

No. 00-1372

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

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HOFFMANN-LA ROCHE INC., and  
ROCHE MOLECULAR SYSTEMS, INC.,

Plaintiffs-Appellants,

v.

PROMEGA CORPORATION

Defendant-Cross-Appellant.

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Appeal from the United States District Court for the  
Northern District of California (San Francisco Division)  
In Civil Action No. C-93-1748 VRW, Judge Vaughn R. Walker

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**BRIEF OF *AMICUS CURIAE* ASSOCIATION OF PATENT LAW FIRMS  
IN SUPPORT OF PLAINTIFF-APPELLANTS' COMBINED PETITION  
FOR PANEL REHEARING AND REHEARING *EN BANC***

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May 28, 2003

## CERTIFICATE OF INTEREST

Counsel for the *amicus curiae* Association of Patent Law Firms and certifies the following:

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

Association of Patent Law Firms.

2. The name of the real party in interest represented by me is:

Association of Patent Law Firms.

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 or associates that appeared for the party or *amicus curiae* now represented by me in the trial court or agency or are expected to appear in this court are:

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Daniel W. McDonald  
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## **ABBREVIATIONS APPEARING IN THIS *AMICUS* BRIEF**

A_____	Joint Appendix page
Example VI	Example contained in the '181 patent (A3020: col. 38, l. 65 - A3022: col. 41, l. 20)
MPEP	<i>Manual of Patent Examining Procedure (MPEP)</i> (8th ed. 2001, rev. February 2003)
PTO	United States Patent and Trademark Office
Slip op.	The March 31, 2003 majority opinion (appended hereto)
Taq	<i>Thermus aquaticus</i> DNA polymerase with an actual molecular weight of 93,910 daltons

**CONCISE STATEMENT OF IDENTITY, INTEREST, AND  
SOURCE OF AUTHORITY TO FILE**

The following statement identifies the *amicus curiae*, its interest in the case, and the source of its authority to file.

1. The *amicus curiae* is the Association of Patent Law Firms, a national association of law firms that devote a majority of their practice to patent law.

2. The *amicus curiae's* interest in this case is based on the exceptional legal issues related to patent law raised in the case, namely the appropriate legal standards for determining inequitable conduct. As the *amicus curiae* has among its members law firms that devote a significant amount of their practice to patent law, the *amicus curiae* has an interest in the development of the law of inequitable conduct.<sup>1</sup>

3. The source of the *amicus curiae's* authority to file is based on the unopposed motion for leave to file the *amicus curiae* brief filed herewith.

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<sup>1</sup> The views expressed herein are those of the Association of Patent Law Firms as an organization, and therefore do not necessarily reflect the views of any individual member of the Association of Patent Law Firms. Welsh & Katz, Ltd., although a member firm of the Association of Patent Law Firms, does not support the filing of an *amicus brief* in this case.

## I. ARGUMENT

Inequitable conduct as an affirmative defense to patent infringement brings principles of equity to bear in determining the enforceability of patent rights. Since the defense of inequitable conduct was first recognized by the Supreme Court, *Precision Instr. Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806 (1945), Federal Circuit precedent reveals an ongoing attempt to enunciate standards that will achieve the delicate balance between protecting against a "plague" of unsupported inequitable conduct charges, while simultaneously protecting against the damage inflicted by the acquisition of patents by improper means.

Uniformity and certainty in the Court's inequitable conduct jurisprudence, however, remain elusive.<sup>2</sup> Confusion and uncertainty as to the enforceability of patent rights has an adverse impact on the patent system as a whole.<sup>3</sup> Eliminating uncertainty in the application of the inequitable conduct defense is an issue of exceptional importance to the patent system and patent lawyers, as well as society as a whole, which benefits from the innovation spurred by the patent system.

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<sup>2</sup> Robert J. Goldman, *Evolution of the Inequitable Conduct Defense in Patent Litigation*, 7 HARV. J. LAW & TECH. 37 (1993); Kenneth R. Adamo & Robert P. Ducatman, *The Status of the Rules of Prohibited Conduct Before the Office: "Violation of the Duty of Disclosure" out of "Inequitable Conduct" by "Fraud,"* 68 J. PAT. & TRADEMARK OFF. SOC'Y 193, 194 (1986).

<sup>3</sup> Committee Position Paper, *The Doctrine of Inequitable Conduct and The Duty of Candor in Patent Prosecution: Its Current Adverse Impact on the Operation of the United States Patent System*, 16 AIPLA Q.J. 74, 75 (1988) (footnote omitted).

Despite uncertainties and unexplained variances in application, the Court has seemingly made uniform the statement of the elements of the defense, the burden of proof, and the effect on an issued patent of a finding of inequitable conduct. A finding of inequitable conduct requires the challenger to prove, by clear and convincing evidence, (1) a misrepresentation or omission of a material fact, and (2) an intent to deceive the Patent Office. Slip op. at 4, 20-21; *Kingsdown Med. Consultants, Ltd., v. Hollister Inc.*, 863 F.2d 867, 872, 9 USPQ2d 1384, 1389 (Fed. Cir. 1988). A finding of inequitable conduct renders all claims of the patent unenforceable. *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 882 F.2d 1556, 1563, 11 USPQ2d 1750, 1756 (Fed. Cir. 1989).

Uncertainties arise in defining for each situation what amounts to "material" information and what level of conduct establishes "intent" to deceive the Patent Office.

In this case, the majority opinion defined information as "material" where "there is a substantial likelihood that a reasonable examiner would consider [the information] important in deciding whether to allow the application to issue." Slip op. at 20-21.<sup>4</sup> The majority also determined, however, that materiality is more

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<sup>4</sup> See also 37 C.F.R. § 1.56(b) (defining information material to patentability as information that is not cumulative to information already of record, or being made of record in the application, 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).

likely to be found in an affirmative misrepresentation than in an omission. Slip op. at 21. Because of the exceptional importance of this issue, involving the balancing of policies disfavoring forfeiture of patent rights and encouraging candor before the PTO, and the conflicting precedent upon which the majority opinion relied, *en banc* consideration of this issue by the entire Court is necessary.

In this case, the majority opinion found sufficient "intent" to deceive the PTO based solely on evidence that (1) the inventors had executed an oath during prosecution attesting that all statements made in the patent were true, and (2) an affirmative misrepresentation (i.e., Example VI) was made. Precedent requires clear and convincing evidence not simply of intent to do that which was done, but clear and convincing evidence of an intent to deceive the PTO. Because it is unclear whether the intent found sufficient in this case is consistent with precedent or creates a new, lower standard as to the requisite level of intent required to support an inequitable conduct claim, this uncertainty should be addressed by the Court *en banc*.

**A. The Majority's Materiality Conclusion as to Example VI Should Be Considered by the Court *En Banc* Because Such a Finding Represents an Issue of Exceptional Importance.**

In this case the patentee disclosed in the specification of the patent Example VI, the commercial method and best mode for making the claimed invention, a purified form of Taq. The patentee drafted Example VI in the past tense, although

it had never been performed exactly as written. Use of the past tense to characterize Example VI violated an MPEP rule requiring prophetic examples to be written in the present tense.<sup>5</sup> Failure to comply with the MPEP rule constituted a technical violation of the rules.

Referencing a line of precedent in which the Court addressed affirmative misrepresentations made in affidavits submitted to overcome prior art rejections made by examiners during prosecution, the majority opinion stated, "affirmative misrepresentations by the patentee, in contrast to misleading omissions, are more likely to be regarded as material." Slip op. at 21, *citing Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1571, 220 USPQ 289, 300 (Fed. Cir. 1983).

While stated generally by the majority opinion as applying to *all* affirmative misrepresentations, the rule stated in *Rohm & Haas* was developed in connection with affidavits submitted to overcome an examiner's prior art rejections. The *Rohm & Haas* opinion stated, "In contrast to cases where allegations of fraud are based on the withholding of prior art, there is no room to argue that submission of false affidavits is not material." *Rohm & Haas*, 722 F.2d at 1571, 220 USPQ at 300 (holding patent unenforceable because the patentee filed affidavits containing false data during prosecution that allowed the patentee to successfully overcome the examiner's rejections); *see also Refac Int'l Ltd. v. Lotus Dev. Corp.*, 81 F.3d

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<sup>5</sup> MPEP § 608.01(p) (8th ed., 2001, rev. February 2003).

1576, 1583, 38 USPQ2d 1665, 1671 (Fed. Cir. 1996) ("Affidavits are inherently material . . . The affirmative act of submitting an affidavit must be construed as being intended to be relied upon. It is not comparable to omitting an unnecessary act."). It is unclear whether this line of cases stands for the proposition that any misrepresentation in any affidavit is *per se* material, regardless of the surrounding facts.

Another line of cases, however, has addressed situations with closer factual identity to the case at issue here. In these cases, the Court has refused to find materiality, even for affirmative misrepresentations. *See Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1570, 43 USPQ2d 1398, 1407 (Fed. Cir. 1997) (reversing a district court's inequitable conduct determination holding the applicant's mischaracterization in the application of the plasmid used in an example was not material because the misrepresentation did not make the examples provided in the specification inoperative); *and Seiko Epson Corp. v. Nu-Kote Int'l, Inc.*, 190 F.3d 1360, 1367, 52 USPQ2d 1011, 1017 (Fed. Cir. 1999) ("Technical violations of PTO procedures, absent fraud or intentional deception, are not inequitable conduct as would invalidate the patent. The courts have consistently rejected the notion of *per se* forfeiture based on non-fraudulent failure to comply with a rule of practice before the PTO.").

Finally, another line of cases has addressed failure to provide information to the PTO (i.e., "omission" cases). In these cases, the Court has consistently required clear and convincing evidence of the materiality of an omission to support a finding of inequitable conduct. *See, e.g., Life Techs. Inc. v. Clontech Labs.*, 224 F.3d 1320, 1326, 56 USPQ2d 1186, 1191 (Fed. Cir. 2000) (holding reference that motivated inventors, because not anticipatory prior art, was not material); *Dayco Prods., Inc. v. Total Containment, Inc.*, No. 02-1497, slip. op. at 7 (Fed. Cir. May 23, 2003).

In the omission cases, the Court has also applied the rule that "[a] reference that is simply cumulative to other references does not meet the threshold of materiality that is predicate to a holding of inequitable conduct." *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1582, 18 USPQ2d 1001, 1014-15 (Fed. Cir. 1991), *citing Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1440, 17 USPQ2d 1834, 1839 (Fed. Cir. 1991); and *Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, 244 F.3d 1365, 1377-78, 58 USPQ2d 1321, 1329 (Fed. Cir. 2001) (finding no clear and convincing evidence of materiality because omitted references were cumulative to art already of record). Therefore, art that is cumulative to that already of record is not material and cannot support a finding of inequitable conduct.

In this case, because the patentee affirmatively provided Example VI to the PTO, the technical violation of MPEP rules did not constitute an omission. Further, the technical violation was not made in an affidavit filed during prosecution, but instead was made in the specification of the patent. Because one apparent premise for finding *per se* materiality, or at least presumptive materiality, in a misrepresentation made in an affidavit is that the applicant provides the affidavit knowing what the examiner considers material and with the express purpose of overcoming a rejection of the claims, this difference may be significant.

Example VI, like the examples in the *Eli Lilly* case, was made before any substantive review by the examiner to indicate what subject matter was important to patentability. Nevertheless, the majority opinion in this case attempted to distinguish the *Eli Lilly* case in a footnote, *see* Slip op. at 22 n.1, and, apparently without questioning of its applicability to the case at hand, applied the reduced standard of materiality set forth in *Rohm & Haas*.

Regardless of one's opinion as to the propriety of applying a reduced materiality threshold to cases like the present, the issue is of such importance and the precedent sufficiently unclear as to merit more than a conclusory response.<sup>6</sup> For this reason, APLF urges the Court to consider *en banc* the proper threshold for

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<sup>6</sup> The level of materiality required in assessing inequitable conduct claims based upon technical violations of PTO rules is an area of exceptional importance to patent law and patent lawyers, especially since patent prosecution is fraught with areas in which the PTO rules can be violated, often inadvertently.

materiality, and the relevance of the Court's cumulative information cases, in cases addressing affirmative misrepresentations made in the specification that constitute technical violations of PTO rules.

**B. The Majority's Intent Conclusion as to Example VI, Which Appears Inconsistent with Precedent, Should Be Considered by the Court *En Banc* Because the Issue Is of Exceptional Importance.**

Even if an affirmative misrepresentation is found material, a showing of intent to deceive must be made before a patent is rendered unenforceable. Slip op. at 4. This Court has clearly stated that the intent prong of the inequitable conduct analysis assesses not whether the applicant intentionally misrepresented or omitted a material fact, but whether the applicant did so with intent to deceive the PTO. *See Therma-Tru Corp. v. Peachtree Doors Inc.*, 44 F.3d 988, 995, 33 USPQ2d 1274, 1279 (Fed. Cir. 1995) ("[I]ntent as an essential predicate to patent unenforceability does not mean that the inventor intended to do what he did in patent prosecution; it means that the inventor intended to deceive or mislead the examiner into granting the patent."). The requirement of deceptive intent ensures that accidental or careless, though potentially material, misrepresentations or omissions do not render a patent unenforceable.

In this case, the majority opinion identified two primary facts establishing intent: (1) the inventors "attested that all statements made in the [patent] were true;" and (2) an affirmative misrepresentation was made. Slip op. at 19. The

majority opinion thus appears to approve a standard under which intent is based simply on the intent to do what the applicant did, and arguably not on proof of intent *to deceive* the PTO. *See Therma-Tru*, 44 F.3d at 995, 33 USPQ2d at 1279.

The Court has found that even studied ignorance of the facts, a reckless indifference to the truth and the complete absence of evidence of good faith need not support a finding of intent to deceive the PTO. *See Hewlett-Packard*, 882 F.2d at 1562, 11 USPQ2d at 1755. The majority opinion's implied standard raises questions in view of precedent. A departure from the Court's precedent requiring clear and convincing proof of intent to deceive the PTO carries the potential to seriously effect the development of the law of inequitable conduct and the business affairs of patentees.

Therefore, regardless of the future path the Court chooses in to follow in connection with inequitable conduct cases, *en banc* consideration is necessary to properly address this important issue and to provide uniformity to the consideration of the appropriate level of intent necessary to support a finding of inequitable conduct.

## II. CONCLUSION

For the foregoing reasons, rehearing *en banc* should be granted to revisit the proper standards applicable to assessments of materiality and intent in the context of an allegation of inequitable conduct founded on an affirmative misrepresentation.

Respectfully submitted,

May 28, 2003

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