

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

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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

Plaintiffs-Appellants,

v.

BECKTON, DICKINSON & COMPANY
and NOVA BIOMEDICAL CORPORATION,

Defendants-Appellees

and

BAYER HEALTHCARE LLC,

Defendant-Appellee.

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

BRIEF OF *AMICUS CURIAE*

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IN SUPPORT OF NEITHER PARTY

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TABLE OF CONTENTS

CERTIFICATE OF INTEREST i

TABLE OF AUTHORITIESiv

STATEMENT RE CONSENT OF PARTIES.....vi

STATEMENT OF INTEREST OF *AMICUS CURIAE* 1

SUMMARY OF ARGUMENT 1

RESPONSE TO QUESTIONS POSED BY THE COURT6

ARGUMENT.....9

I. The Patent Statute Specifically Permits A Defense To A Claim of Patent Infringement of Valid Claims but Only if at Least One Claim of the Patent Is Procured by Inequitable Conduct..... 9

II. Supreme Court Precedent Also Requires Recognition of a Defense Based on Inequitable Conduct but Setting Its Boundaries are Within the Powers of the Lower Courts.....12

III. Proposal of *Amicus*.....14

CONCLUSION.....20

TABLE OF AUTHORITIES

Cases	Page
<i>Beckman Instruments, Inc. v. LKB Produkter AB</i> , 892 F.2d 1547 (Fed. Cir. 1989).....	18
<i>Bose, In re</i> , 580 F.3d 1240 Fed. Cir. 2009).....	8
<i>Burlington Industries, v. Dayco Corp.</i> , 849 F.2d 1418 (Fed. Cir. 1988).....	3
<i>Digital Control, Inc. v. Charles Mach. Works</i> , 437 F.3d 1309 (Fed. Cir. 2006).....	2
<i>eBay Inc. v. MercExchange, L.L.C.</i> , 547 U.S. 388 (2006).....	14, 17, 21
<i>Exergen Corp. v. Wal-Mart Stores, Inc.</i> , 575 F.3d 1312 (Fed. Cir. 2009).....	 7
<i>Hazel-Atlas Glass Co. v. Hartford-Empire Co.</i> , 322 U.S. 238 (1944).....	13
<i>Innogenetics, N.V. v. Abbott Labs.</i> , 512 F.3d 1378 (Fed. Cir. 2008).....	2
<i>J. P. Stevens & Co. v. Lex Tex Ltd, Inc.</i> , 747 F.2d 1553 (Fed. Cir. 1984).....	2
<i>Keystone Driller Co. v. Gen. Excavator Co.</i> , 290 U.S. 240 (1933)	13
<i>KSR Int’l Co. v. Teleflex, Inc</i> , 550 U.S.398 (2007).....	8
<i>Optium Corp. v. Emcore Corp.</i> , 603 F.3d 1313, 1321 (Fed. Cir. 2010).....	7
<i>Pharmacia Corp. v. Par Pharm, Inc.</i> , 417 F.3d 1369 (Fed. Cir. 2005).....	2

<i>Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.</i> , 324 U.S. 806 (1945).....	13
<i>Therasense, Inc. v. Becton, Dickinson & Co.</i> , 2010 WL 1655391 (Fed. Cir. 2010).....	1

Statutes and Regulations

35 U.S.C. § 116.....	11
35 U.S.C. § 251.....	11
35 U.S.C. § 253.....	11
35 U.S.C. § 256.....	11
35 U.S.C. § 282.....	10
35 U.S.C. § 284.....	20
35 U.S.C. § 285.....	16
35 U.S.C. § 288.....	10, 11, 12, 15
37 C.F.R. § 1.56.....	4, 5, 6, 14, 15, 17, 18, 19, 20, 21
Manual of Patent Examining Procedure, § 2010.....	17

Other Authorities

<i>A PATENT SYSTEM FOR THE 21ST CENTURY</i> , R. C. Levin and Mark B. Myers, Statement to the Committee on the judiciary, United States Senate on behalf of the National Academies of Science, Engineering and Medicine, April 5, 2005.....	3
Cotropia, <i>Modernizing Patent Law’s Inequitable Conduct Doctrine</i> , 24 Berkeley Tech. Law J., 723 (2009).....	4

STATEMENT RE CONSENT OF PARTIES

The consent of the parties, through their counsel, has been obtained for the filing of this brief..

**STATEMENT OF INTEREST
OF *AMICUS CURIAE*¹**

The San Diego Intellectual Property Law Association (SDIPLA) is a non-profit association whose members have significant ties to San Diego's world class research institutions and leading wireless, biotechnology and solar industries. Patent protection for innovative technologies has allowed San Diego entrepreneurs to attract capital for the development and commercialization of important new technologies. A major goal of the SDIPLA in the delivery of legal services to the business community of San Diego is to enhance its ability to continue to attract capital to those companies whose success is largely driven by their patent portfolios. Comprising about 500 members, the SDIPLA has grown to one of the largest regional intellectual property bar organizations in the country.

SUMMARY OF ARGUMENT

The questions posed to the parties and the *amici curiae* in this case² strongly suggest that the Court intends to take a fresh look at the jurisprudence relating to claims that a patent applicant committed inequitable conduct in proceedings before

¹ This brief was prepared by members of the *Amicus* Committee on a *pro bono* basis. Counsel for a party did not participate in its preparation and no financial contribution of a party supported its preparation.

² *Therasense, Inc. v. Becton, Dickinson & Co.*, 2010 WL 1655 391 (Fed. Cir. 2010).

the United States Patent & Trademark office (“PTO”). According to that jurisprudence as it exists today, once a court finds that “inequitable conduct” occurred, all of the claims in a patent infected by the conduct are unenforceable even if every claim meets the requirements of patentability established in Title 35 of the United States Code. As a result, defendants in patent suits have a great incentive to plead and attempt to prove inequitable conduct by the patentee.

As the law has developed, an accused infringer must prove inequitable conduct by clear and convincing evidence of two factors, *i.e.*, that the patentee withheld or misrepresented information material to patentability and that the mishandling of the information was done with intent to deceive the PTO. See, *J. P. Stevens & Co., Inc. v. Lex Tex Ltd. Inc.*, 747 F.2d 1553 (Fed. Cir. 1984) and more recently, *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363 (Fed. Cir. 2008).³ However, the level of materiality that must be proven to establish inequitable conduct varies inversely with the level of intent so that, in the words of the court, “a greater showing of one factor” allows “a lesser showing of the other.”⁴ This

³ *Innogenetics* at 512 F.3d 1378 (“...inequitable conduct includes affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information coupled with an intent to deceive.”) (quoting from *Pharmacia Corp. V. Par Pharm., Inc.*, 417 F.3d 1369, 1373 (Fed. Cir. 2005)).

⁴ See, for example, *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1313 (Fed. Cir. 2006) and cases there cited.

sliding standard of materiality applicable to the mishandled information is undoubtedly one of the catalysts of the zealous pursuit in patent litigation of claims of inequitable conduct, claims that have become so pervasive that they have been proclaimed a plague by this Court.⁵

Dissatisfaction with the impact of the rampant claims of inequitable conduct on patent prosecution before the PTO and litigation of infringement claims has led to a veritable Greek chorus of critical comment. At one extreme are calls to eliminate the defense entirely.⁶ On the other, as a result of the confusion in the minds of practitioners and lower courts concerning application of the balancing test requiring weighing the level of materiality against the level of intent to determine when inequitable conduct has occurred, and a desire to avoid disparate outcomes in cases having similar facts, other commentators have suggested that the standard for determining intent be clarified and that the standard of materiality of the mishandled information should be a fixed one, with a wide variety of views concerning what that standard should be.⁷

⁵ *Burlington Indus. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988) (“...the habit of charging inequitable conduct in almost every major patent case has become an absolute plague.”).

⁶ See *A PATENT SYSTEM FOR THE 21ST CENTURY*, R. C. Levin and Mark B. Myers, Statement to the Committee on the judiciary, United States Senate on behalf of the National Academies of Science, Engineering and Medicine, April 5, 2005.

⁷ One view urging a lower standard than “but for” materiality is found in the

Obviously, from the point of view of the alleged infringer, if the Court were to adopt a fixed standard of materiality, the lower it is the better. Thus one view is that the standard of 37 C.F.R. § 1.56 (PTO “Rule 56”) should be employed as the appropriate standard of materiality. Adoption of that point of view, however, would likely result in even greater zeal on the part of defendants in pursuing the defense. Others call for a more demanding standard than that of Rule 56. However, if a higher standard of materiality is adopted, for example one of the “but for” standards of materiality about which more will be said below, egregious misconduct that fails to meet such a standard would go unpunished and hence weaken the incentive of applicants to deal fairly with the PTO.⁸

In the argument below, we propose that the Court take a different approach to dealing with misconduct under the jurisprudential umbrella of inequitable conduct than that used now, an approach which does not require the inherently imprecise balancing of materiality and intent to reach a fixed outcome-- imposition of the death sentence of unenforceability on otherwise valid claims. In place of the

extensive review of the inequitable conduct defense is in Cotropia, *Modernizing Patent Law’s Inequitable Conduct Doctrine*, 24, Berkeley Tech. Law J., 723 (2009). Professor Cotropia also urges that the element of intent not be inferred from materiality of the mishandled information, *i.e.*, the information not disclosed or which has been misrepresented.

⁸ From time to time in this brief we use the term “material misconduct” or words to that effect to refer to conduct that is deemed inequitable. In such situations we mean that information meeting some standard of materiality has been intentionally withheld from, or misrepresented to the PTO.

current approach we urge the court to restructure the defense of inequitable conduct in the following way: (i) permit a finding of inequitable conduct whenever information intentionally withheld or misrepresented by the patentee meets or exceeds the materiality standard of Rule 56, but only impose the ultimate penalty of unenforceability of otherwise valid claims if the nature of the withheld or misrepresented information meets or exceeds an objective “but for” standard of materiality and (ii) require that intent to withhold or misrepresent material information be proven without an inference of intent being drawn from the level of materiality of the information.

Intentional misconduct involving information falling below the “but for” standard of materiality would be punished with a remedy, other than unenforceability, that is tailored by the trial court to reflect the nature of the misconduct. In other words, the trial court’s discretion would be limited to fashioning a remedy for inequitable conduct rather than attempting to apply subjective factors using the balancing test currently in favor to determine if inequitable conduct has occurred without any ability to fashion the punishment to fit the crime. Our reasons for this approach are developed below but we turn first to addressing the questions posed by the Court.

RESPONSE TO QUESTIONS POSED BY THE COURT

1. Should the materiality-intent balancing framework for inequitable conduct be modified or replaced? Yes, it should be replaced. The trial court, appropriately assisted by the jury, should determine whether intentional misconduct has occurred with respect to information that meets or exceeds the materiality standard of Rule 56. If it has, then the conduct will be deemed inequitable and a remedy fixed by the court that depends on materiality of the mishandled information with the ultimate penalty of unenforceability being imposed if the information meets an objective “but for” standard discussed hereinafter. In that regard, the “but for” standard would be met in the circumstance where one or more of the claims of the patent would not have issued had the intentional withholding or misrepresentation of facts relating to patentability not occurred.

2. If so, how? See response to Question 1.

3. What is the proper standard of materiality? What role should the United States Patent and Trademark Office’s rules play in defining materiality? Should a finding of materiality require that but for the alleged misconduct, one or more of the claims would not have issued? See response to Question 1.

4. Under what circumstances is it proper to infer intent from materiality? Although we do not believe that reform of the intent element of the doctrine of inequitable conduct is as important as replacing the balancing test between materiality and intent with a more objective inquiry, an allegation of fraud in any context, including patent prosecution, is so serious that it should never be taken so lightly as to permit intent to be inferred solely from the materiality of the mishandled information. We assume that it can never be the case that the level of materiality of mishandled information is so high that intent can be inferred without any evidence of deceit.⁹

We know of no case in which the court has held that it is never proper to weigh materiality as part of the evidence from which deceptive intent is inferred. However, the Court's reasoned standard for determining intent, and the one that is consistent with our proposal discussed *infra*, is to require proof of a deliberate decision to withhold a known material reference or to make a knowingly false misrepresentation as a predicate to inferring deceptive intention.¹⁰ In these cases, we think the use of evidence of materiality as an aid to determining intent has been significantly downplayed by the Court. And while subjective intent to deceive may indeed be difficult to prove, it should remain an indispensable element of the

⁹ See *Optium Corp. v. Emcore Corp.*, 603 F.3d 1313, 1321 (Fed. Cir. 2010).

¹⁰ See *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F. 3d 1312, 1331 (Fed. Cir. 2009).

analysis nonetheless.¹¹ However, we think the court should go to the next step and divorce materiality from intent.

Amicus believes that one salutary effect of completely divorcing the evidence of intent from the evidence of the materiality of the misrepresented or withheld information may be to reduce the prophylactic practice of applicants to inundate the PTO with prior art of little or only cumulative relevance to patentability in an effort to immunize themselves against a claim of inequitable conduct. This practice imposes an enormous investment of time on the examiner if he or she is to consider all of the documentary evidence submitted to the PTO in order to winnow a little wheat from reams of chaff.¹²

5. Should the balancing inquiry (balancing materiality and intent) be abandoned? Yes. See response to Question 1.

6. Whether the standards for materiality and intent in other federal agency contexts or at common law shed light on the appropriate standards to

¹¹ See e.g., *In re Bose Corp.*, 580 F.3d 1240 (Fed. Cir. 2009) (discussing the requisite intent for fraud on the Patent Office in the context of trademarks).

¹² This practice may become even more pervasive and oppressive as the effect of the Supreme Court's decision in *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007) begins to be felt. By limiting the use of the "teaching, suggestion, or motivation" test for relevance of prior art, of necessity the Court clearly intended to broaden the universe of prior art relevant to patentability. This will eliminate the ability of patent applicants to eliminate reference material from that required to be submitted to the PTO on the ground that it does not contain a teaching, suggestion or motivation that it be combined with other art.

be applied in the patent context. We think not. It is too difficult to generalize concerning materiality and intent because of the varying and very differing contexts in which parties seek decisions from government agencies. It seems very clear that there is a special duty of candor owed the PTO for a number of reasons. Among them is that the applicant for patent is, with few exceptions, engaged in an ex parte proceeding in which there is no adversary who can be counted on to diligently seek evidence which would deny the applicant a patent. Additionally, the PTO does not possess subpoena power, the right to call witnesses or pursue any other procedure which would assist in obtaining evidence from the applicant or any other party. Finally, thousands of patent applications are filed annually and not all patent applications merit huge expenditures to secure allowance. The expense and time consumed in a more adversarial proceeding would make patents prohibitively expensive and reduce their value as an incentive for investing in an enterprise or otherwise incurring the expense of bringing a product into a competitive market.

ARGUMENT

I. The Patent Statute Specifically Permits A Defense To A Claim of Patent Infringement of Valid Claims but Only if at Least One Claim of the Patent Is Procured by Inequitable Conduct.

Because the Court appears to be addressing broadly the issues presented by existing jurisprudence surrounding the defense of inequitable conduct we assume one or more parties will recommend its abolition. We think it unlikely that the

Court would seriously entertain such an approach. However, it bears pointing out that Congress has expressly recognized that, in addition to the defenses of invalidity arising from substantive provisions of the code, the defendant has the right to plead and prove a defense of “unenforceability” of the patent.¹³

Neither § 282 nor any other section of Title 35 specifically spell out any of the grounds of unenforceability that Congress may have contemplated when it enacted § 282 although several provisions of the code permit an inference to be drawn concerning when otherwise valid claims in a patent should, nevertheless, be unenforceable. For example, § 288 without expressly saying so, permits no other inference than that valid claims in a patent containing a single invalid claim procured with “deceptive intention” cannot be enforced.¹⁴ However, it must also be the case that a corollary to the inference of unenforceability if an invalid claim is procured with deceptive intention is the existence of a reverse inference. That inference is that § 288 itself does not preclude the enforcement of valid claims in a

¹³ See 35 U.S.C. § 282(1).

¹⁴ 35 U.S.C. § 288 reads: “Whenever, without deceptive intention, a claim of a patent is invalid, an action may be maintained for the infringement of a claim of the patent which may be valid. The patentee shall recover no costs unless a disclaimer of the invalid claim has been entered at the Patent and Trademark Office before the commencement of the suit.” Since the presence of an invalid claim does not taint a patent’s enforceability by its mere presence unless obtained with deceptive intention, it follows that enforceability must be denied if a claim in the patent is obtained by means of deception.

patent merely because of some deceptive conduct by the applicant if, despite the “deceptive intention” of the applicant, the claim or claims tainted by the misconduct would have been patentable anyway. In other words, a defense of unenforceability based on § 288 requires that the misconduct meet a “but for” standard of materiality, *i.e.*, in the absence of the misconduct, the PTO would have otherwise found the patented claim affected by the misconduct to be invalid.

Other sections of the patent statute suggest that deceptive intention on the part of the patentee meeting a “but for standard” would render valid claims of a patent unenforceable. For example, an invalid claim cannot be repaired by reissue if the claim was originally procured with deceptive intention.¹⁵ Accordingly, if a reissued patent is asserted against an alleged infringer and the original patent contained an invalid claim procured with deceptive intention, that original claim, if omitted from or amended by reissue, would in substance be deemed to remain in the reissued patent and its enforceability defeated by § 288.

Title 35 further provides that invalid claims obtained by deceptive intention cannot be disclaimed¹⁶ and improper designation of inventors with deceptive intention cannot be remedied while an application is pending or after issuance.¹⁷

¹⁵ See 35 U.S.C. § 251

¹⁶ See 35 U.S.C. § 253

¹⁷ See 35 U.S.C. §§ 116, 256. § 116 is obviously intended to complement § 288 by making it impossible to purge a claim obtained by deceptive intention from a

The obvious sanction against a plaintiff asserting infringement of a patent with defects like those mentioned arising from deceptive intention is to refuse enforcement of the patent in which the defects exist.

Notwithstanding the existence of the defenses enumerated above that find their bases in wrongful conduct by the patentee, Title 35 itself does not suggest anywhere that Congress intended that a patent should be judicially determined to be unenforceable in the situation where misconduct by the patentee did not result in the grant of an invalid claim or result in the inventive entity being misstated with deceptive intention. This has led us to conclude that courts cannot impose the remedy of unenforceability in situations other than where that remedy is specifically provided in the Patent Act because Congress did not explicitly or by inference include such a remedy in § 288 or elsewhere.

Accordingly, it is our view that Title 35 does not permit judicial imposition of the ultimate penalty of unenforceability where a patentee's misconduct does not meet a "but for" standard of materiality because Congress has specifically limited that remedy to the circumstance where misconduct does meet that standard. However, we recognize that there is no specific prohibition of the remedy of unenforceability in less egregious circumstances. Nevertheless we believe our proposal that the remedy of unenforceability be reserved for inequitable conduct

patent to permit it to meet the requirements of § 288.

that meets a “but for” standard and that misconduct meeting a lesser standard of materiality be sanctioned less severely is more consistent with the intent of Congress to be inferred from, for example, § 288 than is current jurisprudence.¹⁸

II. Supreme Court Precedent Also Requires Recognition of a Defense Based on Inequitable Conduct but Setting Its Boundaries are Within the Powers of the Lower Courts.

In its questions posed to the parties and the *amici curiae*, the Court identifies a number of cases in which the Supreme Court has held that patents be denied enforcement in cases of misconduct by the patentees.¹⁹ Without engaging in an exhaustive analysis of these cases, it is clear that in all of them the patentee had engaged in such egregious conduct that, but for the misconduct, the PTO would have refused to allow any claims. It is also worth noting that all of these cases were decided before the current statute was enacted. Accordingly, it is not unreasonable to conclude that Congress intended to incorporate these decisions into the 1952 statute through, for example, the inclusion of § 288 discussed *supra*

¹⁸ As we will point out below, while we believe the defense of unenforceability should be off the table in the absence of misconduct that meets a “but for” standard, that does not preclude a court from fashioning a remedy for infringement that takes into account the actual misconduct under the equitable powers of the court.

¹⁹ *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806 (1945); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.* 322 U.S. 238 (1944), *overruled on other grounds by Standard Oil Co. v. United States*, 429 U.S.17 (1976); *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240 (1933).

and, in fact, to broaden the defense of unenforceability to at least include cases in which the presence of a single invalid claim procured with deceptive intention would render even valid claims unenforceable. .

One other conclusion is, in our view, inescapable and that is that this Court cannot eliminate the defense of unenforceability arising from inequitable conduct or limit its applications in a manner that nullifies either Supreme Court precedent or Congressional intent. However, it seems equally clear to us that this Court and the courts over which it has appellate jurisdiction in matters relating to enforcement of patents have the power to impose sanctions for inequitable conduct by patentees in cases in which their misconduct is not so egregious as that specifically condemned by the Supreme Court or for conduct which Congress has determined deprives a patent of enforceability. Instead, *Amicus* considers the power to impose sanctions less than unenforceability to be consistent with the inherent power of courts to limit remedies of patentees based on the principles of equity, a power recently discussed by the Supreme Court in *eBay Inc. v. MercExchange, L.L.C.*²⁰

²⁰ 547 U.S. 388 (2006). Prior to *eBay*, grant of a permanent injunction was the usual result following a successful claim for patent infringement. In *eBay*, the Court mandated that, as grant of an injunction is an exercise of a court's equity powers, before the grant of a permanent injunction in such a case, the prevailing patentee had to satisfy a four-factor test. Those factors require demonstration that plaintiff has suffered irreparable injury; that remedies available at law are inadequate to redress the injury; that an injunction is warranted after considering

III. Proposal of *Amicus*.

As pointed out in the Summary of Argument, *Amicus* proposes a substantial revamp of the jurisprudence applicable to the defense of inequitable conduct when patent infringement is asserted. Specifically, it is proposed that all misconduct that meets or exceeds the materiality standard of 37 C.F.R. 1.56(b), a standard clearly less stringent than a “but for” standard, be deemed inequitable conduct.²¹ However, we do not propose that all conduct deemed inequitable result in otherwise valid claims in a patent tainted by the misconduct being rendered unenforceable. Instead, in cases in which the materiality of the withheld or misrepresented information would not meet an objective “but for” materiality standard, the trial court should impose a remedy short of unenforceability that nonetheless reflects the seriousness of the misconduct. In short, the penalty should be tailored to fit the crime. However, misconduct that meets an objective “but for

the balance between the hardship suffered by the defendant if an injunction is granted against the hardship to the patentee if it is denied; and that there would be no disservice to the public interest by grant of an injunction. *eBay*, 547 U.S. at 391. It requires no citation to point out that a precondition to obtaining equitable relief is that the party seeking it must come to the court with clean hands.

²¹ According to Rule 56(b):

“...information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (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 an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

test” of materiality²² would receive the ultimate penalty, *i.e.*, that a claim otherwise valid in a patent tainted by misconduct that meets the objective “but for” standard²³ would be rendered unenforceable, the result that is mandated by 35 U.S.C. § 288.

Misconduct meeting the materiality standard of Rule 56, but falling short of the “but for” standard would be punished by imposition of sanctions other than unenforceability. We shall not try to be exhaustive in suggesting the kinds of sanctions that could be imposed. A number come readily to mind, however. For example, equitable relief in the form of an injunction could be denied because the

²² *Amicus* highly commends to the Court the materiality standard of parts (1) and (2) of the test proposed to the Senate by the Section of Intellectual Property Law of the American Bar Association in a letter dated February 18, 2009 reading in whole as follows:

(1) that a person having a duty of candor and good faith to the PTO in connection with the patent or application therefor knowingly and willfully misrepresented a material fact or material information to the PTO or omitted a known material fact or known material information from the PTO;

(2) that, in the absence of such misrepresentation or omission, the PTO, acting reasonably, would not have granted or maintained in force at last one invalid claim; and

(3) that the misrepresentation or omission occurred with specific intent to deceive the PTO, and that such intent cannot be established by the mere materiality of the misrepresentation or omission.

Amicus also supports part (3) of the ABA proposal dealing with intent as well if the court is not disposed to eliminate any inference of intent to be derived from the materiality of information withheld from or misrepresented to the PTO. See our response to Question 4, *supra*.

²³ We do not support use of a subjective but for test of materiality for several reasons. Without going deeply into this particular point we note that one of our reasons is that the PTO resists inquiries into the thought process of examiners as it relates to matters relating to the grant or denial of claims.

patentee does not have clean hands. In such a case, otherwise infringing conduct would be permitted to continue under terms like those that are currently being imposed in cases where infringement is found but a permanent injunction is denied upon consideration of the factors mandated in *eBay, supra*. In this situation, the misconduct of the patentee would be an additional factor weighed by the court in determining whether the infringer's continuing practice of the patented invention should be permitted and, perhaps, to what extent.

We recognize that adoption of our proposal still requires balancing by the trial court, but the balancing is of a kind that is already required under *eBay* and, therefore, does not impose a burden on the trial court and reviewing courts not already required when infringement is found to exist and the patentee's right to an injunction is being determined.

Another remedy that, in our view, could be considered is imposition of an award of attorneys' fees to the defendant relative to the expense incurred by it in mounting the defense. We are mindful that, under 35 U.S.C. § 285, awards of attorneys' fees go only to the prevailing party and only in exceptional cases. However, if an award of attorneys' fees to a defendant who does not prevail beyond the establishment of inequitable conduct on part of the plaintiff is not within the inherent equitable powers of the trial court, *Amicus* believes it would not stretch § 285 to unreasonable limits to permit a statutory award to the defendant as

the “prevailing party” on the claim of inequitable conduct because of its exceptional nature. In practical effect such an award would not be significantly different than an award of a portion of attorneys’ fees to patentees in cases of split verdicts of the kind involved in, for example, *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1554 (Fed. Cir. 1989).

There are other reasons why the flexible approach advocated here recommends itself. In that regard, *Amicus* assumes that the PTO was acting within its powers as an administrative agency in adopting the materiality standard embodied in Rule 56. Obviously, if a higher standard of misconduct for determining inequitable conduct than that embodied in Rule 56 is set by the courts, then the only body that can enforce the PTO standard is the agency itself. However, the PTO has made an administrative determination not to enforce Rule 56 in most contexts and to leave enforcement to the courts for a variety of reasons.²⁴

²⁴ See *Manual of Patent Examining Procedure*, §2010. “Determination of inequitable conduct issues requires an evaluation of the intent of the party involved. While some court decisions have held that intent may be inferred in some circumstances, consideration of the good faith of the party, or lack thereof, is often required. In several court decisions, a high level of proof of intent to mislead the Office was required in order to prove inequitable conduct under 37 CFR 1.56. [Citations Omitted]. The Office is not the best forum in which to determine whether there was an “intent to mislead”; such intent is best determined when the trier of facts can observe demeanor of witnesses subjected to cross-examination. A court, with subpoena power, is presently the best forum to consider duty of disclosure issues under the present evidentiary standard for finding an “intent to

Amicus submits that the rationale offered in the MPEP by the PTO for avoiding policing the conduct of patent applicants is so persuasive that it merits being set forth as we have done in its entirety and, therefore, should be respected and supported by this court. We also encourage the court to consider that, should it impose a fixed standard of materiality higher than that embodied in Rule 56, the rule and the salutary effects it would be expected to produce in patent prosecution would be, for all practical purposes, nullified.

mislead." The court proceeding involves two participating adverse parties. This is not the case in the Office, since even "protesting" parties are not permitted to participate under the rules. Also, it is the courts and not the Office that are in the best position to fashion an equitable remedy to fit the precise facts in those cases where inequitable conduct is established. Furthermore, inequitable conduct is not set by statute as a criteria for patentability but rather is a judicial application of the doctrine of unclean hands which is appropriate to be handled by the courts rather than by an administrative body. Because of the lack of tools in the Office to deal with this issue and because of its sensitive nature and potential impact on a patent, Office determinations generally will not deter subsequent litigation of the same issue in the courts on appeal or in separate litigation. Office determinations would significantly add to the expense and time involved in obtaining a patent with little or no benefit to the patent owner or any other parties with an interest.

“Accordingly, the Office does not investigate and reject original or reissue applications under 37 CFR 1.56. Likewise, the Office will not comment upon duty of disclosure issues which are brought to the attention of the Office in original or reissue applications except to note in the application, in appropriate circumstances, that such issues are no longer considered by the Office during its examination of patent applications. Examination of lack of deceptive intent in reissue applications will continue but without any investigation of inequitable conduct issues. Applicant's statement of lack of deceptive intent normally will be accepted as dispositive except in special circumstances such as an admission or judicial determination of fraud or inequitable conduct.”

Another advantage of the flexible approach recommended here may be less obvious. As noted above, under the present case law, if the balancing test is applied in a situation where the level of materiality of the mishandled information affecting patentability is lower than would satisfy a “but for” standard of patentability, but the level of intent is high, the result using the balancing test can be that all of the claims of the tainted patent would be unenforceable even if all were otherwise patentable. In such a case, even if the claims were willfully infringed²⁵ by the defendant, its “inequitable conduct” would go unpunished, a result that, in our view has nothing to recommend it.

CONCLUSION

For all of the foregoing reasons, *Amicus Curiae* San Diego Intellectual Property Law Association respectfully encourages the court to adopt a more flexible and less subjective approach to the defense of inequitable conduct. Under the recommended approach, the trial court will be relieved of the duty to engage in the inherently subjective balancing of the levels of the two prongs of materiality and intent required by the current test for determining inequitable conduct. Instead, it need only determine whether the materiality of the misconduct exceeds that of Rule 56 and fashion a remedy up to and including unenforceability, if the “but for”

²⁵ Willful infringement is, of course, a ground for awarding multiple damages to a

standard of materiality is met, based on the materiality of the misconduct. This balancing test is already largely subsumed in the requirements imposed on a court in determining whether to grant a permanent injunction by the Supreme Court in *eBay*. Additionally, it lends support to the PTO's goal to encourage candor in proceedings before the Office reflected in its Rule 56, a goal which would be sacrificed if a higher standard of materiality were imposed because of the inability of the PTO to effectively police the conduct of patentees and. Perhaps even more importantly, it limits the imposition of the remedy of unenforceability to those cases in which that sanction is specifically intended by Congress.

Respectfully Submitted,

San Diego Intellectual Property
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patentee under 35 U.S.C. § 284.

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) and 29(d). According to software used to prepare this brief it contains 3884 words, excluding the parts of the document that are exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and Federal Circuit Rule 32(b)

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PROOF OF SERVICE

I, _____, certify that I am employed by _____ whose address is _____. On August 2, 2010, I caused an original and twelve copies of this brief to be delivered for filing to:

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On the same date, I caused two copies of this brief to be sent by FedEx to counsel of record for the parties at the following addresses:

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I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Dated: August 2, 2010

By _____