

Nos. 2008-1511, -1512, -1513, -1514, -1595

**IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

THERASENSE, INC. (now known as Abbott Diabetes Care, Inc.)
and ABBOTT LABORATORIES,

Plaintiffs-Appellants,

v.

BECTON, DICKINSON AND COMPANY ,
and NOVA BIOMEDICAL CORPORATION,

Defendants-Appellees,

and

BAYER HEALTHCARE LLC,

Defendant-Appellee.

**On Appeal from the United States District Court
For the Northern District of California**

In Case Nos. 04-CV-2123, 04-CV-3327, 04-CV-3732, and 05-CV-3117

Judge William H. Alsup

**BRIEF OF WASHINGTON LEGAL FOUNDATION
AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFFS-APPELLANTS'
PETITION FOR REHEARING *EN BANC***

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CERTIFICATE OF INTEREST

Counsel for *amicus curiae* Washington Legal Foundation certifies as follows:

1. The full name of every party or amicus represented by me is:

Washington Legal Foundation

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

N/A

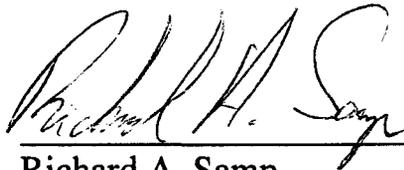
3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None

4. The names of all law firms and the partners and associates that appeared for the party or amicus now represented by me in the trial court or are expected to appear in this case:

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INTERESTS OF *AMICUS CURIAE*

The interests of *amicus curiae* Washington Legal Foundation (“WLF”) are set forth more fully in its motion for leave to file this brief. In brief, WLF is a non-profit public interest law firm that regularly appears before federal and state courts to promote economic liberty, free enterprise, and a limited and accountable government. WLF has participated in numerous court proceedings raising important issues regarding the scope and validity of pharmaceutical patents. *See, e.g., Purdue Pharma, L.P. v. Endo Pharmaceuticals, Inc.*, 438 F.3d 1123 (Fed. Cir. 2006) (opposing expansion of inequitable conduct doctrine).

WLF is concerned that the Federal Circuit’s “inequitable conduct” case law has drifted far afield from its “unclean hands” roots. By lowering the bar for those charging patent invalidity due to inequitable conduct, the Federal Circuit has considerably increased the risks to those asserting patent rights and considerably reduced the market value of all patents. WLF is concerned that if the property rights of patent holders can be so easily eliminated, the public will quickly lose faith in the viability of our patent system.

REASONS FOR GRANTING THE PETITION

I. Rehearing *En Banc* Is Warranted Because the Panel’s Decision Increases Uncertainty Regarding What Constitutes “Material Information” for Purposes of Determining Inequitable Conduct

This petition raises patent law issues of exceptional importance. While

allegations of inequitable conduct are easily made, any such ruling overturns the PTO's decision to allow a patent and has enormous practical and financial consequences for the parties involved, and frequently for their employees as well. WLF agrees with Appellants that rehearing is warranted with respect to both the panel's materiality holding and its intent-to-deceive holding. WLF writes separately to focus particular attention on the panel's significant expansion of the definition of "material information."

The Supreme Court has explained that "[t]he guiding doctrine" in patent cases in which inequitable conduct is alleged "is the equitable maxim that 'he who comes into equity must come with clean hands.'" *Precision Instrument Mfr. Co. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 814 (1945). The "unclean hands" doctrine "closes the door of a court of equity to one tainted with inequity or bad faith relative to the matter in which he seeks relief." *Id.* An important limitation on application of the unclean hands doctrine is that it has never been applied to a plaintiff based simply on the fact that the plaintiff has engaged in misconduct; rather, the doctrine is strictly limited to situations in which "some *unconscionable* act" committed by the plaintiff has "*immediate and necessary* relation to the equity that he seeks in respect of the matter in litigation." *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240, 245

(1933) (emphasis added).

In the ensuing decades, this Court and other federal appeals courts struggled to determine just how close must be the relationship between omitted information and issues raised in PTO proceedings¹ before the omission can be deemed sufficiently material to warrant application of the “unclean hands” doctrine. In general, the Court has defined inequitable conduct as an “affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information” – when coupled with an “intent to deceive.” *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1378 (Fed. Cir. 2008). But the Court has never provided a clear definition of what constitutes “material information.” Rather, it has contented itself with broad generalities: information is said to be “material” where there is “a substantial likelihood” that a reasonable patent examiner would consider it “important” in deciding whether to issue a patent. *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362 (Fed. Cir. 1984). Indeed, although the PTO has attempted to provide a greater degree of clarity regarding what information *it* deems “material,” *see* 37 C.F.R. § 1.56, the Court has never deemed itself

¹ Or between an affirmative misrepresentation and issues raised in PTO proceedings.

limited by the PTO's definition of materiality when addressing inequitable conduct claims.

The panel decision represents a substantial expansion of the Court's understanding of "material information." The decision marks the first occasion on which the Court has invalidated a patent based not on a failure to disclose relevant prior art, but on a failure to disclose *written arguments* regarding what the prior art discloses. That definition of "material information" directly conflicts with the 2008 panel decision in *Innogenetics*. In an effort to eliminate confusion regarding the intent-to-deceive requirement, the Court in 1988 in *Kingsdown* agreed to *en banc* review of a case raising inequitable conduct issues; its decision provided much-needed clarity and somewhat tightened the standards for establishing that a patent applicant intended to deceive the PTO. *Kingsdown Medical Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876-77 (Fed. Cir. 1988) (*en banc*). WLF respectfully suggests that *en banc* review is necessary to provide similar clarity regarding the meaning of "material information."

In the absence of such clarity, one can reasonably expect that patent applicants will respond to the panel decision by inundating the PTO with extraneous material, to minimize the chance that a reviewing court will later deem them to have omitted material information. Indeed, responses of that sort

have already materialized. Patently-O, the patent law blog, recently reported that an application covering an “antibody composition” included over 900 references. See Patently-O, *What Does a Patent Examiner Do with 900+ References* (Jan. 28, 2009), available at <http://www.patentlyo.com/patent/2010/01/what-does-a-patent-examiner-do-with-900-references.html>. The article noted, “The result is that the file history includes 13,689 pages of non-patent or foreign prior art.” *Id.* The attorney for the patent applicant explained his decision to include 900 references as a reaction to the decision in this and similar inequitable conduct cases:

It may also be prudent to identify relevant foreign applications and office actions in an IDS, in view of [the panel decision in this case]. Although the prosecution history of a foreign application cannot be used to construe patent claims, it may now render them unenforceable.

*Id.*² Such “defensive” IDS filings do nothing to improve the quality of the PTO’s review of patent applications; indeed, one can reasonably anticipate that excessively lengthy applications will make it more difficult for patent examiners to determine whether an invention has been anticipated. But applicants can hardly be blamed for reacting in a manner reasonably calculated to reduce the possibility of a later allegation that they omitted “material information.” Rehear-

² See also A. Bukoye, *et al.*, “A New and Troubling Decision for Patent Owners,” JW I.P. e-Alert (Mar. 3, 2010), available at <http://images.j.w.com/ealert/ip/2010/0303sm.html> (“What is troubling about *Therasense* is the difficulty of deriving a reasonable strategy for avoiding its risks.”).

ing *en banc* is warranted to eliminate the need for such filings and to clear up the widespread confusion regarding the meaning of “material information.”

The panel’s efforts to harmonize its decision with *Innogenetics* are unavailing. Slip op. 26-27. In *Innogenetics*, the Court affirmed a grant of summary judgment to the patent holder on the defendant’s inequitable conduct claim, rejecting claims that “Innogenetics’ behavior before the PTO” constituted “a material omission or misrepresentation.” *Innogenetics*, 512 F.3d at 1379. The prosecuting attorney argued before the PTO that certain European Patent Office (EPO) prior art references “do not relate to the invention and, therefore, further discussion of the same is not necessary,” but he admitted in the district court what he failed to disclose to the PTO: that the applicant had told the EPO that those references were “the closest prior art” and that “he did not actually examine the prior art identified.” *Id.* at 1378-79. The Court nonetheless held as a matter of law that the attorney’s withholding of this information from the PTO did not constitute “a material omission or misrepresentation,” explaining that “an applicant is free to advocate its interpretation of its claims and the teachings of prior art.” *Id.* In contrast, the panel here held that Appellants omitted “material information” from the PTO because they failed to disclose arguments made in legal briefs filed with the EPO – even though it is uncontested that Appellants

gave the PTO all relevant prior art (including the '382 patent, which arguably demonstrated that Appellants' invention had been anticipated). Slip. op. 18-27.

The panel sought to distinguish *Innogenetics* on the ground that it involved allegedly inaccurate “lawyer argument” made “to the PTO about prior art,” while here Appellants are alleged to have withheld “lawyer argument” made in other proceedings. *Id.* at 27. As explained above, that characterization of *Innogenetics* is inaccurate. Moreover, it makes little sense to attempt to distinguish the cases on that ground; when assessing the blameworthiness of an applicant’s conduct, submitting questionable legal arguments to the PTO is far more objectionable than failing to submit contradictory legal arguments made in a different forum. The panel also sought to distinguish this case by noting that the representations made to the PTO “were not merely legal argument; they were factual assertions as to the views of those skilled in the art.” *Id.* But Appellants do not stand accused of inequitable conduct based on those factual assertions; rather, the accusation is based on their failure to submit the EPO legal briefs to the PTO.

Rehearing *en banc* is warranted to provide patent applicants with the guidance they so desperately need regarding precisely what “material information” must be supplied to the PTO. As the Petition points out, inequitable conduct defenses are now raised in the majority of all patent suits, thereby requiring

litigants to spend vast resources on satellite litigation that logically is secondary to what should be the principal issue in every invalidity lawsuit: did the applicant adequately demonstrate to the PTO the prerequisites for issuance of a patent?

II. Rehearing *En Banc* Is Warranted Because the Current Definition of “Material Information” Lacks Any Meaningful Limiting Principles

As noted above, the Court has not adopted any substantive definition regarding what constitutes “material information” for purposes of adjudicating inequitable conduct claims. Rather, it has contented itself with broad generalities: information is said to be “material” where there is “a substantial likelihood” that a reasonable patent examiner would consider it “important” in deciding whether to issue as a patent. The result has been that patent holders are repeatedly being surprised, as here, by decisions from this Court retroactively defining as “material” entire categories of information whose disclosure had not previously been deemed necessary by the patent community. *See, e.g., Refac Int’l, Ltd. v. Lotus Development Corp.*, 81 F.3d 1576 (Fed. Cir 1996)(invalidating patent on inequitable conduct grounds based on failure to provide the PTO with what the Court deemed “material information”: that one of the applicant’s unpaid expert witnesses had a prior working relationship with the applicant); *Ferring B.V. v. Barr Labs, Inc.*, 437 F.3d 1181 (Fed. Cir.), *cert. denied*, 549 U.S.

1015 (2006).³ WLF submits that such surprises are inevitable because the current definition of “material information” contains no substantive limiting principle; it is little more than a “I know it when I see it” rule.⁴ Rehearing *en banc* is warranted so that the Court can devise a rule with some workable limits.

In the absence of a substantive limiting principle, one can easily imagine numerous types of information that might be deemed “material” in future cases. For example, a reasonable patent examiner might very well deem *all* conflicting legal arguments to be important, not simply conflicting arguments made (as here) by other attorneys hired by the applicant in other patent proceedings. After all, the reason that the EPO legal briefs were deemed “material” in this case was that they allegedly conflicted with what the applicant was telling the PTO, not because Appellants are somehow legally bound by arguments made before the

³ The “surprise” problem is compounded when, as here, applicants are determined to have acted with intent to deceive, based on a determination that they must have known of the information’s materiality. Such intent-to-deceive findings are troubling in the absence of case law providing warning to an applicant that the type of information at issue could later be deemed “material.”

⁴ The panel stated that “when a question of materiality is close, a patent applicant should err on the side of disclosure.” Slip op. 26. But as Judge Linn pointed out, the Court does not recognize a “close case” standard for judging materiality, Dissenting op. at 15, nor would such a standard provide any meaningful guidance. As Judge Linn stated, “Our circuit already entertains five different standards for materiality. *See Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1315-16 (Fed. Cir. 2006). I do not think we need a sixth.” *Id.*

EPO. Under that theory, an argument made by an opposing counsel before the EPO would be just as “material.” Similarly, the written opinions of one’s non-testifying expert witnesses might be deemed “material,” even though Fed. R. Civ. P. 26(b)(4) normally exempts the disclosure of such opinions from discovery in federal court proceedings. And if the patent applicant here had disclosed the EPO legal briefs along with thousands of other pages of material but had failed to bring the alleged inconsistency in legal arguments to the attention of patent examiners, under existing materiality standards a panel might conclude that such conduct constituted a failure to disclose material information.

Granting rehearing *en banc* would allow the Court to closely examine the recommendations of the National Research Council, which in 2004 recommended “elimination of the inequitable conduct doctrine or changes in its implementation.” National Research Council, *A Patent System for the 21st Century* (2004) at 123, <http://www.nap.edu/html/patentsystem/0309089107.pdf>. One limiting principle to consider: “material information” does not include legal argument but rather is limited to factual material. This case would provide an ideal vehicle to consider adoption of such a principle.

CONCLUSION

WLF requests that the petition for rehearing *en banc* be granted.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Daniel J. Popeo", written over a horizontal line.

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CERTIFICATE OF SERVICE

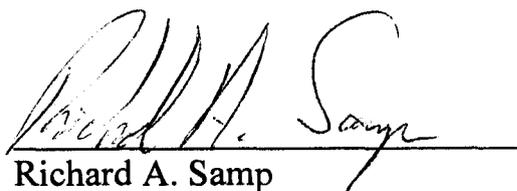
I HEREBY CERTIFY that on this 10th day of March, 2010, two copies of the foregoing brief of *amicus curiae* Washington Legal Foundation were deposited in the U.S. Mail, first-class postage prepaid, addressed as follows:

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