

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

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

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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.

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Appeal from the United States District Court for the Northern District of California  
in consolidated case nos. 04-CV-2123, 04-CV-3327, 04-CV-3732,  
and 05-CV-3117, Judge William H. Alsup.

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**BRIEF OF *AMICI CURIAE***  
**NINE INTELLECTUAL PROPERTY LAW PROFESSORS**  
**IN SUPPORT OF EN BANC REVIEW OF INEQUITABLE CONDUCT**

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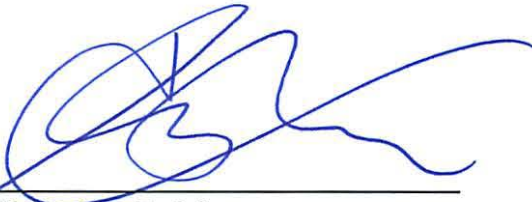
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## I. IDENTITY AND INTEREST OF *AMICI CURIAE*

*Amici Curiae* Nine Intellectual Property Law Professors are law professors who have an interest in the proper development and application of patent laws.<sup>1</sup>

## II. INTRODUCTION

It has been 22 years since the Federal Circuit convened en banc to address the doctrine of inequitable conduct.<sup>2</sup> Much has changed in the practical world of patent litigation since then, and another en banc ruling to clarify doctrine is due.

In particular, panel decisions of this Court have applied differing legal standards for each element of the inequitable conduct defense, and en banc consideration is necessary to secure uniformity of the Court's decisions. Also, in view of the proliferation of inequitable conduct allegations, clarification of the doctrine has increasingly become a question of exceptional importance. While many believed that the panel decision in *Star Scientific*<sup>3</sup> would suffice to bring clarity and uniformity to the doctrine, that promise has not borne fruit.

The problems with the inequitable conduct doctrine have become severe

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<sup>1</sup> *Amici curiae* have no stake in any of the parties to this litigation or the result of this case, other than an interest in seeking correct and consistent development of patent law jurisprudence. No part of this brief was authored by counsel for any party, person or organization besides *amici curiae*. No party to the appeal or its counsel has contributed monetarily to this brief or its preparation.

<sup>2</sup> *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988).

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

enough to attract Congress' attention, and proposals to codify and reform the defense have been included in several recent bills.<sup>4</sup> The committee report accompanying the 2007 Senate bill<sup>5</sup> provides three reasons for including inequitable conduct reform: (1) the absence of a clear standard of materiality, (2) the collapse of the intent element into materiality, and (3) the courts' lack of discretion in selecting a remedy.<sup>6</sup> Although inequitable conduct was not included in the 2009 patent reform bill, Senator Hatch has expressed the desire to include it.<sup>7</sup>

Accordingly, because of the lack of uniformity in the Court's decisions, and because of the exceptional importance of this issue, *amici* submit that en banc review should be granted under either provision of Rule 35(a) of the Federal Rules of Appellate Procedure, to clarify and restate the inequitable conduct doctrine.

### III. ARGUMENT

At its core, a *prima facie* claim of inequitable conduct includes three

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<sup>4</sup> See Christian E. Mammen, "Controlling the 'Plague': Reforming the Doctrine of Inequitable Conduct," 24 BERKELEY TECH. L. J. 1331, 1378-1392 (2010) (analyzing proposals in 2007 patent reform legislation) (available at <http://ssrn.com/abstract=1339259>); Christopher A. Cotropia, "Modernizing Patent Law's Inequitable Conduct Doctrine," 24 BERKELEY TECH. L.J. 723, 737-741 (2009) (summarizing proposals in 2005 and 2006 patent reform legislation).

<sup>5</sup> S. 1145, 110<sup>th</sup> Cong. (as reported in Senate, Apr. 18, 2007).

<sup>6</sup> S.Rep. No. 110-259, at 32 (2008); *see also id.* at 60 (additional views of Senators Specter and Hatch, criticizing *Ferring B.V. v. Barr Labs, Inc.*, 437 F.3d 1181 (Fed. Cir. 2006)).

<sup>7</sup> Press Release, Orrin Hatch, Senator, "Senators Hatch, Leahy Introduce Patent Reform Act of 2009" (Mar. 3, 2009), available at [http://hatch.senate.gov/public/index.cfm?FuseAction=PressReleases.Detail&PressRelease\\_id=ce26c6f0-1b78-be3e-e028-418ea18126e5](http://hatch.senate.gov/public/index.cfm?FuseAction=PressReleases.Detail&PressRelease_id=ce26c6f0-1b78-be3e-e028-418ea18126e5).

elements: (1) an affirmative misrepresentation of material fact, a submission of false material information, or a failure to disclose (noncumulative) material information; (2) intent to deceive the Patent Office; and (3) an equitable balancing of materiality and intent to determine whether the conduct is sufficiently culpable to warrant a finding of unenforceability.<sup>8</sup> *Amici curiae* here address two illustrative examples of a lack of uniformity in the Court’s precedents that warrant en banc review.

**A. Intent: Cases Inconsistently Apply Inconsistent Standards.**

It is widely accepted that direct evidence of intent to deceive the Patent Office is often difficult to find, and that circumstantial evidence must often be considered as the only evidence of intent.<sup>9</sup> Indeed, scholars have noted the difficulty of judging the intent element, given the tensions between the judgmental moral stance of the doctrine, the natural instincts and motivations of inventors, and the duty-of-disclosure rules.<sup>10</sup>

Before *Kingsdown*, the *J.P. Stevens* case permitted a showing of “gross negligence” to prove intent by circumstantial evidence, explaining, “Gross negligence is present when the actor, judged as a reasonable person in his position,

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<sup>8</sup> *E.g.*, *Star Scientific*, 537 F.3d at 1366; *Digital Control v. Charles Mach. Works*, 437 F.3d 1309, 1313 (Fed. Cir. 2006).

<sup>9</sup> *E.g.*, *Larson Mfg. Co. of South Dakota, Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1340 (Fed. Cir. 2009); *Star Scientific*, 537 F.3d at 1366.

<sup>10</sup> *E.g.*, Robin Feldman, “The Role of the Subconscious in Intellectual Property Law,” 2 HASTINGS SCI. & TECH. L. J. 1, 23 (2010).

**should have known of the materiality of a withheld reference.”<sup>11</sup>**

In *Kingsdown*, this Court rejected the “gross negligence” standard, ruling en banc that “a finding that particular conduct amounts to ‘gross negligence’ does not of itself justify an intent to deceive.”<sup>12</sup> That should have been enough to dispose of gross negligence’s companion concept, the “should have known” test.

Indeed, it appeared for a time that that was the case. In *Hoffmann-La Roche Inc. v. Lemmon Co.*,<sup>13</sup> this Court reversed a district court finding that the applicant intended to deceive the patent office because he was “grossly negligent since he should have known of the materiality of the withheld information.” Citing *Kingsdown*, this Court reversed the district court, reiterating the holding that gross negligence alone cannot support a finding of intent.<sup>14</sup>

In 2001, this Court inverted *J.P. Stevens*’ relationship of “gross negligence” and “should have known,” holding that an applicant “cannot intentionally avoid learning of [withheld information’s] materiality, even through gross negligence; in such cases the district court may find that the applicant should have known of the

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<sup>11</sup> *J.P. Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553, 1560 (Fed. Cir. 1984) (emphasis added) (“Proof of deliberate scheming is not needed; gross negligence is sufficient.”).

<sup>12</sup> *Kingsdown*, 863 F.2d at 876.

<sup>13</sup> *Hoffmann-La Roche Inc. v. Lemmon Co.*, 906 F.2d 684, 687-688 (Fed. Cir. 1990).

<sup>14</sup> 906 F.2d at 687 (quoting district court decision).

materiality of the information.”<sup>15</sup> *Ferring* reiterated the ascendance of the “should have known” test, affirming a grant of summary judgment of inequitable conduct where, *inter alia*, “the applicant knew or **should have known of the materiality of the information.**”<sup>16</sup> This is precisely the same formulation that the Court equated with “gross negligence” in *J.P. Stevens*.

In 2009, this Court revisited the intent standard in *Star Scientific*, explaining the importance of proving that “material information was withheld with the specific intent to deceive the PTO.”<sup>17</sup> Because direct evidence is rarely available, circumstantial evidence may be used to prove intent, but, *Star Scientific* holds, only if an inference of intent is “the single most reasonable inference able to be drawn from the evidence.”<sup>18</sup> This means that “a district court clearly errs in overlooking one inference in favor of an equally reasonable inference.”<sup>19</sup>

In sum, there are two inconsistent lines of precedent on the intent issue: the *Kingsdown-Star Scientific* line, which holds that “gross negligence” cannot prove intent; and the *Brasseler-Ferring* line, which holds that intent can be established

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<sup>15</sup> *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1380 (Fed. Cir. 2001).

<sup>16</sup> *Ferring B.V. v. Barr Labs, Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006) (emphasis added); see also *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1313 (Fed. Cir. 2008) (applying “should have known” test).

<sup>17</sup> *Star Scientific*, 537 F.3d at 1366.

<sup>18</sup> *Id.*

<sup>19</sup> *Id.* at 1367 (quoting *Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 528 F.3d 1365, 1376 (Fed. Cir. 2008)).

where the applicant “should have known” of the materiality of withheld information. The two lines are in conflict because *J.P. Stevens* and *Brasseler* essentially equate the “gross negligence” and “should have known” standards.

In *Therasense*, the district court used the “should have known” test,<sup>20</sup> but the panel majority cites neither line of cases in affirming the inequitable conduct ruling.<sup>21</sup> Instead, the majority addresses the district court’s five findings on the intent issue—but fails to address the legal sufficiency of any of those findings.<sup>22</sup>

The first finding, that the statements were “absolutely critical in overcoming the examiner’s earlier rejections,” relates solely to the materiality of the information. But “materiality does not presume intent, which is a separate and essential component of inequitable conduct.”<sup>23</sup>

The second finding, that the statements “would have been very important to an examiner,” is an (incomplete) statement of the reasonable examiner test for materiality. Again, materiality does not presume intent.

The third finding, that both individuals knew of the information and decided not to disclose it, is not the standard for intent. In fact, *Star Scientific* specifically

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<sup>20</sup> *Therasense, Inc. v. Becton, Dickinson and Co.*, 565 F.Supp.2d 1088, 1113 (N.D. Cal. 2008).

<sup>21</sup> The majority cites *Ferring*, but for a different point. *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1289, 1308 (Fed. Cir. 2010).

<sup>22</sup> *Id.* at 1306-1308.

<sup>23</sup> *Star Scientific*, 537 F.3d at 1366.

rejects this reasoning.<sup>24</sup>

The fourth and fifth findings, that the two individuals' explanations were not credible, also contravenes *Star Scientific*. Had the analysis followed *Star Scientific*, it would have been necessary to conclude that the **single most reasonable inference** was that both individuals provided non-credible testimony.<sup>25</sup> But instead of engaging in such an analysis, the majority deemed the district court's credibility determinations to be "virtually unreviewable."<sup>26</sup>

Thus, in addressing each of the district court's five findings, the majority ruled in a manner inconsistent with this Court's precedent in *Star Scientific*.

**B. Materiality: Cases Inconsistently Apply the 1977 and 1992 Versions of Rule 56.**

Although the equitable defense of inequitable conduct is unquestionably judicially created,<sup>27</sup> it is also unquestionably and inexorably linked to the "duty of disclosure" rules of the Patent Office.<sup>28</sup> Since 2006, this Court's precedents have frequently diverged from the current Patent Office rules by applying the "reasonable examiner" test for materiality. In *Therasense*, however, the majority

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<sup>24</sup> *Star Scientific*, 537 F.3d at 1366 ("The fact that information later found material was not disclosed cannot, by itself, satisfy the deceptive intent element of inequitable conduct. ... Rather, to prevail on the defense, the accused infringer must prove by clear and convincing evidence that the material information was withheld with the specific intent to deceive the PTO.").

<sup>25</sup> *Id.*

<sup>26</sup> *Therasense*, 593 F.3d at 1309.

<sup>27</sup> *Digital Control*, 437 F.3d at 1315.

<sup>28</sup> *Mammen*, 24 BERKELEY TECH. L.J. at 1336 n. 15.

applied the current Patent Office rule without addressing the “reasonable examiner” standard. En banc review is necessary to clarify the materiality test.

Shortly after *Kingsdown*, the Patent Office determined the 1977 “reasonable examiner” standard<sup>29</sup> should be revised “in view of the large amount of resources that are being devoted to duty of disclosure issues both within and outside the Office without significantly contributing to the reliability of the patents being issued.”<sup>30</sup> Accordingly, it revised Rule 56, to “specify more precisely the information” that should be disclosed to the Patent Office.<sup>31</sup>

Former PTO Commissioner Harry Manbeck explained his reasoning:

“[In 1990-1991] I concluded that existing Rule 56 was indeed too imprecise, and could, and probably was, leading to unjustifiable charges of inequitable conduct in litigation.”<sup>32</sup>

For a time, it appeared that this Court would follow suit, applying the 1977 standard to patents prosecuted before 1992, and the 1992 standard to patents prosecuted after 1992.<sup>33</sup> However, in 2006, a panel of this Court ruled that the

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<sup>29</sup> 37 C.F.R. § 1.56 (1977) (“Rule 56”).

<sup>30</sup> 54 Fed. Reg. 11,334 (proposed Mar. 17, 1989).

<sup>31</sup> 56 Fed. Reg. 37,321 (proposed Aug. 6, 1991).

<sup>32</sup> Harry F. Manbeck, Jr., “Evolution and Future of New Rule 56 and the Duty of Candor: The Evolution and Issue of New Rule 56,” 20 AIPLA Q.J. 136, 139-140 (1992); *see also* Arti K. Rai, “Growing Pains in the Administrative State: The Patent Office’s Troubled Quest for Managerial Control,” 157 U. PA. L. REV. 2051, 2079 (2009) (suggesting judicial deference to PTO rules).

<sup>33</sup> *E.g.*, *Purdue Pharma L.P. v. Endo Pharms. Inc.*, 438 F.3d 1123, 1129 (Fed. Cir. 2006); *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs. Ltd.*, 394 F.3d 1348, 1352-1353 (Fed. Cir. 2005).



1992 revision to Rule 56 did not supplant the 1977 “reasonable examiner” rule.<sup>34</sup>

This ruling itself introduced a lack of uniformity in the Court’s decisions.

Since *Digital Control*, this Court has fairly consistently applied the “reasonable examiner” standard.<sup>35</sup> In *Therasense*, however, the Court once again cited the 1992 version of Rule 56.<sup>36</sup> Thus, once again, there is a lack of uniformity in the Court’s decisions concerning which standard applies to patents prosecuted after 1992. It is not accurate to postulate, as the Court did in *Digital Control*, that the two standards are substantively nearly the same.<sup>37</sup> The Patent Office clearly rejected the “reasonable examiner” standard because of its flaws, and adopted a more objective test in its place.

En banc review is necessary to establish the proper standard of materiality for patents prosecuted after 1992. Some *amici* submit that the Court should exclusively apply the 1992 version of Rule 56 to post-1992 patents.<sup>38</sup>

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<sup>34</sup> *Digital Control*, 437 F.3d at 1316.

<sup>35</sup> *E.g.*, *Star Scientific*, 537 F.3d at 1367.

<sup>36</sup> *Therasense*, 593 F.3d at 1300-1301.

<sup>37</sup> *Digital Control*, 437 F.3d at 1316.

<sup>38</sup> *See* Mammen, 24 BERKELEY TECH. L.J. at 1392-1396; *see also* Gerald S. Mossinghoff, “The Duty of Candor and Good Faith to the United States Patent and Trademark Office, Remarks to the American Bar Association, Intellectual Property Law Section at the 17<sup>th</sup> Annual Intellectual Property Law Conference,” (April 12, 2002), available at <http://www.oblon.com/media/index.php?id=44> (“My own view is that the courts should apply the version (or versions) of Rule 56 that was (were) in effect at the time the conduct objected to occurred.”).

### C. Uncertainty Encourages Overuse of the Doctrine.

It has been widely asserted, and stands to reason, that the uncertain and shifting boundaries of the inequitable conduct doctrine serve to encourage accused infringers to assert the defense as often as possible. Add to that the “severe” remedy, as acknowledged by the majority,<sup>39</sup> and those incentives only increase.

One recent study supports this intuitive conclusion, indicating that the rate at which inequitable conduct is pled in the district courts has increased dramatically in the past several years.<sup>40</sup>

To this observation, some might respond that the Court’s elaboration of the detailed pleading requirements under Rule 9(b) in *Exergen*<sup>41</sup> may suffice to stem the increased assertion of unjustified inequitable conduct allegations.<sup>42</sup> But this response is at best partly valid: Until litigants know that materiality and intent will be evaluated consistently, uncertainty will remain, and will continue to be exploited. As one recent article puts it, inequitable conduct is the “wild card of patent litigation,” whose “fundamental infirmities” survived *Exergen*.<sup>43</sup>

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<sup>39</sup> *Therasense*, 593 F.3d at 1300.

<sup>40</sup> Mammen, 24 BERKELEY TECH. L. J. at 1353, 1360-1363.

<sup>41</sup> *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326-1328 (Fed. Cir. 2009).

<sup>42</sup> Lisa A. Dolak, “Beware the Inequitable Conduct Charge! (Why Practitioners Submit What They Submit),” 91 J. PAT. & TRADEMARK OFF. SOC’Y 558, 568-570 (2009).

<sup>43</sup> Sean M. O’Connor, “Defusing the ‘Atomic Bomb’ of Patent Litigation: Avoiding and Defending Against Allegations of Inequitable Conduct After

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McKesson et al.," 9 J. MARSHALL REV. INTELL. PROP. L. 330, n.4 and  
accompanying text (2010).

## PROOF OF SERVICE

I hereby certify that the Brief of *Amici Curiae* Nine Intellectual Property Law Professors in Support of En Banc Review of Inequitable Conduct was served upon principal counsel for Therasense, Inc.; Abbott Laboratories; Becton, Dickinson and Company; Nova Biomedical Corporation; and Bayer Healthcare LLC on March 8, 2010 by forwarding two copies each via U.S. Mail, addressed to:

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Additionally, the original and eighteen copies have also been sent via  
overnight Federal Express to:

Clerk of the Court  
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Dated this 8<sup>th</sup> day of March, 2010.

By: \_\_\_\_\_  
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