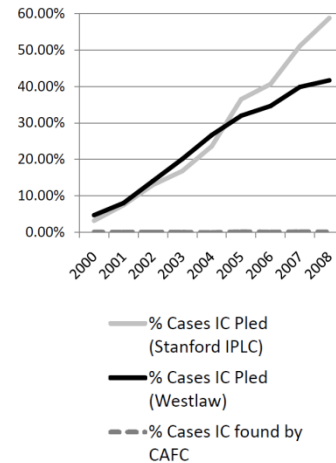
Perhaps because it has become easier to prove inequitable conduct, the rate at which it is pled has steadily increased over the past 10 years. However, the number of cases in which inequitable conduct has been found and upheld by the Federal Circuit has remained fairly constant. In those cases in which inequitable conduct was found by the district court, the Federal Circuit has affirmed in about 41% of the cases, vacated in about 16% of the cases, and found no inequitable conduct as a matter of law in about 43% of the cases.

In those cases in which inequitable conduct was *not* found by the district court, the Federal Circuit has affirmed in about 92% of the cases, vacated in about 5% of the cases, and found inequitable conduct as a matter of law in about 3% of the cases.

### *The questions presented in Therasense*

After losing a panel decision (with a dissent by Judge Linn), counsel for Therasense filed a petition for rehearing *en banc*; this petition was joined by briefs from several *amici*, including a brief written by Christian Mammen, the moderator of tonight's panel. In its *en banc* order, the Court asked the parties to address the following issues:

1. Should the materiality-intent-balancing framework for inequitable conduct be modified or replaced?
2. If so, how? In particular, should the standard be tied directly to fraud or unclean hands? ... If so, what is the appropriate standard for fraud or unclean hands?
3. What is the proper standard for materiality? What role should [PTO rules] play in defining materiality? Should a finding of materiality require that but for the alleged misconduct, one or more claims would not have issued?
4. Under what circumstances is it proper to infer intent from materiality?
5. Should the balancing inquiry (balancing materiality and intent) be abandoned?
6. Whether the standards for materiality and intent in other federal agency contexts or at common law shed light on the appropriate standards to be applied in the patent context.



*The positions argued by members of tonight's panel*

All of the panelists agree that the balancing inquiry (balancing the materiality of a misrepresentation or omission with the level of intent to deceive the PTO) should be abandoned. Summaries of each of the briefs are given below.

*Summary of the brief authored by Christian Mammen (panel moderator), representing five intellectual property law professors*

The law professors' brief is focused on improving clarity and certainty via bright-line rules and standards of proof.

For materiality, the law professors favor the current (1992) version of Rule 56 over the objective but-for test, because it provides clear, specific guidance that can be applied *ex ante* (e.g., during prosecution, when disclosure decisions are being made).

For intent, the law professors emphasize the clear and convincing burden of proof. While *Star Scientific's* "single most reasonable inference" test is generally useful, there may be instances where the single most reasonable inference still falls short of a clear and convincing demonstration of intent. When intent must be proven by circumstantial evidence, the law professors suggest that can be done via proof that the applicant knew of the withheld information, its materiality, and the duty to disclose, yet nonetheless made a deliberate decision to withhold the reference. The law professors favor abolishing all discussion of "gross negligence" and "should have known."

The law professors would abandon the balancing step for two reasons. First, with elevated, on-off standards for materiality and intent in place of the old sliding scales, balancing is not necessary. Second, in practice, it is often ignored or misapplied.

Consistent with these bright-line rules, the law professors would not permit a range of remedies, which in any event could increase litigants' willingness to "roll the dice" by pursuing weak allegations of inequitable conduct.



Dr. Christian Mammen has been a Resident Scholar at UC Hastings since 2009. Previously, he was a partner at Day Casebeer Madrid & Batchelder and an associate at Heller Ehrman, where his practice focused on patent litigation. Mammen holds a doctorate in law from Oxford University, and recently published one of the leading law review articles on inequitable conduct reform.

*Summary of the brief co-authored by  
William (Larry) Respass, representing the San Diego  
Intellectual Property Law Association*

Because of prior decisions of the Supreme Court and enactment of Section 288 of Title 35, the Federal Circuit cannot eliminate the defense of inequitable conduct as some have suggested. However, it should replace the current jurisprudence for determining inequitable conduct, which requires the trial court to employ the materiality/intent balancing test.

The Federal Circuit should hold that inequitable conduct exists when intent to deceive is proven by direct evidence (without inferring intent from materiality) and materiality of the misrepresented or omitted information meets the standard set forth in Rule 56. However, the penalty of unenforceability should only be imposed when materiality meets the objective “but for” standard. Inequitable conduct in which materiality does not meet the higher but for standard should be penalized by a lesser punishment. For example, a permanent injunction could be denied the patentee by weighing the misconduct with other factors used by the trial court to determine if a permanent injunction should be granted.

Dr. Respass holds a BS in Chemistry from the Virginia Military Institute (1961); a PhD in Organic Chemistry from the Massachusetts Institute of Technology (1966); and a JD from George Washington University. His extensive experience includes service in the US Air Force (1966-9); CCPA Law Clerk and Technical Advisor to J. Lindsay Almond (1972-74); associate and partner, Lyon & Lyon (1974-83); VP & General Counsel of Hybritech (1983-6); VP & General Counsel of GenProbe (1986-8); Senior VP & General Counsel of Ligand Pharmaceuticals (1988-2000); Senior VP & General Counsel of Graviton (2000-2); Senior VP & General Counsel of Applied Molecular Evolution (2002-04); Senior VP & General Counsel of Nanogen (2004-9).

*Summary of the brief authored by Hans Sauer,  
representing the Biotechnology Industry Association*

BIO is the principal trade association of the U.S. biotechnology industry, with over 1,150 corporate, academic, and non-profit members. In BIO's view, the current inequitable conduct doctrine creates unnecessary business uncertainty in biotechnology, and is detrimental to the U.S. patent system overall. The court's restatement of the doctrine should focus on the public interest in clarity and validity of patent rights, and less on the interests of private litigants or the institutional interests of the Patent Office.

Patents are presumed valid, and the public is entitled to rely on that presumption for investment and business decisions. BIO believes that the current inequitable conduct doctrine does not sufficiently account for that public reliance interest. Bad-faith applicants who deceive the PTO into issuing invalid claims cause public harm for which an unenforceability remedy may be appropriate. But to declare a valid patent right unenforceable also creates public harm, because it undoes years of commercial decision-making and investment in the marketplace that was correctly undertaken in reliance on valid patent rights. Accordingly, BIO believes that the best public interest balance is achieved if the remedy of unenforceability is tied to a validity defect of the patent in suit.

Material information should thus be defined as facts that establish invalidity of at least one issued claim. Tying materiality to a validity defect in this way makes the materiality inquiry more objective and "binary:" information is either material or it is not. This would eliminate any need to balance the level of materiality against the level of intent. Intent would separately be established from all the circumstances, and should neither be grounded in gross negligence nor be inferred from materiality alone. Intent to deceive should be specific, i.e. the evidence would have to show that the individual charged with inequitable conduct not only intended to make the representation or to withhold material information, but that he or she intended to deceive the PTO. After both elements are established by clear and convincing evidence, a trial court would have discretion to consider intervening equities when deciding whether the inequitable conduct warrants the severe sanction of unenforceability.

BIO does not believe the judicial standard needs to be identical with the PTO's administrative Rule 56 standard, as long as conduct that is lawful under PTO regulations is not later declared unlawful in civil actions between private litigants.



Hans Sauer is Deputy General Counsel for Intellectual Property for the Biotechnology Industry Organization (BIO), a major trade association representing over 1,150 biotechnology companies and other member organizations from the medical, agricultural, environmental, and industrial sectors in the United States and internationally. At BIO, Mr. Sauer advises the organization's board of directors, amicus committee, and various staff committees on patent and other intellectual property-related matters.

Prior to his current position, Mr. Sauer was Chief Patent Counsel for MGI Pharma, Inc., in Bloomington, MN, and Senior Patent Counsel for Guilford Pharmaceuticals Inc. in Baltimore, MD.

Mr. Sauer has 15 years of professional in-house experience in the biotechnology industry, where he worked on several research and drug development programs, being responsible for patent prosecution and portfolio oversight, clinical trial health information privacy, and sales and marketing legal compliance.

Mr. Sauer has an M.S. degree in Biology from the University of Ulm in his native Germany, a Ph.D. in Neuroscience from the University of Lund, Sweden, and a J.D. from Georgetown University Law Center in Washington, D.C., where he serves as adjunct professor.

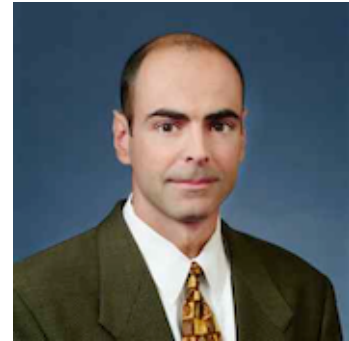
*Summary of the brief co-authored by Frederick Hadidi,  
representing 22 patent prosecution firms and practitioners*

The assumption driving current inequitable conduct jurisprudence – at least those cases involving the failure to disclose a reference – is that patent attorneys are strongly motivated to conceal the closest art. This results in severe substantive and procedural disadvantages for the accused attorney, making it too easy to establish deceptive intent where none exists.

For instance, when it is shown that a reference with a threshold level of materiality was not disclosed, the burden shifts to the practitioner to provide a good faith explanation for the nondisclosure. If the accused attorney can't remember the basis for the decision to withhold the reference, courts frequently infer deceptive intent because the inability to recall the rationale underlying the decision – even if it was many years in the past – is equated with a lack of credibility.

An accused attorney is typically not allowed to intervene at the district court or on appeal, and a finding of inequitable conduct may lead to costly and potentially career-ending investigations by the OED and state bar organizations.

The impact of a mistaken finding of inequitable conduct is so severe that at a minimum, the issues of materiality and intent must be decided separately. The existing analytical framework for determining when misconduct before the PTO will give rise to antitrust (*Walker Process*) liability should also apply in an inequitable conduct analysis. The *Walker Process*-type test we propose includes (1) but-for materiality of the alleged misrepresentation or omission, and (2) specific intent to deceive the PTO that is determined independently of the materiality inquiry.



Frederick Hadidi has been a partner at Chao Hadidi Stark & Barker LLP since 2004; his practice includes appellate, licensing, and pre-litigation matters. He previously worked as a solo practitioner and at the Silicon Valley offices of Skadden Arps Slate Meagher & Flom, Pennie & Edmonds, and Heller Ehrman White & McAuliffe. Fred has a J.D. from Stanford Law School and a B.S.E.E. from Cornell University.