

Nos. 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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Appeals 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 EISAI CO., LTD. AND EISAI INC. AS *AMICI CURIAE***  
**ON REHEARING *EN BANC* IN SUPPORT OF NEITHER PARTY**

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## CERTIFICATE OF INTEREST

Pursuant to Fed. Cir. R. 47.4, counsel for *Amici Curiae* Eisai Co., Ltd. and Eisai Inc., certifies the following:

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

Eisai Co., Ltd.  
Eisai Inc.

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. There are no parent corporations or publicly held companies that own 10 percent or more of the stock of Eisai Co., Ltd. Eisai Inc. is wholly owned by Eisai Corporation of North America, which is wholly owned by Eisai Co., Ltd.

4. The names of all law firms and partners or associates that appeared for Eisai Co., Ltd. or Eisai Inc. in the trial court or are expected to appear in this court are:

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## STATEMENT OF INTEREST

Eisai Co., Ltd. and Eisai Inc. (collectively, “Eisai”), as *amici curiae*, respectfully submit this brief in support of neither party in response to the Court’s invitation for *amici* briefs on the potential reconsideration of this Court’s inequitable conduct doctrine.<sup>1</sup>

Eisai submits this brief with the benefit of experience of having litigated through an inequitable conduct defense that Eisai believes serves as a hornbook example of the wasteful burden on the judicial system and parties that current legal doctrine has created. Eisai notes that the inequitable conduct defense discussed below has been resolved without involvement by this Court, and accordingly this appeal will have no impact on that defense. Eisai provides responses to the Court’s questions that it believes would establish a legal framework that is consistent with fundamental principles of the inequitable conduct doctrine, is workable, and is fair to all sides of the issue.

Before turning to the Court’s questions, we provide a brief overview of the experience Eisai went through that has given Eisai vivid insight into the problems with the current inequitable conduct standards.

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<sup>1</sup> Pursuant to Fed. Cir. R. 29(a), counsel for Eisai requested, and received, consent from counsel for all the parties to the filing of its *amicus* brief. No party to this appeal had any involvement in the preparation of this brief.

In the late 1980s, Eisai developed a new drug, donepezil hydrochloride — a compound for the treatment of patients with Alzheimer’s disease. By selectively inhibiting the activity of a certain brain enzyme without concomitant side effects, donepezil extends the period during which the Alzheimer patients are able to maintain their cognitive function. Eisai’s scientists received numerous awards for donepezil, including a special commendation in the 1997 U.K. Prix Galien Awards — one of the pharmaceutical industry’s most prestigious awards.

After extensive clinical trials, Eisai sought approval from the U.S. Food and Drug Administration (“FDA”) to market donepezil under the trade name Aricept®. The FDA gave donepezil “fast track” review — a procedure reserved for drugs that are “intended for the treatment of a serious or life-threatening condition and . . . demonstrate[] the potential to address unmet medical needs.” 21 U.S.C.

§ 356(a)(1); *see also* FDA, *Fast Track, Accelerated Approval and Priority Review*, available at <http://www.fda.gov> (search for “Fast Track, Accelerated Approval and Priority Review”; then follow “Fast Track, Accelerated Approval and Priority Review” hyperlink) (last visited July 30, 2010). Under this “fast track” review, the FDA approved Aricept® on November 25, 1996. Since its launch in 1997, Aricept® has been the market-leading drug for the treatment of Alzheimer’s disease, with billions of dollars of sales, supporting Eisai’s research into other drug products.



Aricept® is protected by a U.S. patent covering the active ingredient donepezil and its use to treat Alzheimer's disease. The patent expires November 25, 2010. Some *twenty-two* generic drug companies have filed "Paragraph III" certifications with the FDA, *see* 21 U.S.C. § 355(j)(2)(A)(vii)(III), respecting the patent and agreeing to wait until it expires to begin selling a product covered by the patent.

One company, however, which had previously sought from Eisai but had been denied certain rights in the compound, filed a "Paragraph IV" challenge to the patent, *see* 21 U.S.C. § 355(j)(2)(A)(vii)(IV), prompting Eisai to bring a lawsuit for patent infringement under 35 U.S.C. § 271(e)(2). *See Eisai Co. v. Teva Pharms. USA, Inc.*, No. 2:05-cv-05727, 2008 WL 1722098, at \*1 (D.N.J. Mar. 28, 2008). The original basis for the defendant's challenge to the Aricept® patent was an assertion that the compound was "obvious" under 35 U.S.C. § 103. *Id.* The obviousness defense was litigated for a year, at which time it was abandoned in favor of a different theory of obviousness. *See Teva Pharms. USA, Inc. v. Eisai Co.*, No. 2:08-cv-02344, D.I. 10, at 8 n.5 (D.N.J. Sept. 3, 2008).

The new obviousness defense was litigated for another year, at which time the defendant conceded to patent validity. At that point, the defendant sought to raise a defense of inequitable conduct. *See Eisai Co.*, 2008 WL 1722098, at \*1. The motion to amend to add this defense was filed within days after the rejection

by a different district court of an inequitable conduct defense asserted by the same defendant against Eisai in unrelated litigation. This Court eventually affirmed that finding of no inequitable conduct. *Eisai Co. v. Dr. Reddy's Labs., Ltd.*, No. 03-Civ.-9053, 2007 WL 1437834 (S.D.N.Y. May 14, 2007), *aff'd*, 533 F.3d 1353, 1359-62 (Fed. Cir. 2008).

The defendant's theory of inequitable conduct in the Aricept® case was based upon an allegation that, during the prosecution of the Aricept® patent before the U.S. Patent and Trademark Office ("PTO"), Eisai had failed to disclose one of its earlier patents claiming a different drug molecule (that had failed in development) combined with an industry article published four years before Eisai's patent application mentioned once briefly in Eisai's files. *Eisai Co.*, 2008 WL 1722098, at \*3-\*4, \*7-\*9. The defendant argued that this information, taken together, might have been used for a double patenting rejection of application claims in the Aricept® patent *not including the claim specific to donepezil* — *i.e.*, the compound that the company cared most about and that was at issue in the lawsuit.

Thus, the "inequitable" conduct allegations levied against Eisai were premised on references that were insufficient to support an invalidity argument and were not asserted to be material to the patentability of the compound at issue in the lawsuit.

With this theory, however, the defendant threatened an at-risk launch of infringing product, prompting preliminary injunction proceedings. *Eisai Co.*, 2008 WL 1722098, at \*1. After extensive submissions, including voluminous expert declarations, the district court concluded that the allegations of inequitable conduct lacked substantial merit. *Id.* at \*3-\*9. In granting Eisai's motion, the district court found that the inequitable conduct theory "require[d] the piling of inference on inference." *Id.* at \*9. The district court also observed that the inequitable conduct charge was weaker than the defense which had been asserted and failed in the prior litigation. *Id.* at \*7 (referring to *Eisai Co.*, 2007 WL 1437834 (S.D.N.Y. May 14, 2007)).

The injunction ruling was not appealed. After these proceedings, the defendant moved to compel discovery alleged to be related to its inequitable conduct defense, which the district court eventually denied (after litigation before both the magistrate and the district court judge). *See Eisai Co. v. Teva Pharms. USA, Inc.*, No. 2:05-cv-05727, 2009 WL 4666937, at \*3-\*6 (D.N.J. Dec. 8, 2009); *Eisai Co. v. Teva Pharms. USA, Inc.*, No. 2:05-cv-05727, 2010 WL 2629062, at \*3 (D.N.J. June 28, 2010). The parties ultimately agreed to stay the remainder of the litigation until the patent expires, at which time the case would become moot. *Eisai Co. v. Teva Pharms. USA, Inc.*, No. 2:05-cv-05727, D.I. 291, at 1-2 (D.N.J. July 19, 2010).

Eisai's experience of the burden and expense of successfully defending itself against inequitable conduct charges has given Eisai a strong interest in requesting that this Court articulate a clear legal standard for inequitable conduct that reserves this important defense for extraordinary instances of true intentional deception, but prevents routine assertions.

This standard would ensure that the doctrine of inequitable conduct fulfills its underlying purpose of redressing fraud on the patent office. *See Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814-16 (1945); *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1315 (Fed. Cir. 2006). Most importantly, Eisai urges this Court to articulate a standard for the inequitable conduct defense that is grounded in the concept of intentional deception to obtain a patent through actual misconduct, and that is not susceptible of abuse as simply a back-up weapon for an alleged infringer who has no meritorious validity or infringement defense.

**EISAI'S PROPOSED FORMULATION OF THE DEFENSE,  
WHICH REQUIRES STRINGENT PROOF  
OF MATERIALITY AND DECEPTIVE INTENT, AND AFFORDS  
EQUITABLE DISCRETION IN FASHIONING A REMEDY**

Before discussing the background, reasoning, and support for Eisai's proposed articulation of the inequitable conduct defense, Eisai recites below the full proposed articulation so that it may be understood and discussed in context:

**INEQUITABLE CONDUCT DEFENSE**

The defense of inequitable conduct requires proof, by clear and convincing evidence, that a person with a duty of disclosure to the PTO, misrepresented or failed to disclose information, known to be material, to the examiner during examination of the patent with the specific intent to deceive the patent examiner into granting a patent. The burden of production and proof at all times remains with the party asserting the defense of inequitable conduct.

**MATERIALITY**

Information is material if there is a substantial likelihood that a reasonable examiner, examining the subject matter claimed by the application for the patent in suit, would have found unpatentable the subject matter of at least one claim of that patent, based on that information alone or in combination with other information.

Information that is cumulative to information already of record or previously considered by the PTO, or material only to patent application claims cancelled or withdrawn from consideration, is not material.

**INTENT TO DECEIVE**

To prove a person with a duty of disclosure to the PTO intended to deceive the examiner into granting the patent, facts must be proven that establish the specific intent of the person to deceive the examiner by the actions of that person beyond (A) the facts that establish materiality of the information alleged to have been misrepresented or not disclosed, (B) the facts that establish the person's knowledge or awareness of that information, and (C) the acts constituting the alleged non-disclosure or misrepresentation. The facts must prove that the person believed that information was material, and deliberately misrepresented or failed to disclose that information because it was material with the specific intent to deceive the examiner into granting the patent.

**REMEDY**

If the district court finds that inequitable conduct occurred, the district court must balance the equities to determine an appropriate remedy, which may include:

- (A) Denying equitable relief to the patent holder and limiting the remedy to damages;

- (B) holding the claims in which inequitable conduct occurred unenforceable; and
- (C) holding the patent unenforceable.

## ARGUMENT

### I. **UNDULY LENIENT, AND UNNECESSARILY BROAD, LANGUAGE IN A MINORITY OF THIS COURT'S PRECEDENTS HAS RESULTED IN THE EXCESSIVE ASSERTION OF UNFOUNDED INEQUITABLE CONDUCT DEFENSES.**

As this Court has previously observed, “the habit of charging inequitable conduct in almost every major patent case has become an absolute plague” on the patent system. *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988). The proliferation of unsubstantiated charges of inequitable conduct was not only wasting judicial resources, but also bringing into disrepute the entire patent bar. In an attempt to cure this “plague,” and to restore the doctrine of inequitable conduct to its original purpose of preventing “fraud on the Patent Office,” *id.*, this Court has insisted on a stringent standard of requiring specific intent to deceive in order to find inequitable conduct. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (*en banc* in relevant part). Overruling a series of prior decisions that have permitted a finding of deceitful intent upon a mere showing of “gross negligence,” *see, e.g., Driscoll v. Cebalo*, 731 F.2d 878, 885 (Fed. Cir. 1984), *Kingsdown* “established that no longer

would negligence alone support a holding of inequitable conduct,” *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1196 (Fed. Cir. 2006) (Newman, J., dissenting).

For a while, *Kingsdown* appeared to mitigate the problem of excessive inequitable conduct allegations. After *Kingsdown* repudiated the “gross negligence” standard, the number of inequitable conduct cases brought to the Federal Circuit declined dramatically. See Donald R. Dunner, *et al.*, *A Statistical Look at the Federal Circuit’s Patent Decisions: 1982-1994*, 5 Fed. Cir. B.J. 151, 173-76 (1995).

Yet, gradually the “plague” of inequitable conduct began to return, as subsequent decisions of this Court resurrected some of the approaches repudiated by *Kingsdown*. Thus, relying on the line of cases expressly overruled by *Kingsdown*, some panels of this Court used watered-down language referring to a negligence standard of “where a patent applicant knew, *or should have known*, that withheld information would be material to the PTO’s consideration of the patent application.” *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997) (citing *Driscoll*, 731 F.2d at 885) (emphasis added); see also *Ferring B.V.*, 437 F.3d at 1191 (quoting *Critikon*, 120 F.3d at 1257); *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1314 (Fed. Cir. 2008) (same). As members of this Court have accurately observed, the “‘should have known’ prong sets forth a simple negligence standard, lower even than the ‘gross negligence’



standard that was expressly rejected in *Kingsdown*.” *Larson Mfg. Co. of S. Dakota v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1344 (Fed. Cir. 2009) (Linn, J., concurring).

Moreover, these decisions compounded the problem by permitting litigants to argue that intent to deceive should be inferred largely (if not solely) from the information’s materiality. *See, e.g., Ferring B.V.*, 437 F.3d at 1191 (referring to an inference of intent where “(1) the applicant knew of the information; (2) the applicant knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding”); *Praxair*, 543 F.3d at 1313-14 (same). These decisions “not only ignore *Kingsdown*,” but also “impose a positive inference of wrongdoing, replacing the need for evidence with a ‘should have known’ standard of materiality, from which deceptive intent is inferred, even in the total absence of evidence.” *Ferring B.V.*, 437 F.3d at 1196 (Newman, J., dissenting); *see also Larson Mfg. Co.*, 559 F.3d at 1343-44 (Linn, J., concurring); *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1350 (Fed Cir. 2008) (Rader, J., dissenting) (“Merging intent and materiality at levels far below the *Kingsdown* rule has revived the inequitable conduct tactic.”); *Taltech Ltd. v. Esquel Enters. Ltd.*, 604 F.3d 1324, 1341-42 (Fed. Cir. 2010) (Gajarsa, J., dissenting) (the approach that “conflates the issues of

materiality and intent ... improperly reads the element of intent to deceive out of our inequitable conduct precedent”) (citation omitted).

As a result, these decisions “resurrect[ed] the plague of the past, ignoring the *Kingsdown* requirements of clear and convincing evidence of a misrepresentation or omission material to patentability, made intentionally and for the purpose of deception.” *Ferring, B.V.*, 437 F.3d at 1197 (Newman, J., dissenting); *see also Larson Mfg. Co.*, 559 F.3d at 1342 (Linn, J., concurring) (“this precedent has significantly diverged from the Supreme Court’s treatment of inequitable conduct and perpetuates what was once referred to as a ‘plague’ that our en banc court sought to cure in *Kingsdown*”) (citations omitted). The abandonment of the stringent evidentiary requirement of intent resulted in an “ongoing pandemic of baseless inequitable conduct charges that pervade our patent system.” *Taltech*, 604 F.3d at 1335 (Gajarsa, J., dissenting).

## **II. EISAI’S PROPOSAL IS DEMANDING BUT WORKABLE AND CONSISTENT WITH HISTORICAL FORMULATIONS AND UNDERLYING PURPOSES OF THE INEQUITABLE CONDUCT DOCTRINE.**

Any reformed standard for determining inequitable conduct that this Court adopts must reflect the foundational purpose of this defense — to remedy fraud on the PTO. *See, e.g., Digital Control*, 437 F.3d at 1315. The Supreme Court decisions that generated the inequitable conduct doctrine, and the subsequent lower

court decisions applying this precedent, teach that this doctrine is “akin to that of common law fraud, albeit broader.” *Id.* (citations omitted). The standard that Eisai proposes in this brief is consistent with this principle: It seeks to ensure that the inequitable conduct defense does not sweep within its reach conduct that does not constitute patent fraud, in order to remove the temptation for patent infringers to utilize the inequitable conduct defense as simply a less-demanding method of attacking a patent’s validity. *See supra* at 7-8.

At the same time, however, Eisai’s proposed standard recognizes that the inequitable conduct doctrine, while rooted in the common law of fraud, must be tailored to the specific context of the patent law and articulate a standard that is easy both for patentees to follow and for the courts to administer. Eisai, therefore, proposes a standard that adheres closely to this Court’s precedent requiring a two-fold showing of both the materiality of the withheld or misrepresented information and of the deceptive intent. *See, e.g., Impax Labs., Inc. v. Aventis Pharms., Inc.*, 468 F.3d 1366, 1374 (Fed. Cir. 2006). In framing the appropriate judicial inquiry with respect to each of these prongs, however, the proposed standard removes the overlays that have distorted the inequitable conduct doctrine’s purpose of preventing patent fraud, watered down the materiality and intent requirements, and converted the doctrine into a last-resort defense for defendants without a meritorious invalidity or noninfringement position. This proposed reformed

standard, which is grounded in the defense's underlying policy of remedying patent fraud and is capable of principled judicial application, would guard effectively against the resurgence of the "plague" of unwarranted charges of inequitable conduct.

**A. The Proposed Standard Retains the Concept of Materiality and Intent, While Continuing to Require a High Standard of Proof.**

As is the case under the existing case-law, Eisai proposes that the inequitable conduct defense be reserved only for cases where a person that owes a duty of disclosure to the PTO, *see, e.g., Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995), misrepresented or failed to disclose material information to the examiner during the examination of the patent, and did so with the specific intent to deceive the patent examiner, *see, e.g., Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365, 1374 (Fed. Cir. 2008). All of these elements, including the materiality of the information in question and the deceitful intent, must be separately established by clear and convincing evidence, *AstraZeneca Pharms. LP v. Teva Pharms. USA, Inc.*, 583 F.3d 766, 770 (Fed. Cir. 2009) (citation omitted), with the burden of production and proof remaining with the party asserting the defense of inequitable conduct, *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008).

**B. Information Is Material Only If It Would Have Caused a Reasonable Examiner to Find the Subject Matter of at Least One Patent Claim Unpatentable.**

With respect to the first, materiality, prong of the inequitable conduct test, Eisai proposes that the misrepresented or withheld information be considered material only if there is a substantial likelihood that a “reasonable examiner” (an objective standard), “examining the subject matter claimed by the application for the patent in suit” (which puts the question of materiality into context), would have found the subject matter of at least one patent claim unpatentable based on that information alone or in combination with other information. *See supra* at 7-8. This standard would provide a unitary workable standard for determining materiality, eliminating the confusion and uncertainty resulting from the current existence of several different standards for materiality applied by this Court. *See Digital Control*, 437 F.3d at 1315-16; 6 Donald S. Chisum, *Chisum on Patents* § 19.03[3][a], at 19-219 to 19-224 (MB 2000); *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1289, 1319 (Fed. Cir. 2010) (Linn, J., concurring in part and dissenting in part), *vacated pending reh’g en banc*, 2010 WL 1655391 (Fed. Cir. Apr. 26, 2010) (*en banc*) (*per curiam*).

The proposed standard fairly encapsulates the purpose of this Court’s inquiry into materiality, namely to ensure that the information would be deemed material when it would have objectively affected a decision by a reasonable examiner to

issue at least one claim of the patent. *See, e.g., Symantec Corp. v. Computer Assocs. Int'l, Inc.*, 522 F.3d 1279, 1297 (Fed. Cir. 2008); *Digital Control*, 437 F.3d at 1314. This requirement also reflects this Court's original "reasonable examiner" standard as an appropriate measurement when determining materiality, *see Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1440 (Fed. Cir. 1991) — a standard that survived the PTO's subsequent amendment of that standard, *see Star Scientific*, 537 F.3d at 1367. The standard is akin to a "high" level of materiality standard articulated in various of this Court's precedents. *See, e.g., Optium Corp. v. Emcore Corp.*, 603 F.3d 1313, 1321 (Fed. Cir. 2010). We note that the standard does not incorporate expressly a test of "reliance" by an examiner only because an articulation of "reliance" may become hard to apply in a situation of nondisclosure. Eisai's proposed articulation of the materiality standard, however, does account for instances where an examiner "relied" on the misrepresentation.

Eisai also does not propose a test which is based on a regulation established by the PTO. Eisai believes that it is the role of this Court to define the equitable defense of inequitable conduct, applicable in litigation, and not leave that definition to regulations promulgated by the PTO. This is true particularly where the PTO has been promulgating regulations in response to the history of seemingly

conflicting precedent by this Court — a conflict that this very case is now trying to resolve.

The proposed standard's objective focus on the assessment of a reasonable examiner would make the standard workable to administer. At the same time, however, this standard is appropriately a stringent one: It would not permit a finding of materiality where the misrepresentation merely "may have influenced the patent examiner," *Digital Control*, 437 F.3d at 1315, a test potentially so vague it allows would-be infringers to invoke far-fetched or even meritless theories of how something might influence an examiner in some respect. Rather, the standard would insist on an objective determination that a reasonable examiner would indeed have found the subject matter of at least one patent claim unpatentable had the information been disclosed accurately.<sup>2</sup>

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<sup>2</sup> Under the proposed standard, this Court should continue to hold that "information is not material if it is cumulative of other information already disclosed to the PTO." *Star Scientific*, 537 F.3d at 1367 (citing *Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 1000 (Fed. Cir. 2007)). This Court should also clarify expressly that information pertaining solely to patent application claims that are either cancelled or withdrawn from consideration by the applicant, should not be considered material. This consideration would remedy the mischievous suggestion in *Driscoll* — the opinion repudiated by *Kingsdown* — that an applicant can commit inequitable conduct with respect to a patent claim that is cancelled. *See Driscoll*, 731 F.2d at 885. Putative infringers presently search through lengthy file histories to find some information arguably material to some claim that appeared temporarily in a prosecution history, even though it is entirely possible that a prosecution may have gone very differently if that claim continued in the application rather than having been cancelled or withdrawn.

**C. Nondisclosure of Material Information of Which the Applicant Is Aware Is Not Itself Enough to Prove Specific Intent to Deceive.**

With respect to the second prong of the inequitable conduct defense — an intent to deceive the patent examiner into granting the patent — the standard proposed by Eisai would require that such intent be established by specific facts beyond: (1) the facts establishing materiality of the information misrepresented or not disclosed; (2) the person’s knowledge of the information; and (3) the acts constituting non-disclosure or misrepresentation. *See supra* at 8.

The first and second requirements would remedy the problem created by this Court’s cases that conflated materiality and intent, and led to infringers routinely seeking an inference of intent to deceive largely from the finding that the information was material and the person’s knowledge of that information. *See, e.g., Ferring B.V.*, 437 F.3d at 1191; *Praxair*, 543 F.3d at 1313-14; *see also supra*, at 11-12. These much-criticized decisions potentially — and improperly — could “read[] the element of intent to deceive out of [this Court’s] inequitable conduct precedent.” *Taltech Ltd.*, 604 F.3d at 1341-42 (Gajarsa, J., dissenting); *see also Ferring B.V.*, 437 F.3d at 1196 (Newman, J., dissenting); *Larson Mfg. Co.*, 559 F.3d at 1343-44 (Linn, J., concurring); *Aventis Pharma S.A.*, 525 F.3d at 1350 (Rader, J., dissenting).



The first and second requirements would also clarify that language in cases discussing intent based on evidence that “a patent applicant knew, *or should have known*,” about the materiality of the withheld information, *Critikon*, 120 F.3d at 1256 (emphasis added); *see also supra*, at 10-11, is inappropriate because it relies on repudiated precedent. *See, e.g., Larson Mfg. Co.*, 559 F.3d at 1344 (Linn, J., concurring); *Ferring B.V.*, 437 F.3d at 1196-97 (Newman, J., dissenting). This requirement would restore *Kingsdown*’s proper insistence that *specific intent* to deceive the PTO — a standard higher than that of negligence or even “gross negligence” — be found before a patentee may be held liable for inequitable conduct. *See Kingsdown*, 863 F.2d at 876 (*en banc* in relevant part).

The third requirement of the proposed standard would further this purpose of ensuring that *specific intent to deceive* is found before inequitable conduct liability is imposed. The “plague” exists in part because alleged infringers can almost always find some information somewhere in the patentee’s files that does not also exist in the patent prosecution history (corporate files are always larger than file histories), can almost always try to make some argument of materiality, and make some argument that at some point the applicant was aware of the existence of the information. To end the plague, these kinds of allegations must be ended. We have seen vividly that decisions merely reinforcing the need for a finding of intent to deceive (as *Kingsdown* sought to do) are not enough. Eisai’s proposal spells out

more clearly the need for proof of facts demonstrating that the person accused of inequitable conduct believed that the information *was* material and misrepresented or failed to disclose that information *because* it was material with the intent to deceive the examiner into granting the patent. Eisai's proposal is consistent with this Court's admonition that

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.

*Star Scientific*, 537 F.3d at 1366 (citing *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*, 439 F.3d 1335, 1340 (Fed. Cir. 2006); *Kingsdown*, 863 F.2d at 876 (*en banc* in relevant part)).<sup>3</sup>

By insisting on additional facts supporting an inference of deceitful intent, the standard proposed by Eisai would “strictly enforce the burden of proof and elevated standard of proof in the inequitable conduct context.” *Star Scientific*, 537 F.3d at 1365.

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<sup>3</sup> As is the case under the existing case-law, circumstantial evidence may be used to prove facts establishing intent to deceive. But circumstantial evidence still must be *evidence* of intent — not just the showings of materiality, knowledge of information, and the facts constituting nondisclosure or misstatement, coupled with a request for an inference of intent. *See, e.g., Star Scientific*, 537 F.3d at 1366.

**D. District Courts Should Have the Discretion to Fashion the Appropriate Remedy for a Finding of Inequitable Conduct.**

Under the current inequitable conduct doctrine, the only remedy the district court may impose upon finding a violation is the drastic remedy of holding the entire patent unenforceable. The fact that the sole remedy is so devastating makes inequitable conduct a tool of leverage to would-be infringers even if the defense is unlikely to succeed after full litigation. Nothing in the traditional principles of equity, however, requires that a court limit itself solely to one category of harsh remedy. On the contrary, an equity court possesses considerable discretion in fashioning the appropriate remedy for a litigant's misconduct. *See, e.g., Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944). By aligning the remedy with principles of equity, this Court would lessen the incentive for accused infringers to concoct meritless theories as leverage.

Eisai therefore proposes that, in addition to the existing remedy of holding the entire patent unenforceable, this Court also consider authorizing the district courts to employ less severe remedies, such as holding the specific patent claims in which inequitable conduct occurred unenforceable or denying equitable forms of relief to the patent holder. *See supra* at 8-9. Eisai does not suggest in this brief what the remedy should be in a given set of circumstances, but rather would leave that to the equitable discretion of the district court in the context of actual sets of

facts of the overall case. The form of the remedy, however, should *not* depend on the level of intent to deceive — inequitable conduct may *only* be found when there is specific intent to deceive and there are no lesser levels of intent that could support the defense. The particular remedy could account for overall circumstances in the litigation (one example could be efforts to cure or disclose the inequitable conduct), and must be other than the specific facts constituting the inequitable conduct defense.

### CONCLUSION

This Court should reform the inequitable conduct doctrine by setting forth a stringent yet workable standard for determining both the materiality of the withheld information and the intent to deceive, and by ensuring that this standard remains faithful to the doctrine's principal purpose of remedying fraud on the patent office. Having been through the "trenches" in litigating inequitable conduct, Eisai proposes herein a formulation that should be workable in actual practice, and fair to both sides of the issues.

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Dated: August 2, 2010

By:

A handwritten signature in black ink, appearing to read "Bruce M. Wexler", written over a horizontal line.

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## CERTIFICATE OF SERVICE

I, Igor V. Timofeyev, hereby certify that on August 2, 2010, I served the foregoing Brief of Eisai Co., Ltd. and Eisai Inc. as *Amici Curiae* on Rehearing *En Banc* in Support of Neither Party, by causing two copies to be delivered by overnight courier to the following:

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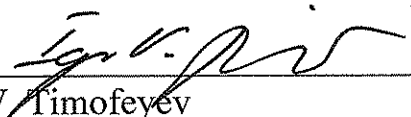
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## CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rules of Appellate Procedure 29(c)(5)-(d), and 32(a)(7), I hereby certify that the word count of the word-processing system used to prepare this brief is 4,882, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and this Court's Rule 32(b).

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