

IN THE
United States Court of Appeals
for the Federal Circuit

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

v.

BECTON, DICKINSON AND COMPANY,
and NOVA BIOMEDICAL CORPORATION,
Defendants-Appellees,

and

BAYER HEALTHCARE LLC,
Defendant-Appellee.

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

BRIEF OF AMICUS CURIAE
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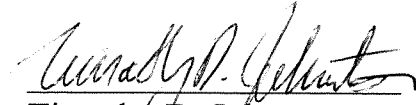
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August 2, 2010

CERTIFICATE OF CONSENT

Counsel for *amicus curiae*, Boston Patent Law Association, certifies that, after conference with individual representatives, Abbott Laboratories has consented, and Becton, Dickinson and Co., Nova Biomedical Corporation, and Bayer Healthcare LLC have no objection, to the filing of this *amicus curiae* brief.

Dated: August 2, 2010


Timothy D. Johnston

CERTIFICATE OF INTEREST

Counsel for *amicus curiae*, Boston Patent Law Association, certifies the following:

1. The full name of every party or *amicus* represented by me is:
Boston Patent Law Association
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:
None
3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or *amicus curiae* represented by me are:
None
4. There is no such corporation as listed in paragraph 3.
5. The names of all law firms and the partners or associates that appeared for the party or *amicus* now represented by me in the trial court or agency or are expected to appear in this court are:

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TABLE OF CONTENTS

| | |
|---|-----|
| CERTIFICATE OF CONSENT | i |
| CERTIFICATE OF INTEREST..... | ii |
| TABLE OF CONTENTS | iii |
| TABLE OF AUTHORITIES..... | iv |
| IDENTITY AND INTEREST OF <i>AMICUS CURIAE</i> | 1 |
| INTRODUCTION | 1 |
| ARGUMENT..... | 2 |
| I. THE COURT EMPLOYS VAGUE AND CONFLICTING TESTS FOR MATERIALITY..... | 2 |
| II. THE ABUNDANCE OF MATERIALITY TESTS CREATES COMPLICATIONS FOR APPLICANTS, PETITIONERS, AND EXAMINERS ALIKE | 7 |
| A. Uncertainty With Respect To Materiality Leads To Over-Citation..... | 7 |
| B. Over-Citation Compromises The Effective And Efficient Examination Of Applications | 11 |
| C. Compliance With The Patchwork Of Materiality Tests Is Costly..... | 12 |
| III. THIS COURT SHOULD ADOPT AN OBJECTIVE “BUT FOR” TEST FOR MATERIALITY..... | 14 |
| CONCLUSION..... | 17 |
| CERTIFICATE OF COMPLIANCE..... | 19 |
| CERTIFICATE OF SERVICE..... | 20 |

TABLE OF AUTHORITIES

Cases

| | |
|---|---------|
| <i>American Hoist & Derrick Co. v. Sowa & Sons, Inc.</i> , 725 F.2d 1350 (Fed. Cir. 1984)..... | 3, 4, 6 |
| <i>Critikon v. Becton Dickinson Vascular Access, Inc.</i> , 120 F.3d 1253 (Fed. Cir. 1997)..... | 10 |
| <i>Dayco Prods., Inc. v. Total Containment, Inc.</i> , 329 F.3d 1358 (Fed. Cir. 2003)..... | 5 |
| <i>Digital Control, Inc. v. Charles Mach. Works</i> , 437 F.3d 1309 (Fed. Cir. 2006)..... | 5, 6 |
| <i>Espeed, Inc. v. Brokertec U.S.A., L.L.C.</i> , 480 F.3d 1129 (Fed. Cir. 2007)..... | 10 |
| <i>Ferring B.V. v. Barr Labs., Inc.</i> , 437 F.3d 1181 (Fed. Cir. 2006)..... | 6 |
| <i>Hazel-Atlas Glass Co. v. Hartford-Empire Co.</i> , 322 U.S. 238 (1944)..... | 15 |
| <i>Innogenetics, N.V. v. Abbott Labs.</i> , 512 F.3d 1363 (Fed. Cir. 2008)..... | 8 |
| <i>Keystone Driller Co. v. General Excavator Co.</i> , 290 U.S. 240 (1933)..... | 15 |
| <i>McKesson Info. Solutions, Inc. v. Bridge Med., Inc.</i> , 487 F.3d 897 (Fed. Cir. 2007)..... | 8 |
| <i>Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.</i> , 324 U.S. 806 (1945)..... | 15 |
| <i>Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.</i> , 537 F.3d 1357 (Fed. Cir. 2008)..... | 6 |

| | |
|--|---|
| <i>Therasense, Inc. v. Becton, Dickinson and Co.</i> , 565 F. Supp. 2d 1088 (N.D. Cal. 2008) | 6 |
| <i>Therasense, Inc. v. Becton, Dickinson and Co.</i> , 593 F.3d 1289 (Fed. Cir. 2010), <i>vacated pending reh’g</i> <i>en banc</i> , 2010 WL 1655391 | 6 |
| <i>Therasense, Inc. v. Becton, Dickinson and Co.</i> , No. 2008-1511, -1512, -1513, -1514, -1595, 2010 WL 1655391 (Fed. Cir. April 26, 2010) | 1 |
| <i>Young v. Lumenis, Inc.</i> , 492 F.3d 1336 (Fed. Cir. 2007) | 8 |

Constitutional Provisions

| | |
|--------------------------------------|---|
| U.S. Const. art. I, § 8, cl. 8 | 1 |
|--------------------------------------|---|

Regulations

| | |
|------------------------|---------------|
| 37 C.F.R. § 1.17 | 13 |
| 37 C.F.R. § 1.56 | <i>passim</i> |

Regulatory Materials

| | |
|---|-----------|
| 54 Fed. Reg. 11334 (1989) | 4 |
| 57 Fed. Reg. 2021 (1992) | 5, 11, 15 |
| 71 Fed. Reg. 38808 (2006) | 11, 12 |
| Manual of Patent Examining Procedure § 2001.06(a) | 8 |
| Manual of Patent Examining Procedure § 2004 | 10 |

Miscellaneous

- ABA Section of Intellectual Property Law, *A Section White Paper: Agenda for 21st Century Patent Reform* (2007), available at <http://www.abanet.org/intelprop/home/PatentReformWP.pdf> 16
- Benjamin Brown, *Inequitable Conduct: A Standard in Motion*, 19 *Fordham Intell. Prop. Media & Ent. L.J.* 593 (2009)..... 14
- Christian E. Mammen, *Controlling the “Plague”: Reforming the Doctrine of Inequitable Conduct*, 24 *Berkeley Tech. L. J.* 1329 (2009) 4, 5
- Christopher A. Cotropia, *Modernizing Patent Law’s Inequitable Conduct Doctrine*, 24 *Berkeley Tech. L. J.* 723 (2009)..... 12, 14
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- Dennis Crouch, *Information Disclosure: Less is More for PTO?*, *Patently-O*, Sept. 17, 2008, <http://www.patentlyo.com/patent/2008/09/information-dis.html>..... 10
- Edwin S. Flores and Sanford E. Warren, Jr., *Inequitable Conduct, Fraud, and Your License to Practice Before the United States Patent & Trademark Office*, 8 *Tex. Intell. Prop. L.J.* 299 (2000).....9-10
- Nat’l Research Council for the Nat’l Academies, *A Patent System for the 21st Century* 147 (Stephen A. Merrill et al., eds. 2004)..... 11
- Sean M. O’Connor, *Defusing the “Atomic Bomb” of Patent Litigation: Avoiding and Defending Against Allegations of Inequitable Conduct After McKesson et al.*, 9 *J. Marshall Rev. Intell. Prop. L.* 330 (2009) 3-4

Legislative Materials

S. Rep. No. 110-259 (2008)..... 7, 12

IDENTITY AND INTEREST OF *AMICUS CURIAE*

The Boston Patent Law Association (“BPLA”) is an intellectual property association that provides educational programs and a forum for the interchange of ideas and information concerning intellectual property rights. The BPLA believes that the inequitable conduct doctrine has a place in patent law, but is concerned that the doctrine has become bloated and unworkable, to the detriment of the patent system. The BPLA respectfully submits this brief, in support of neither party, in response to the Court’s request for briefs that address the proper standard for materiality and the role that the rules of the United States Patent and Trademark Office (“PTO”) should play in defining materiality. The BPLA has authority to file this brief pursuant to this Court’s order. *Therasense, Inc. v. Becton, Dickinson and Co.*, Nos. 2008-1511, -1512, -1513, -1514, -1595, 2010 WL 1655391 (Fed. Cir. April 26, 2010).

INTRODUCTION

The founding principal and spirit of patent law, announced in the Constitution, is to “promote the Progress of Science and the useful Arts.” U.S. Const. art. I, § 8, cl. 8. Patents fulfill this role and are vital to the American economy. The current framework for evaluating inequitable conduct, however, is directly at odds with this uniquely utilitarian goal. The

patchwork of vague and conflicting tests for the materiality prong of the inequitable conduct analysis encourages applicants to flood the PTO with information that often has little, if any, bearing on patentability. This creates undue burden and expense for applicants, overwhelms examiners, and ultimately frustrates the examination of patent applications.

The solution is simple. The Court should abandon its multiple materiality tests and adopt an objective “but for” test whereby information would not be deemed material unless it invalidates one or more patent claims.¹

ARGUMENT

I. THE COURT EMPLOYS VAGUE AND CONFLICTING TESTS FOR MATERIALITY

The BPLA is of the view that much of the confusion and uncertainty surrounding the inequitable conduct doctrine stems from the fact that this Court employs multiple, vague and conflicting tests to measure the materiality of information.

¹ Although beyond the scope of this brief, the BPLA also believes that the intent analysis should be de-linked from the materiality analysis and brought back in line with the common law fraud principles on which the inequitable conduct doctrine is grounded.

In *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350 (Fed. Cir. 1984), this Court recognized four separate tests for materiality:

1. an objective “but for” test, under which information is material only if a patent should not have issued in light of it;
2. a subjective “but for” test, used where the examiner actually would not have granted the patent if the information was available;
3. a “but it may have” test, for cases where the information may have influenced the examiner’s decisions in prosecution; and
4. the “reasonable examiner” test in the 1977 version of Rule 56, which defined information as material “where there is a substantial likelihood that a reasonable examiner would consider it important to deciding whether to allow the application to issue as a patent.”

Id. at 1362. As explained below, yet a fifth test was recognized in 2006.

In *dicta*, the *American Hoist* Court seemed to back the fuzzy “reasonable examiner” test but declined to commit to “any single standard,” citing the linkage between the materiality and intent analyses (*i.e.*, a lesser showing of materiality might suffice in the face of a greater showing of intent and vice versa). *Id.* at 1363. At least one commentator has credited this *dicta*—which preserved a multiplicity of materiality tests—with contributing to the proliferation of inequitable conduct allegations in the 1980s and creating confusion regarding the scope of Rule 56. *See* Sean M.

O'Connor, *Defusing the "Atomic Bomb" of Patent Litigation: Avoiding and Defending Against Allegations of Inequitable Conduct After McKesson et al.*, 9 J. Marshall Rev. Intell. Prop. L. 330, 353 (2009).

Following *American Hoist*, the "reasonable examiner" test became the dominant—although not exclusive—test. This malleable standard, under which almost anything can be deemed material, did not improve matters. By the late 1980s, the PTO recognized that the "reasonable examiner" test needed to be revised, citing "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." 54 Fed. Reg. 11334, 11334 (1989); *see also* Christian E. Mammen, *Controlling the "Plague": Reforming the Doctrine of Inequitable Conduct*, 24 Berkeley Tech. L. J. 1329, 1335-36 (2009). This determination led to the 1992 amendments to Rule 56, which significantly narrowed the definition of materiality.² The PTO made those amendments to "present a clearer and more objective definition of what information [it] considers material to

² Under the 1992 version of Rule 56 (as well as the current version), information is *only* material if it is not cumulative and it, alone or in combination with other information: (1) establishes a *prima facie* case of unpatentability of a claim; or (2) refutes, or is inconsistent with, a position the applicant took in (i) opposing an argument of unpatentability relied on by the PTO or (ii) arguing for patentability. 37 C.F.R. § 1.56(b) (1992).

patentability.” 57 Fed. Reg. 2021, 2024 (1992). And, it expressed the hope that the amended rule would reduce litigation regarding inequitable conduct:

The amendment to § 1.56 was proposed to address the criticism concerning a perceived lack of certainty in the materiality standard. The rule as promulgated will provide greater clarity and hopefully minimize the burden of litigation on the question of inequitable conduct before the Office, while providing the office with the information necessary for effective and efficient examination of patent applications.

Id. at 2023.

For some time after the 1992 amendments, the Court suggested that the “reasonable examiner” test would “gradually fade into irrelevance,” by only applying it retroactively to patents issued before 1992. *Mammen, supra*, at 1337 and note 30. But in 2003, the Court indicated that the “reasonable examiner” test might still have legs. *See Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1362-64 (Fed. Cir. 2003). Three years later, in *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309 (Fed. Cir. 2006), the Court resurrected the “reasonable examiner” test, concluding that the 1992 amendments to Rule 56 did not supplant it. *See id.*

at 1314-16. In short, the Court reduced the 1992 version of Rule 56 to simply a fifth test for materiality.³

After *Digital Control*, the Court appeared to return to the “reasonable examiner” test as its favored test for materiality. See, e.g., *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1367 (Fed. Cir. 2008); *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1187 (Fed. Cir. 2006). Yet in the instant case, after citing the “reasonable examiner” test in passing, the district court instead applied the current version of Rule 56. See *Therasense, Inc. v. Becton, Dickinson and Co.*, 565 F. Supp. 2d 1088, 1110-13 (N.D. Cal. 2008). And on appeal, the panel did not even mention the “reasonable examiner” test. See *Therasense, Inc. v. Becton, Dickinson and Co.*, 593 F.3d 1289, 1300-05 (Fed. Cir. 2010), *vacated pending reh’g en banc*, 2010 WL 1655391.⁴

³ Echoing *American Hoist*, the Court reasoned that multiple materiality tests dovetailed with the materiality-intent balancing framework. *Id.* at 1316 (“[T]o the extent that one standard requires a higher showing of materiality than another standard, the requisite finding of intent may be lower.”) As noted in footnote 1, *supra*, the BPLA believes that the materiality and intent analyses should be independent, in which case this justification for multiple materiality tests dissolves.

⁴ Presumably, both this Court and the district court confined their analyses to the current Rule 56 because they viewed the declarations and EPO submissions at issue as “inconsistent” per Rule 56(b)(2); thus, there was no reason to go beyond the text of the rule.

The end result is that this Court has applied no less than five different tests for materiality. This creates unpredictability, not only in federal court litigation, but also before the PTO, since practitioners must operate under the shadow of all five tests, none of which offer bright-line guidance and all of which inevitably conflict with one another in application. Indeed, this framework invites the nonsensical scenario in which a patentee who has complied with Rule 56 before the PTO could nonetheless be found to have committed inequitable conduct under the “reasonable examiner” test.

II. THE ABUNDANCE OF MATERIALITY TESTS CREATES COMPLICATIONS FOR APPLICANTS, PETITIONERS, AND EXAMINERS ALIKE

A. Uncertainty With Respect To Materiality Leads To Over-Citation

The breadth of the “reasonable examiner” test, compounded by the multiplicity of other materiality tests, has led to an unprecedented expansion of the scope of potentially material information.⁵ Indeed, today, almost anything can be material. *See* S. Rep. No. 110-259, at 60 (2008)

⁵ The universe of potentially material information is already staggering. It includes not only prior art references and information best known to the applicant (*e.g.*, information regarding public use or first sale), but also search reports, office actions, responses to office actions, affidavits, briefs, and litigation documents for all related U.S. and foreign applications.

("[V]irtually any information can be characterized as 'material' to the examination of a patent application.")

Under the current framework, co-pending U.S. applications, activity in those applications, and even information from related foreign applications may, in some cases, need to be cited to the PTO. *See, e.g., McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897 (Fed. Cir. 2007) (applying the "reasonable examiner" test); Manual of Patent Examining Procedure § 2001.06(a). The panel's decision in the instant case has now added attorney arguments made to foreign patent offices to the list—a result contrary to the well-established rule in domestic prosecution that attorney argument characterizing prior art is not material when that prior art is already before the examiner. *See, e.g., Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1379 (Fed. Cir. 2008); *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1349 (Fed. Cir. 2007).⁶

⁶ The Court should clarify that this rule applies to attorney argument from foreign prosecutions as well. The varying rules and customs of foreign jurisdictions make argument in front of one office potentially inappropriate for presentation to another. Moreover, examiners understand attorney argument as just that, nothing more. So long as the reference itself is before the examiner, characterizations of the reference from anywhere in the world should not be considered material. The BPLA does not take a position, however, as to whether declarations submitted by applicants or practitioners, such as those at issue in the instant case, can render otherwise non-material attorney argument material.

Moreover, faced with an ever-expanding universe of material information, it is quite possible that an applicant or attorney will inadvertently miss a reference, perhaps in a single application, even though it was cited in other related applications. Because intent and materiality are often conflated, such inadvertent failure could be found to constitute inequitable conduct.

The uncertainty as to what is material, coupled with the extraordinary consequences of being found guilty of inequitable conduct, has created an epidemic of over-citation. Applicants and practitioners often err on the side of caution by citing information to the PTO that is clearly cumulative of other cited art or that may be marginally relevant at best. Although Rule 56 does not require citation of information that is cumulative or not material, most applicants nonetheless submit such documents because it is safer and more cost effective to do so, rather than take the time to review them. *See* Edwin S. Flores and Sanford E. Warren, Jr., *Inequitable Conduct, Fraud,*

and Your License to Practice Before the United States Patent & Trademark Office, 8 Tex. Intell. Prop. L.J. 299, 308 (2000).⁷

Not surprisingly, the average number of references cited on the face of a patent has risen steadily and drastically over the past forty years, from fewer than five references in 1971 to more than thirty in 2009. Dennis Crouch, *Information Disclosure: Less is More for PTO?*, Patently-O, Sept. 17, 2008, available at <http://www.patentlyo.com/patent/2008/09/information-dis.html>; Dennis Crouch, *Citing References to the PTO*, Patently-O, Jul. 13, 2010, available at <http://www.patentlyo.com/patent/2010/07/my-entry.html>.

Ironically, even if applicants and practitioners err on the side of over-citation, they increase the risk of being found accused of inequitable conduct for “burying” a material reference amongst the many others they were encouraged to cite. *See Espeed, Inc. v. Brokertec U.S.A., L.L.C.*, 480 F.3d 1129, 1137 (Fed. Cir. 2007) (“[W]e agree with the district court that the

⁷ This Court’s precedents not only indirectly encourage over-citation, but actually expressly do so. *See Critikon v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1257 (Fed. Cir. 1997) (indicating preference for disclosure in close cases concerning materiality). The PTO also encourages over-citation. *See* M.P.E.P. § 2004 (“When in doubt, it is desirable and safest to submit information. Even though the attorney, agent, or applicant doesn’t consider it necessarily material, someone else may see it differently and embarrassing questions can be avoided.”).

‘blizzard of paper’ submitted to the PTO in conjunction with the declaration stating that the Super System did not include ‘new rules,’ left the examiner with the impression that the examiner did not need to conduct any further...investigation.”) (internal citations omitted).

B. Over-Citation Compromises The Effective And Efficient Examination Of Applications

Over-citation is contrary to the goal of Rule 56, which is to provide the PTO with the information “necessary for effective and efficient examination of patent applications.” 57 Fed. Reg. at 2023. Over-citation burdens already thinly-stretched examiners, who have little time to sift through information having no bearing on patentability. *See* Nat’l Research Council for the Nat’l Academies, *A Patent System for the 21st Century* at 147 (Stephen A. Merrill et al., eds. 2004) (“Except in the case of an RCE, the entire time that the examiner spends on a single application, from initial search and examination to allowance, appeal or abandonment, averages 20 hours, although the time varies among technologies.”). Although technically required to review each document cited in an Information Disclosure Statement (“IDS”), examiners cannot realistically do so when literally hundreds are cited at a time. *See* 71 Fed. Reg. 38808, 38809 (2006). In short, examiners often suffer from “information overload” which, in turn,

compromises the quality of examination. *See* Christopher A. Cotropia, *Modernizing Patent Law’s Inequitable Conduct Doctrine*, 24 Berkeley Tech. L. J. 723, 770-72 (2009). Both Congress and the PTO agree—citing too many references has a negative impact on the effectiveness and efficiency of PTO examinations. *See* S. Rep. No. 110-259, at 61; 71 Fed. Reg. at 38808-38810.

C. Compliance With The Patchwork Of Materiality Tests Is Costly

Ensuring compliance with the patchwork of tests for materiality can be very costly. To illustrate this point, consider the number and types of documents that applicants must track (*e.g.*, from a single “related” application) with respect to a given application to capture potentially material documents under the current framework. These include:

- known prior art references;
- search reports;
- office actions;
- arguments made in response to office actions;
- notices of allowance;
- affidavits; and
- briefs and other documents filed in litigation arising out of the related application.

This universe is large and seemingly still growing.

The number of so-called “related” applications is often large as well, multiplying the burden of tracking and citing the documents listed above. For example, related applications may include any number of foreign counterpart applications, as well as co-pending U.S. applications linked by a priority chain. Further, certain applications may be “related” for disclosure purposes even when they are not part of the same patent family. Applications may be deemed related when they have substantially the same claim language, share substantially similar or common specifications, or relate to substantially similar technologies (*e.g.*, representing an inventor or a company’s iterative product development or research).

As a result of tracking and citing all of these documents across numerous related U.S. and/or foreign applications, the costs from PTO⁸ and

⁸ The culture of over-citation leads applicants to reflexively cite references at many stages of prosecution, often with a required fee. For instance, an IDS filed after a first Office Action costs \$180. If an applicant is made aware of a reference after receiving a notice of allowance, a Request for Continued Examination, at a cost of \$810 (\$405 for small entities), is required to have it considered. Should a reference be discovered after payment of the issue fee, the application must be withdrawn from issue (because the duty of disclosure extends until a patent issues), a process that requires petitioning the PTO at a cost of \$130. 37 C.F.R. § 1.17.

legal fees⁹ can quickly balloon. Indeed, these costs can be so substantial as to price some applicants—especially small companies and individuals—out of expanding their patent portfolio. *See Cotropia, supra*, at 773. This frustrates research and development and ultimately the public disclosure of innovation, a result which is plainly counter to the spirit of U.S. patent law.

III. THIS COURT SHOULD ADOPT AN OBJECTIVE “BUT FOR” TEST FOR MATERIALITY

Applicants, practitioners, examiners, and the public would all benefit from a clarified materiality test that reduces the incentive to over-cite. To that end, the BPLA supports scrapping the Court’s various materiality tests in favor of an objective “but for” test, under which information would be deemed material only if it invalidates one or more claims.

The objective “but for” test has several advantages. First, it would realign the inequitable conduct doctrine with its roots in common law fraud, under which only misrepresentations and omissions that are truly outcome determinative are deemed material. *See Benjamin Brown, Inequitable Conduct: A Standard in Motion*, 19 *Fordham Intell. Prop. Media & Ent. L.J.* 593, 618 (2009). Importantly, such an approach would be consistent with

⁹ Companies or inventors with large patent portfolios can find it particularly difficult and expensive to update citations across their portfolios. If multiple attorneys or law firms are involved, additional costs will be incurred in the transfer of information between attorneys.

the foundational Supreme Court inequitable conduct decisions in which the patents at issue were actually procured by misconduct. See *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240, 243-44 (1933); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 241 (1944); *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 816 (1945). Where an act or omission does not impact issuance of a patent, the public is not harmed and accused infringers can have little to complain about. Adopting the objective “but for” test would discourage litigants from levying inequitable conduct charges based on such “insignificant” conduct, as there would be little incentive to pursue costly litigation to advance such theories.

Second, an objective “but for” test should make the defense of inequitable conduct more difficult to allege and prove than under the “reasonable examiner” test. This, in turn, should reduce the frequency with which inequitable conduct is asserted, thereby containing the “plague” of inequitable conduct and the related litigation costs.

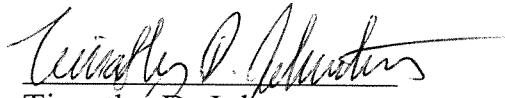
Third, an objective “but for” test will further the goal of providing the PTO with the “information necessary for effective and efficient examination of patent applications.” 57 Fed. Reg. at 2023. The clear definition of materiality supplied by the “but for” test will provide applicants and

practitioners with more certainty regarding exactly what needs to be cited to the PTO, thereby reducing the incentive to over-cite. Applicants and practitioners would, therefore, be more likely to cite the most pertinent information without so much of the extraneous material that is often included today. In turn, this practice will allow examiners to better assess the patentability of the claims at hand.

The concern that an objective “but for” test will lead to *under-citation* to the PTO is unfounded. The proposed test would only apply to the *post hoc* judicial analysis of inequitable conduct. Applicants would still be bound by the definition of materiality in Rule 56—which is clearly broader than the “but for” test—when determining what to cite to the PTO. In this way, a “but for” test will address the uncertainty and fear attendant with the inequitable conduct doctrine that leads to *over-citation*, while leaving intact the floor set by Rule 56 that discourages *under-citation*. See ABA Section of Intellectual Property Law, *A Section White Paper: Agenda for 21st Century Patent Reform* 22 (2007), available at <http://www.abanet.org/intelprop/home/PatentReformWP.pdf> (“While the Section favors limiting the unenforceability defense in court actions to ‘but for’ fraud, limiting this defense is not inconsistent with maintaining a comprehensive duty of candor and good faith in practice before the Office.”).

CONCLUSION

The BPLA favors a strong and well-administered patent system that is fair to all parties, fosters innovation, and promotes competition. By holding applicants and practitioners to high standards before the PTO, the inequitable conduct doctrine furthers that goal, at least in theory, and is important to our *ex parte* examination process. But in its current state, the doctrine now serves more to confuse and burden the patent system than to aid it. Adopting an objective “but for” test as the sole test for materiality is a much-needed first step toward reforming the inequitable conduct doctrine.



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August 2, 2010

CERTIFICATE OF COMPLIANCE

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August 2, 2010

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