

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 *AMICI CURIAE*
OLE K. NILSSEN AND GEO FOUNDATION, LTD.
IN SUPPORT OF PLAINTIFFS-APPELLANTS
ABBOTT DIABETES CARE, INC. AND ABBOTT LABORATORIES'
BRIEF ON REHEARING EN BANC SUPPORTING REVERSAL
July 30, 2010

Leland W. Hutchinson, Jr.

Jonathan Hill

Matthew J. Kramer

FREEBORN & PETERS LLP

311 South Wacker Drive, Suite 3000

Chicago, Illinois 60606-6677

Tel: (312) 360-6000

Attorneys For Amici Curiae Ole K. Nilssen and Geo Foundation, Ltd.

CERTIFICATE OF INTEREST

Counsel for *amici curiae* Ole K. Nilssen and Geo Foundation, Ltd. certifies the following:

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

Ole K. Nilssen and Geo Foundation, Ltd.

2. The names of the real parties in interest are the same as those listed above.

3. All parent corporations and the publicly held companies that own 10 percent or more of the stock of the parties or *amici curiae* represented by me are:

None

4. The names of all law firms and the partners or associates that appeared for the parties or *amici curiae* now represented by me in the trial court or agency or are expected to appear in this court are:

FREEBORN & PETERS LLP: Leland W. Hutchinson, Jr.,
Jonathan Hill, and Matthew J. Kramer

July 30, 2010


Leland W. Hutchinson, Jr.

TABLE OF CONTENTS

TABLE OF AUTHORITIES.....	ii
STATEMENT OF IDENTITY, INTEREST, AND SOURCE OF AUTHORITY TO FILE.....	vii
INTRODUCTION.....	1
ARGUMENT	6
I. PTO RULE 56 PROVIDES THE EXCLUSIVE MATERIALITY STANDARD FOR INEQUITABLE-CONDUCT DETERMINATIONS.....	6
II. TRADITIONAL EQUITABLE LIMITATIONS RESTRAIN INEQUITABLE CONDUCT	15
III. DECEPTIVE INTENT MUST BE PROVED BY CLEAR AND CONVINCING EVIDENCE, INDEPENDENT OF MATERIALITY	18
A. The “Should-Have-Known” Standard For Deceptive Intent Cannot Be Countenanced.....	19
B. A Finding Of High Materiality Does Not Lessen The Evidentiary Burden Of Proving Deception	21
IV. INEQUITABLE CONDUCT REQUIRES A CLEAR CONNECTION BETWEEN THE MISCONDUCT AND THE PATENT RIGHTS ASSERTED IN LITIGATION.....	24
V. THE INEQUITIES OF THE PATENTEE MUST OUTWEIGH THOSE OF THE ACCUSED INFRINGER	28
CONCLUSION	29

TABLE OF AUTHORITIES

	Page(s)
CASES	
<i>Advanced Magnetic Closures, Inc. v. Rome Fastner Corp.</i> , 607 F.3d 817 (Fed.Cir. 2010).....	23
<i>Agfa Corp. v. Creo Products Inc.</i> , 451 F.3d 1366 (Fed.Cir. 2006).....	13
<i>Aptix Corp. v. Quickturn Design Sys., Inc.</i> , 269 F.3d 1369 (Fed.Cir. 2001).....	15
<i>Aventis Pharma S.A. v. Amphaster Pharmaceuticals, Inc.</i> , 525 F.3d 1334 (Fed.Cir. 2008).....	20, 23
<i>Bender v. Dudas</i> , 490 F.3d 1361 (Fed.Cir. 2007).....	11
<i>Buckman Co. v. Plaintiffs' Legal Committee</i> , 531 U.S. 341 (2001).....	14
<i>Burlington Indus., Inc. v. Dayco Corp.</i> , 849 F.2d 1418 (Fed.Cir. 1988).....	9
<i>Cargill, Inc. v. Canbra Foods, Ltd.</i> , 476 F.3d 1359 (Fed.Cir. 2007).....	19
<i>Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.</i> , 467 U.S. 837 (1984).....	10, 11, 12
<i>City of Milwaukee v. Illinois and Michigan</i> , 451 U.S. 304 (1981).....	12, 13
<i>Consolidated Aluminum Corp. v. Foseco Int'l Ltd.</i> , 910 F.2d 804 (Fed.Cir. 1990).....	15
<i>Cooper Techs. Co. v. Dudas</i> , 536 F.3d 1330 (Fed.Cir. 2008).....	11
<i>Davis v. Monroe County Bd. of Educ.</i> , 526 U.S. 629 (1999).....	21

<i>Dayco Prods., Inc. v. Total Containment, Inc.</i> , 329 F.3d 1358 (Fed.Cir. 2003).....	10
<i>Digital Control, Inc. v. Charles Machine Works</i> , 437 F.3d 1309 (Fed.Cir. 2006).....	passim
<i>Digital Equip. Corp. v. Diamond</i> , 653 F.2d 701 (1st Cir. 1981).....	7
<i>Dollar Sys., Inc. v. Avcar Leasing Sys., Inc.</i> , 890 F.2d 165 (9th Cir. 1989).....	18
<i>eBay, Inc. v. MercExchange, L.L.C.</i> , 547 U.S. 388 (2006).....	17
<i>Ernst & Ernst v. Hochfelder</i> , 425 U.S. 185 (1976).....	20
<i>eSpeed, Inc. v. BrokerTec USA, L.L.C.</i> , 480 F.3d 1129 (Fed.Cir. 2007).....	22
<i>Feist v. Young</i> , 138 F.2d 972 (7th Cir. 1943).....	25, 28
<i>Ferring B.V. v. Barr Labs, Inc.</i> , 437 F.3d 1181 (Fed.Cir. 2006).....	13, 19
<i>Gillman v. Stern</i> , 114 F.2d 28 (2d Cir. 1940).....	24
<i>Goodyear Tire & Rubber Co. v. Overman Cushion Tire Co.</i> , 95 F.2d 978 (6th Cir. 1938).....	28
<i>Grupo Mexicano v. Alliance Bond Fund</i> , 527 U.S. 308 (1999).....	17, 27
<i>Hazel-Atlas Glass Co. v. Hartford-Empire Co.</i> , 322 U.S. 238 (1944).....	16, 28
<i>In re Bose Corp.</i> , 580 F.3d 1240 (Fed.Cir. 2009).....	21

<i>In re Omeprazole Patent Litigation</i> , 483 F.3d 1364 (Fed.Cir. 2007).....	18
<i>Jarrow Formulas, Inc. v. Nutrition Now, Inc.</i> , 304 F.3d 829 (9th Cir. 2002).....	24
<i>Johnson v. Yellow Cab Transit Co.</i> , 321 U.S. 383 (1944).....	18
<i>Jones v. Hardy</i> , 727 F.2d 1524 (Fed.Cir. 1984).....	27
<i>Keystone Driller Co. v. General Excavator Co.</i> , 290 U.S. 240 (1933).....	passim
<i>Kingsdown Medical Consultants, Ltd. v. Hollister Inc.</i> , 863 F.2d 867 (Fed.Cir. 1988)	3, 4, 21
<i>Larson Mfg. Co. of South Dakota, Inc. v. Aluminart Prods. Ltd.</i> , 559 F.3d 1317 (Fed.Cir. 2009).....	3, 21, 23, 26
<i>Long Island Care At Home, Ltd. v. Coke</i> , 551 U.S. 158 (2007).....	11
<i>Lujan v. Defenders of Wildlife</i> , 504 U.S. 555 (1992).....	27
<i>Mobil Oil Corp. v. Higginbotham</i> , 436 U.S. 618 (1978).....	12
<i>Nat’l Cable & Telecom. Ass’n v. Brand X Internet Servs.</i> , 545 U.S. 967 (2005).....	11, 12
<i>Nilssen v. Osram Sylvania, Inc.</i> , 440 F. Supp. 2d 884 (N.D.Ill. 2006)	22
<i>Nilssen v. Osram Sylvania, Inc.</i> , 504 F.3d 1223 (Fed.Cir. 2007).....	passim
<i>Northeast Women’s Center, Inc v. McGonagle</i> , 868 F.2d 1342 (3d Cir. 1989).....	24

<i>Norton v. Curtiss</i> , 433 F.2d 779 (CCPA 1970).....	7, 8, 18, 25
<i>Ohio Oil Co. v. Sharp</i> , 135 F.2d 303 (10th Cir. 1943).....	18
<i>Orion IP v. Hyundai Motor America</i> , 605 F.3d 967 (Fed.Cir. 2010).....	23
<i>Pfizer, Inc v. International Rectifier Corp.</i> , 186 U.S.P.Q. 511 (D. Minn. 1975)	8
<i>Praxair, Inc. v. ATMI, Inc.</i> , 543 F.3d 1306 (Fed.Cir. 2008).....	19
<i>Precision Instrument Mfg. Co. v. Auto Maint. Mach. Co.</i> , 324 U.S. 806 (1945)	1, 16, 25
<i>Rambus Inc. v. Infineon Technologies AG</i> , 318 F.3d 1081 (Fed.Cir. 2003).....	2
<i>Shinsaku Nagano v. McGrath</i> , 187 F.2d 753 (7th Cir. 1951).....	20
<i>Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.</i> , 537 F.3d 1357 (Fed.Cir. 2008).....	2, 16, 19, 23
<i>TSC Industries, Inc. v. Northway, Inc.</i> , 426 U.S. 438 (1976)	14
<i>United States v. American Bell Tel. Co.</i> , 128 U.S. 315 (1888)	6
<i>Winbond Electronics Corp. v. Int’l Trade Comm’n</i> , 262 F.3d 1363 (Fed.Cir. 2001).....	15

STATUTES

35 U.S.C. § 2	6
35 U.S.C. §§ 102	6
35 U.S.C. §§ 103	6

35 U.S.C. § 282	5
35 U.S.C. § 288	5
OTHER AUTHORITIES	
37 C.F.R. § 1.56 (1992).....	passim
37 C.F.R. § 1.56 (1977).....	9
37 C.F.R. § 10.68 (2000).....	11, 13
42 Fed.Reg. 5587 (Jan. 28, 1977).....	14
57 Fed.Reg. 2021 (Jan. 17, 1992).....	9
71 Fed.Reg. 38,808, 38,809 (July 10, 2006).....	14
FED. R. EVID. 401	14
Hon. Randall R. Rader, <i>Always At The Margin: Inequitable Conduct In Flux</i> , 59 AM. U. L. REV. 777 (2010).....	3, 26
Senate Report No. 110-259 (Jan. 24, 2008).....	26
U.S. CONST. art. I, §8, cl. 8.....	1
Wright, Miller, Kane, <i>Federal Practice and Procedure, Civil 2d</i> § 2946	5, 28

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

1. *Amicus curiae* Ole K. Nilssen (“Nilssen”) is a prolific inventor who has assembled a portfolio of over 240 patents. Since June 2000, *amicus curiae* Geo Foundation, Ltd. (“Geo”) has been the exclusive licensee of all of Nilssen’s patents, holding the right to enforce and/or sub-license that intellectual property.

2. Having extremely valuable interests in, and/or rights under, Nilssen’s portfolio of patents, *amici* are interested in the appropriate legal standards for determining inequitable conduct.

3. *Amici* derive their authority to file this brief from the Court's April 26, 2010 Order granting Appellants’ Motion for Rehearing En Banc, which indicates that “[b]riefs of amici curiae will be entertained, and any such amicus briefs may be filed without leave of court...” Separately, all parties have consented to this filing pursuant to Federal Circuit Rule 29(a).

INTRODUCTION

Pursuant to this Court's Order of April 26, 2010, *amici* Ole K. Nilssen ("Nilssen") and Geo Foundation, Ltd. ("Geo") submit this Brief of *Amici Curiae* to address the critically important issues raised by the Court concerning the standards governing the inequitable-conduct doctrine. Those standards, in many cases, have strayed both from Supreme Court precedent, as well as limitations imposed by separation-of-powers principles. As such, a doctrine designed to promote equity has become untethered from its equitable origins, and, on too many occasions, has served as an instrument for producing profound injustice in a manner contravening the constitutional mandate "[t]o promote the progress of...useful arts." U.S. CONST. art. I, §8, cl. 8.

This Constitutional directive has long served society well by enticing inventors to publicly share their inventions, exchanging trade-secret protection for a limited-time grant of the right to exclude others from practicing those inventions. For this "patent bargain" to remain beneficial to society, it is important to preclude enforcement of patents that have been improperly obtained. *Precision Instrument Mfg. Co. v. Auto Maint. Mach. Co.*, 324 U.S. 806, 816 (1945) ("The far-reaching social and economic consequences of a patent...give the public a paramount interest in seeing that patent [grants] spring from backgrounds free from fraud or other inequitable conduct..."). It is equally important, however, to avoid turning

the patent-prosecution process into a trap for the unwary or unskilled who may see a patent declared unenforceable in litigation for technical, procedural irregularities having little or even no bearing on the patentability of any asserted claim. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed.Cir. 2008) (“[I]t is also inequitable to strike down an entire patent where the patentee only committed minor missteps or acted with minimal culpability or in good faith.”).

No less troubling, applicants compliant with the United States Patent and Trademark Office’s (the “PTO”) disclosure rules may nevertheless lose their patent rights because judicial materiality standards conflict with those duly promulgated by the PTO. This exposes both inventors and practitioners to substantial risks which grossly impair the attractiveness of the patent bargain. *See, e.g., Rambus Inc. v. Infineon Technologies AG*, 318 F.3d 1081, 1102 n.10 (Fed.Cir. 2003) (standard-setting organizations require a well-defined patent policy: “after-the-fact morphing of a vague, loosely defined policy to capture actions not within the actual scope” will chill participation).

Such risks were originally well-mitigated because the inequitable-conduct doctrine applied only in instances of gross misconduct and deceit. During the formative years of the doctrine, the Supreme Court recognized that “unconscionable conduct” could bar, under unclean-hands principles, patent enforcement by the culpable party. *See, e.g., Keystone Driller Co. v. General*

Excavator Co., 290 U.S. 240, 245 (1933). Such conduct had to be both “unconscionable” and bear an “immediate and necessary relation” to the matter in litigation, “in some measure affect[ing] the equitable relations between the parties....” *Id.*

As currently applied, however, the inequitable-conduct doctrine does not uniformly demand these conditions precedent. In the words of Chief Judge Rader, the inequitable-conduct doctrine “grew from a tiny bush on the patent landscape that inhibited gross fraud into a ubiquitous weed that infects every prosecution and litigation involving patents.” Hon. Randall R. Rader, *Always At The Margin: Inequitable Conduct In Flux*, 59 AM. U. L. REV. 777, 781 (2010); *see also Larson Mfg. Co. of South Dakota, Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1342 (Fed.Cir. 2009) (Linn, J., concurring) (inequitable-conduct “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 Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 n.15 (Fed.Cir. 1988) (*en banc*)”) (internal citations omitted). The problem is exacerbated by the Court’s refusal to defer exclusively to the PTO’s materiality standard in assessing compliance with the duty of disclosure.

Amici thus suggest that the Court render the inequitable-conduct doctrine more equitable and predictable in four primary ways:

First, apply 37 C.F.R. § 1.56 (1992) (“PTO Rule 56”) as the exclusive standard governing a patent applicant’s duty of disclosure to the PTO. The PTO has been authorized by Congress to regulate its own proceedings. And the PTO has done so by defining what is “material to patentability,” and, thus, subject to disclosure. Separation-of-powers principles compel judicial deference to that materiality definition. It is also fundamentally unfair and incongruous for an applicant whose obligation to disclose a fact is expressly excused by PTO rule to be later adjudged to have committed misconduct under more sensitive and nebulous judicially imposed materiality standards. *See* 37 C.F.R. § 1.56(a) (“There is no duty to submit information which is not material to the patentability of any existing claim.”).

Second, require clear and convincing evidence of deceptive intent— independent of materiality and beyond mere proof of negligence. The unclean-hands doctrine (of which the inequitable-conduct doctrine is but a species) requires a “violation of conscience.” Mere negligence, or even gross negligence, does not render the misconduct unconscionable, as this Court recognized in its *en banc* decision in *Kingsdown*. The presumption of intent from a showing of high materiality, and/or from an absence of a good-faith explanation, further conflicts with Supreme Court precedents and *Kingsdown*.

Third, demand a causal nexus between the asserted patent rights and the misconduct. Unclean hands is not a tool for punishing “extraneous transgressions.” *Keystone*, 290 U.S. at 245. Only where the intentional misconduct bears “an immediate and necessary relation” to the rights asserted in litigation may the unclean-hands doctrine properly bar enforcement of such rights.¹ *Id.* If a patent is to be deemed unenforceable under judicially established unclean-hands principles, faithful adherence to the “immediate and necessary relation” requirement is necessary both to ensure equitable results, and to remain within the sphere of appropriate judicial-equity powers.

Fourth, where misconduct did not procure allowance of an invalid claim, consider all equities (including misconduct by the accused infringer) before closing the courtroom doors to the patentee. Relief should not be foreclosed where the “defendant has been guilty of misconduct that is more unconscionable than that committed by plaintiff.” 11A Wright, Miller, Kane, *Federal Practice and Procedure, Civil 2d* § 2946, at 112. Simply put, equity requires that consideration be given to countervailing inequities by the accused infringer, such as willful infringement of valid patent claims.

¹ Congress has eliminated a causal-link requirement where one claim (even an unasserted claim) is both invalid and deceptively procured. 35 U.S.C. § 288. Because Congress did not also eliminate causation under section 35 U.S.C. § 282, the showing remains necessary where Section 288 is inapplicable.

ARGUMENT

I. PTO RULE 56 PROVIDES THE EXCLUSIVE MATERIALITY STANDARD FOR INEQUITABLE-CONDUCT DETERMINATIONS.

In its April 26 order, this Court solicited argument concerning the proper definition of materiality, as well as the proper role of PTO Rule 56 in defining materiality. *Amici* respectfully assert that this Court's materiality standards offend separation-of-powers principles by regarding Rule 56 as merely *optional* authority, and not binding at the expense of earlier common-law standards. *See, e.g., Digital Control, Inc. v. Charles Machine Works*, 437 F.3d 1309, 1316 (Fed.Cir. 2006) (the 1992 version of Rule 56 "does not supplant or replace our case law").

The judiciary has long recognized that Congress has the sole power both to grant patents and to control the circumstances of their issuance. *United States v. American Bell Tel. Co.*, 128 U.S. 315, 359 (1888) (the issuance of a patent "exercise[s]...the power of the government according to modes regulated by acts of congress"). Pursuant to this empowerment, Congress created statutory conditions for patentability, *see* 35 U.S.C. §§ 102, 103, while the PTO administers the evaluation of whether patent applications satisfy those requirements, *see* 35 U.S.C. at § 2. More particularly, under 35 U.S.C. § 2(b)(2)(A), Congress entrusted the PTO with the power to "establish regulations...which...shall govern the conduct of proceedings in the Office."

PTO Rule 56 establishes the “duty to disclose information material to patentability” in furtherance of the “public interest” in “effective patent examination.” Since 1949, the PTO has promulgated three versions of this disclosure rule. Courts have correspondingly developed a body of law interpreting and enhancing these regulations, such that the judiciary today deems wrongful the failure to disclose information expressly excused from disclosure by the PTO. *Amici* respectfully submit that, although courts may properly construe ambiguous regulations, they may not impose disclosure duties which contradict established regulations. The latter usurps legislative prerogative.

The PTO’s first version of Rule 56, in 1949, stated that “any application...in connection with which any *fraud* is practiced on the [PTO], may be stricken from the files.” *Digital Equip. Corp. v. Diamond*, 653 F.2d 701, 707 (1st Cir. 1981) (emphasis added); *see also Digital Control*, 437 F.3d at 1315. This rule neither defined “fraud” nor “materiality.”

In *Norton v. Curtiss*, this Court’s predecessor expressly recognized that its sole charter was to construe and apply Rule 56: “the only issue we have power to decide is whether the Commissioner abused his authority in holding that the conduct of Curtiss did not warrant striking his application under Patent Office Rule 56.” 433 F.2d 779, 791 (CCPA 1970). Because Rule 56, at that time, prohibited “fraud,” the *Norton* court interpreted the elements of fraud. *Id.* at 792. This

included the traditional materiality definition: the material fact “must be the ‘efficient, inducing, and proximate cause, or the determining ground’ of the action taken in reliance thereon.” *Id.* at 794 (quoting 37 C.J.S. Fraud § 18 (1943)). But the Court, to give “meaning” to the duty of disclosure, endorsed a view of materiality which also includes “consideration of factors apart from the objective patentability of the claims at issue.” *Id.* at 795. The Court nevertheless made clear that Rule 56 provided the governing standards for inequitable conduct. *Id.* at 797 (“[W]e have recognized the requirement that the provisions of Rule 56 be interpreted more broadly in this area of inequitable conduct...”).

Still, other courts have employed a more nebulous standard, finding materiality where information “*may* be relevant to an issue of patentability.” *See, e.g., Pfizer, Inc v. International Rectifier Corp.*, 186 U.S.P.Q. 511, 519 (D. Minn. 1975) (emphasis added). Even though *Pfizer* represents a very expansive view of inequitable conduct, the court still expressly recognized that the conduct became inequitable only because a legal disclosure duty had been violated. 186 U.S.P.Q. at 544 (“Pfizer’s conduct...was material to the question of whether or not the Patent Office might have stricken the...application under Patent Office Rule 56.”).

In 1977, the PTO amended Rule 56 to require disclosure of “material information” which presented “a *substantial likelihood* that a reasonable examiner *would* consider important in deciding whether to allow the application to issue as a

patent.” 37 C.F.R. § 1.56 (1977) (emphasis added). Following the first decade in which the “reasonable examiner” standard had been applied in inequitable-conduct cases, this Court observed that “the habit of charging inequitable conduct in almost every major patent litigation ha[d] become an absolute plague.” *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed.Cir. 1988). Fully cognizant of the “burden of litigation on the question of inequitable conduct,” the PTO sought to “minimize” that burden, while ensuring that it would receive “information necessary for effective and efficient examination of patent applications.” 57 Fed.Reg. 2021, 2023 (Jan. 17, 1992).

In 1992, the PTO amended Rule 56 to, *inter alia*, “clarify the duty of disclosure.” *Id.* at 2021. Although the PTO made clear that Rule 56 does not “define fraud or inequitable conduct which have elements of both materiality and of intent,” *id.* at 2024, the Rule was still intended to “provide greater clarity” in the definition of “materiality,” *id.* at 2023. Further, the Rule was also intended to “strike a balance between the need of the Office to obtain and consider all known relevant information pertaining to patentability before a patent is granted and the desire to avoid or minimize unnecessary complications in the enforcement of patents.” *Id.* at 2021. According to the PTO, this clarified materiality standard would “hopefully minimize the burden of litigation on the question of inequitable conduct before the Office.” *Id.* at 2023.

As amended in 1992, PTO Rule 56 established a more focused disclosure duty that deems non-cumulative information “material to patentability” only where it: (i) helps establish “a *prima facie* case of unpatentability” or (ii) is inconsistent with a patentability position taken before the PTO. This Court has recognized that the 1992 amendments “more narrowly defined materiality.” *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1363-64 (Fed.Cir. 2003). Plainly, this Court’s reasonable-examiner standard (as well as the older common-law tests) creates a broader duty of disclosure than does PTO Rule 56 and imposes a duty to disclose information which the PTO expressly deems *immaterial*, and *not* subject to any disclosure duty. *See* PTO Rule 56 (“There is *no duty* to submit information which is *not material* to the patentability of any existing claim.”) (emphasis added).

Whether the judiciary must defer to the PTO’s expertise and authority to control the disclosure duties of applicants appearing before it presents an important separation-of-powers question. In *Digital Control*, one panel of this Court rejected any such deference. 437 F.3d at 1316 (the PTO’s 1992 materiality standard “does not supplant or replace our case law”). Respectfully, this conclusion was erroneous for several reasons.

First, PTO Rule 56 has the force of law respecting an applicant’s disclosure duty. *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S.

837, 843 (1984) (“The power of an administrative agency to administer a congressionally created program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress.”) (internal citations and quotations omitted). “Such legislative regulations are given *controlling weight* unless they are arbitrary, capricious, or manifestly contrary to the statute.” *Id.* at 844 (emphasis added).² PTO Rule 56’s definition of information “material to patentability” is clearly the type of gap-filling procedural rule (defining the nature and scope of information that the PTO deems relevant to the proper prosecution of a patent application) that must be accorded *Chevron* deference. *See Nat’l Cable & Telecom. Ass’n v. Brand X Internet Servs.*, 545 U.S. 967, 982 (2005) (“*Chevron*’s premise is that it is for agencies, not the courts, to fill statutory gaps.”) (citing *Chevron*, 467 U.S. at 843-44); *Long Island Care At Home, Ltd. v. Coke*, 551 U.S. 158, 165 (2007) (“When an agency fills such a ‘gap’ reasonably, and in accordance with other applicable (*e.g.*, procedural) requirements, the courts accept the result as legally binding.”).

² This Court has, in other cases, accorded deference to properly promulgated PTO procedural rules, including PTO-disclosure requirements. *See, e.g., Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1337 (Fed.Cir. 2008) (accorded *Chevron* deference to PTO rules relating to the “conduct of proceedings in the Patent Office”); *Bender v. Dudas*, 490 F.3d 1361, 1367 (Fed.Cir. 2007) (deference granted to PTO’s definition of “full disclosure” under 37 C.F.R. § 10.68(a)(1) (2000)).

Applying broader, nebulous judicial-materiality standards improperly renders meaningless PTO Rule 56 as an objective measure of an applicant's duty of disclosure. *See City of Milwaukee v. Illinois and Michigan*, 451 U.S. 304, 320 (1981) ("Federal courts lack authority to impose more stringent...limitations under federal common law than those imposed by the agency charged by Congress with administ[r]ation...."); *Mobil Oil Corp. v. Higginbotham*, 436 U.S. 618, 625 (1978) ("[W]hen [the Act] does speak directly to a question, the courts are not free to 'supplement' Congress' answer so thoroughly that the Act becomes meaningless."). It is one thing for the courts to construe a materiality standard; it is quite another for the judiciary to set a more sensitive standard in contravention of PTO policy. *See Brand X*, 545 U.S. at 1003 (expert policy judgment places agency in better position than the judiciary to resolve technical and complex questions). Separation-of-powers principles permit the former, but not the latter.

Nor do principles of *stare decisis* justify continued adherence to common-law materiality standards, as this Court's *Digital Control* decision appears to suggest. Required deference to legislative authority includes the recognition that an "agency...must consider...the wisdom of its policy on a continuing basis." *Brand X*, 545 U.S. at 981 (quoting *Chevron*, 467 U.S. at 863-64). When the policy is administratively narrowed, the courts must defer to the new policy regardless of their prior decisions. "[W]hen Congress addresses a question previously governed

by a decision rested on federal common law the need for such an unusual exercise of lawmaking by the federal courts disappears.” *City of Milwaukee*, 451 U.S. at 314 (citations omitted).

Second, refusal to apply PTO Rule 56 as the exclusive materiality standard places patent applicants in an untenable position by negating their ability to rely on Rule 56’s direction that information that is not material to patentability need not be disclosed. Indeed, years after that reliance, the law presently permits the resulting patent to be held unenforceable for failure to disclose information that the PTO expressly stated did **not** need to be disclosed. *See Ferring B.V. v. Barr Labs, Inc.*, 437 F.3d 1181, 1202 n.3 (Fed.Cir. 2006) (Newman, J., dissenting) (“The court in *Digital Control* holds, in contradiction of precedent, that it will hold practitioners to the standard of the pre-1992 version of Rule 56 for patents prosecuted after 1992, even though that standard no longer exists.”); *Agfa Corp. v. Creo Products Inc.*, 451 F.3d 1366, 1384 (Fed.Cir. 2006) (Newman, J., dissenting).

For example, in *Nilssen v. Osram Sylvania, Inc.*, this Court deemed the mere existence of “related litigation” to be material, even though no information therein was found to have any relevance to the patent in prosecution. 504 F.3d 1223,

1233-34 (Fed.Cir. 2007).³ Such a result is fundamentally unfair to patent applicants who have followed PTO Rule 56.

Third, continuing application of broader materiality standards frustrates the PTO's ability to effectively and efficiently examine patent applications:

Although [PTO Rule 56] clearly imposes a duty to disclose material information, that rule neither authorizes nor requires anyone to file...irrelevant documents with the Office. ***Such documents add little to the effectiveness of the examination process and, most likely, negatively impact the quality of the resulting Office determinations.***

71 Fed.Reg. 38,808, 38,809 (July 10, 2006) (emphasis added); cf. *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 351 (2001) (“[State law] fraud-on-the-FDA claims would...cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court. Applicants would then have an incentive to submit a

³ Such information could not have even satisfied the 1977 “reasonable-examiner” standard. The PTO based that standard on the Supreme Court’s definition of materiality in *TSC Industries, Inc. v. Northway, Inc.*, 426 U.S. 438 (1976), so that the PTO could receive information that is relevant, but not “trivial.” 42 Fed.Reg. 5587, 5589 (Jan. 28, 1977). In *TSC*, the Supreme Court expressly rejected the weaker “may-have-been-important” materiality standard in favor of requiring “a ***substantial likelihood*** that the disclosure of the omitted fact” would have “significantly altered the ‘total mix’ of information made available.” *TSC*, 426 U.S. at 449 (emphasis added). In *Osram*, the mere existence of related litigation had no “tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence” and, therefore, could not have satisfied even the minimal relevance standard set forth in FED. R. EVID. 401.

deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application.”).

In order for a failure to disclose information to be deemed inequitable, it must violate a legal disclosure duty. The PTO, acting under Congressional authority, is empowered to define what information must legally be disclosed to obtain a patent. Under proper separation-of-powers principles, defining materiality is inherently a legislative task. There is no room for the courts to supplant the PTO's current materiality standard.

II. TRADITIONAL EQUITABLE LIMITATIONS RESTRAIN INEQUITABLE CONDUCT.

This Court has repeatedly observed that inequitable conduct is a species of traditional unclean hands. *See, e.g., Aptix Corp. v. Quickturn Design Sys., Inc.*, 269 F.3d 1369, 1379 (Fed.Cir. 2001) (“[T]he unclean hands doctrine is the source of our ability to declare a patent unenforceable....”); *Winbond Electronics Corp. v. Int'l Trade Comm'n*, 262 F.3d 1363, 1372 (Fed.Cir. 2001) (same); *Consolidated Aluminum Corp. v. Foseco Int'l Ltd.*, 910 F.2d 804, 812 (Fed.Cir. 1990) (“Indeed, what we have termed ‘inequitable conduct’ is no more than the unclean hands doctrine applied to particular conduct before the PTO.”). The inequitable-conduct doctrine “was borne out of a series of Supreme Court cases in which the Court refused to enforce patents whereby the patentee had engaged in fraud in order to

procure those patents.” *Digital Control*, 437 F.3d at 1315⁴; *see also Star Scientific*, 537 F.3d at 1365-66 (inequitable conduct “was originally applied only in cases of ‘fraud on the Patent Office’”) (citations omitted).⁵

Beginning with *Keystone*, the Supreme Court first recognized “unclean hands” as a defense warranting dismissal of patent-infringement actions brought by parties who had engaged in certain unconscionable conduct. 290 U.S. at 244-47. The Supreme Court later explained that “[t]his maxim...closes the doors of a court of equity to one tainted with inequitable conduct or bad faith relative to the matter in which he seeks relief...” *Precision Instrument*, 324 U.S. at 814.

While each case in the trilogy of Supreme Court inequitable-conduct holdings involved fraud, *Star Scientific*, 537 F.3d at 1365-66, the Supreme Court did not expressly require that fraud be shown. It did, however, explicitly mandate that the doctrine should only bar relief where a party committed some “unconscionable act” having “an immediate and necessary relation...to the matter in litigation.” *Keystone*, 290 U.S. at 245.

⁴ Citing *Precision Instrument*, 324 U.S. at 806; *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944); and *Keystone*, 290 U.S. at 240.

⁵ *Precision Instrument*, for example, was a case where the “history of the patents and contracts in issue [were] steeped in perjury and undisclosed knowledge of perjury,” and where one of the asserted patents “was admittedly based upon false data which destroyed whatever just claim it might otherwise have had to the status of a patent.” 324 U.S. at 816.

Constitutional limits on judicial authority prohibit any “wrenching departure” from these equitable principles, absent an act of Congress. For example, in *Grupo Mexicano v. Alliance Bond Fund*, Justice Ginsburg, citing the “grand aims of equity,” asserted in dissent “a general power to grant relief whenever legal remedies are not ‘practical and efficient’....” 527 U.S. 308, 321 (1999). The Supreme Court rejected this view:

We do not question the proposition that equity is flexible; but in the federal system, at least, that flexibility is confined within broad boundaries of traditional equitable relief.

Id. at 322. When new conditions might call for “a wrenching departure from past practice,” the Court held, it is for Congress, and not the judiciary, to make the new law. *Id.*⁶ At least three aspects of this Court’s inequitable-conduct doctrine embrace such a “wrenching departure:” (i) weakened intent standards; (ii) the failure to demand a causal nexus between the misconduct, on the one hand, and a claim in litigation, on the other, and (iii) the failure to consider the infringer’s own culpability.

⁶ This rule was again applied in *eBay, Inc. v. MercExchange, L.L.C.* to reverse the longstanding judicial presumption of injunctive relief in patent cases because that doctrine exceeded “traditional equitable principles” and constituted “a major departure from the long tradition of equity practice [that] should not be lightly implied” absent some indication that “Congress intended such a departure.” 547 U.S. 388, 391-92 (2006) (internal citations and quotations omitted).

III. DECEPTIVE INTENT MUST BE PROVED BY CLEAR AND CONVINCING EVIDENCE, INDEPENDENT OF MATERIALITY.

Deceptive intent is a critical component of unclean hands. *See Johnson v. Yellow Cab Transit Co.*, 321 U.S. 383, 392-93 (1944); *Dollar Sys., Inc. v. Avcar Leasing Sys., Inc.*, 890 F.2d 165, 173 (9th Cir. 1989) (“Bad intent is the essence of the defense of unclean hands.”); *Ohio Oil Co. v. Sharp*, 135 F.2d 303, 308 (10th Cir. 1943) (“[N]ot every actionable wrong amounting to a trespass or an invasion of the property rights of others is iniquitous, inequitable or unconscionable.”). Put differently, conduct cannot be said to be “unconscionable” absent “violation[] of conscience.” *Keystone*, 290 U.S. at 245. Thus, even though the Supreme Court may not have expressly mandated a full showing of common law or “technical” fraud, a showing of intentional deception is plainly indispensable.

Although the requisite bad faith may be proved by circumstantial—as opposed to direct—evidence, the burden of proving deceptive intent by clear and convincing evidence remains with the accused infringer asserting the defense. *In re Omeprazole Patent Litigation*, 483 F.3d 1364, 1374-76 (Fed.Cir. 2007); *Norton*, 433 F.2d at 797 (“the rule as to burden of proof has not changed.”). As explained below, clear and convincing evidence of deception can never properly be found by relying solely on evidence of materiality to infer intent under a “should-have-

known” rubric, no matter how high the level of materiality. Nor may evidence of materiality properly lessen the burden of proof on intent.

**A. The “Should-Have-Known” Standard
For Deceptive Intent Cannot Be Countenanced.**

The notion that materiality and intent are distinct elements of inequitable conduct is beyond dispute. *See, e.g., Star Scientific*, 537 F.3d at 1366 (citing *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1274 (Fed.Cir. 2001)) (“[M]ateriality does not presume intent, which is a separate and essential component of inequitable conduct.”). However, a line of this Court’s scattered precedent eviscerates that principle by inferring deceptive intent where the applicant “should have known” of the materiality. *See, e.g., Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1313-1314 (Fed.Cir. 2008) (citing *Ferring*, 437 F.3d at 1191); *Cargill, Inc. v. Canbra Foods, Ltd*, 476 F.3d 1359, 1366-67 (Fed.Cir. 2007).

Materiality alone, no matter how strong the showing may be, should not permit the inference of deceptive intent absent other proof. As Chief Judge Rader observed, recent inequitable-conduct decisions have over-emphasized materiality, without proper consideration of deceptive-intent evidence:

More recently...the judicial process has too often emphasized materiality almost to the exclusion of any analysis of the lofty intent requirement for inequitable conduct. Merging intent and materiality at levels far below the *Kingsdown* rule has revived the inequitable conduct tactic.

Aventis Pharma S.A. v. Amphaster Pharmaceuticals, Inc., 525 F.3d 1334, 1350-51 (Fed.Cir. 2008) (Rader, J., dissenting) (citing *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223 (Fed.Cir. 2007), as an example of the Court's divergence from *Kingsdown*).

Instead, clear and convincing evidence of deception should comprise, at the very least, evidence that the applicant **actually** (not constructively) appreciated materiality. Absent such appreciation, there can be no deceptive motive, and, thus, no logical inference of intent to deceive.

Panel decisions imputing to the patent applicant **constructive** knowledge of materiality (on grounds that he "should have known" of the materiality) unquestionably apply a negligence standard. *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 198 n.18 (1976) (whether "defendant knew or reasonably could foresee" is a negligence standard). These decisions fall well short of the traditional requirement that the applicant act in "violation[] of conscience." *Keystone*, 290 U.S. at 245; *see also Shinsaku Nagano v. McGrath*, 187 F.2d 753, 758-59 (7th Cir. 1951) ("The [unclean-hands] doctrine, which applies only to willful as distinguished from negligent misconduct, is not...applicable to every inconsistent act of a party but to conduct which is 'unconscionable' or 'morally reprehensible.'").

Moreover, such decisions squarely conflict with this Court's *en banc* rejection of even gross negligence as sufficient to prove inequitable conduct. *Kingsdown*, 863 F.2d at 872 (quoting *FMC Corp. v. Manitowoc Co., Inc.*, 835 F.2d 1411, 1415 (Fed.Cir. 1987)) (“to be guilty of inequitable conduct, one must have intended to act inequitably.”). In no other legal field is deceptive intent established by evidence of simple or even gross negligence.⁷

Thus, only after proof of the actor's subjective, actual *appreciation* of high materiality can deceptive intent be inferred under the rule that an actor is presumed to intend the consequences of his actions. Otherwise, the “high-materiality” prong merely conflates materiality and intent in contravention of the principle that intent “is a separate and essential component of inequitable conduct.” *Larson*, 559 F.3d at 1343-44 (Linn, J., concurring).

**B. A Finding Of High Materiality Does Not Lessen
The Evidentiary Burden Of Proving Deception.**

Lowering the quantum of intent evidence sufficient to establish inequitable conduct exacerbates the departure from traditional equitable practices. For

⁷ See, e.g., *Davis v. Monroe County Bd. of Educ.*, 526 U.S. 629, 642, (1999) (explaining that, in a prior Title IX case, the Court “declined the invitation to impose liability under what amounted to a negligence standard—holding the district liable for its failure to react to teacher-student harassment of which it knew or *should have known*.”) (emphasis included); *In re Bose Corp.*, 580 F.3d 1240, 1244 (Fed.Cir. 2009) (“By equating ‘should have known’ of the falsity with a subjective intent, the Board erroneously lowered the fraud standard to a simple negligence standard.”).

example, this Court has stated that “[i]n cases where the omission or misrepresentation is highly material, *less evidence of intent* will be required in order to find that inequitable conduct has occurred.” *eSpeed, Inc. v. BrokerTec USA, L.L.C.*, 480 F.3d 1129, 1135 (Fed.Cir. 2007) (emphasis added, internal quotations omitted). In cases lacking clear and convincing evidence that the patentee actually appreciated materiality, this proposition improperly permits courts to find inequitable conduct upon less than clear and convincing evidence of deceptive intent, such as from the mere fact that testimonial evidence of good faith has been discredited.

In *Osram*, for example, the district court found Nilssen’s failure to inform the PTO of a lawsuit that he had filed against Motorola to be highly material as a matter of law under Section 2001.06(c) of the Manual of Patent Examining Procedure (“MPEP”). There was no dispute that Nilssen knew of the *Motorola* litigation, but there was equally no dispute that Nilssen also knew that nothing happened in *Motorola* which could have affected the pending applications. *Nilssen v. Osram Sylvania, Inc.*, 440 F. Supp. 2d 884, 909-10 (N.D.Ill. 2006). The district court then inferred intent from its finding of “high materiality” and its disbelief of Nilssen’s explanations for the nondisclosure. *Id.* It did so even though there was (i) no direct or affirmative evidence that Nilssen intended to deceive the PTO by omitting this fact; (ii) his denial of knowledge of MPEP § 2001.06(c) was

plausible; and (iii) he plainly had no motive to withhold information irrelevant to patentability. This Court affirmed the intent finding without explanation, while generally acknowledging Nilssen's defenses "were not per se unreasonable," and while specifically recognizing the possibility that Nilssen's "[f]ailure to cite the Motorola litigation to the PTO may have been an oversight." *Osram*, 504 F.3d at 1235.⁸

More recently, however, this Court has clarified that, regardless of materiality, the clear-and-convincing evidentiary standard requires that an inference of deceptive intent be the "single most reasonable inference able to be drawn from the evidence," and the Court also cautioned that discredited explanations of good faith do not themselves constitute affirmative evidence of deception. *Star Scientific*, 537 F.3d at 1366; *see also Larson*, 559 F.3d at 1340; *Advanced Magnetic Closures, Inc. v. Rome Fastner Corp.*, 607 F.3d 817, 829-30 (Fed.Cir. 2010); *Orion IP v. Hyundai Motor America*, 605 F.3d 967, 979 (Fed.Cir. 2010). *Amici* respectfully submit that the *Star Scientific* line of cases properly

⁸ As noted above, the *Osram* decision was subsequently cited by Judge Rader in his *Aventis* dissent as an example of recent cases that have "too often emphasized materiality almost to the exclusion of any analysis of the lofty intent requirement for inequitable conduct [thereby] [m]erging intent and materiality at levels far below" what the law ostensibly requires. *Aventis*, 525 F.3d at 1350-51 (Rader, J., dissenting).

accords with the longstanding principle that deceptive intent be proved by clear and convincing evidence.

IV. INEQUITABLE CONDUCT REQUIRES A CLEAR CONNECTION BETWEEN THE MISCONDUCT AND THE PATENT RIGHTS ASSERTED IN LITIGATION.

The failure to demand a causal nexus between misconduct and allowance of asserted patents rights marks another “wrenching departure” from the traditional unclean-hands calculus. The Supreme Court plainly did not intend for the inequitable-conduct doctrine to vindicate every intentional transgression in the PTO, without any regard for its impact (or lack thereof) on the patent rights asserted in litigation. In *Keystone*, for example, the Supreme Court mandated that there be an “immediate and necessary relation” between the misconduct and rights in litigation, and also required that such relation affect the parties. 290 U.S. at 245.⁹ Unclean hands does not punish for “extraneous transgressions.” *Id.* Rather, “the plaintiff’s conduct must be such that the prosecution of its rights will of itself

⁹ See *Jarrow Formulas, Inc. v. Nutrition Now, Inc.*, 304 F.3d 829, 841 (9th Cir. 2002) (“[U]nclean hands does not constitute misconduct in the abstract, unrelated to the claim to which it is asserted as a defense.”) (internal citations and quotations omitted); *Northeast Women’s Center, Inc v. McGonagle*, 868 F.2d 1342, 1355 (3d Cir. 1989) (“[T]he unclean hands doctrine can be applied only to conduct relating to the matter in litigation...”); *Gillman v. Stern*, 114 F.2d 28, 32 (2d Cir. 1940) (Hand, J.) (“misstatement which influences nobody” constitutes “trifling misconduct” and will not bar patentee’s cause of action).

involve the protection of the wrongdoing.” *Feist v. Young*, 138 F.2d 972, 976 (7th Cir. 1943).

Thus, information which may be deemed “material” to the PTO does not support an unclean-hands defense unless it bears an “immediate and necessary relation” to the rights in litigation. Unclean hands serves as a tool to enforce the overarching principle that a court should “prevent[] a wrongdoer from enjoying the fruits of his transgressions....” *Precision Instrument*, 324 U.S. at 814-15. Where patent rights have *not* been obtained by improper means, there is no cause for the court to close its doors.

Yet, courts appear to have lost sight of this principle. By resolving a perceived ambiguity in the PTO’s regulatory prohibition on “fraud,” the *Norton* court evolved the inequitable-conduct doctrine to refuse enforcement of a patent on grounds of a “deliberate, intentional misrepresentation to the Patent Office during prosecution...*even though the patent might otherwise be valid in every respect.*” 433 F.2d at 795 n. 15 (emphasis added). As Chief Judge Rader recently wrote, however, the Supreme Court did not apply unclean hands for this purpose:

[T]he Supreme Court did not make any connection between its inequitable conduct doctrine and an incentive to disclose prior art to the patent officer during prosecution. In other words, this doctrine was not born as a universal principle to encourage a patent owner to disclose (excessive amounts of) prior art, but only as a remedy for truly abusive behavior.

* * *

[T]he doctrine grew to embrace any kind of perfidy, no matter how inconsequential to the grant of a patent. In other words, any misstatement or overstatement, even if irrelevant to the issuance or validity of a patent, became subject to this “atomic bomb remedy” against fraud.

59 AM. U. L. REV. at 781-82.¹⁰ Others have taken note of this phenomenon. *See, e.g.,* Senate Report No. 110-259, dated January 24, 2008, at p. 33, note 155 (citing the misconduct findings from *Osram* to be the result of a failure to “giv[e] *necessary* consideration to” how relevant the misconduct was to the Examiner’s decision regarding “*whether to allow the patent*”) (emphasis added).

Faithful adherence to the “immediate-and-necessary-relation” requirement, as a matter of federal equity jurisprudence, demands a “but-for” causal relation between the offending conduct and the allowance of claims. Thus, unclean hands should not be found where misconduct is wholly unrelated to patentability. For example, in *Nilssen v. Osram*, all 11 patents-in-suit were, in contravention of this unclean-hands principle, held unenforceable because the patentee underpaid post-issuance patent maintenance fees. 504 F.3d at 1230-33. Judge Rader correctly recognized that such conduct “hardly involve[s] the gross misconduct and deceit that characterized the original Supreme Court cases.” 59 AM. U. L. REV. at 782.

¹⁰ Judge Linn also recently observed that Federal Circuit precedent “has significantly diverged from the Supreme Court’s treatment of inequitable conduct and perpetuates what was once referred to as a plague...” *Larson*, 559 F.3d at 1342 (Linn, J., concurring).

At bottom, if an asserted patent right was not obtained as a result of misconduct, the unclean-hands doctrine cannot apply to deem the conduct inequitable and bar the patentee's cause-of-action.

To be sure, Congress has, by statute, effectively loosened the requirement that misconduct bear on the actual patent claims asserted in litigation. Section 288 renders the patent entirely invalid for inequitable conduct if even only one invalid claim (unasserted or asserted) was deceptively procured. Unasserted claims are, of course, not a "matter in litigation" to which misconduct might relate. *See, e.g., Jones v. Hardy*, 727 F.2d 1524, 1528 (Fed.Cir. 1984) (each claim defines a separate invention). But Congress is not bound by traditional equity jurisprudence. The judiciary is. *See Grupo*, 527 U.S. at 329 ("[O]ur traditionally cautious approach to equitable powers...leaves any substantial expansion of past practice to Congress."). Thus, absent Section 288's application, the accused infringer necessarily lacks constitutional standing to complain of conduct related to an unasserted claim. *See, e.g., Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (complaining party "must have suffered an 'injury in fact'...fairly traceable to the challenged action...."). Faithful application of the unclean-hands doctrine certainly provides no such standing. Indeed, Supreme Court precedent forecloses "extraneous transgression" as a basis for asserting an unclean-hands injury. *Keystone*, 290 U.S. at 145.

**V. THE INEQUITIES OF THE PATENTEE MUST
OUTWEIGH THOSE OF THE ACCUSED INFRINGER.**

The inequitable-conduct doctrine further deviates from the unclean-hands doctrine by barring a patentee's cause-of-action, regardless of the accused infringer's own culpability. Proper application of unclean hands, however, does not necessarily foreclose relief where the "defendant has been guilty of misconduct that is more unconscionable than that committed by plaintiff." 11A Wright, Miller, Kane, *Federal Practice and Procedure, Civil 2d* § 2946, at 112; *accord Feist*, 138 F.2d at 975 ("[I]f the defendant has been guilty of conduct more unconscionable and unworthy than that of the plaintiff, the [unclean-hands] rule may be relaxed."); *Goodyear Tire & Rubber Co. v. Overman Cushion Tire Co.*, 95 F.2d 978, 983 (6th Cir. 1938) (same).

Far too often, however, patent cases prematurely end on inequitable-conduct grounds before the merits of the infringement claims are even reached. This precludes judicial consideration of countervailing inequities by the accused infringer (*e.g.*, willful infringement of valid patent claims), which might otherwise eclipse the egregiousness of the patentee's inequitable conduct, and thereby render inappropriate a finding of unclean hands.

Consideration of countervailing inequities is consistent with the tenant of equity that a court "will not extend its aid to a wrongdoer." *Hazel-Atlas*, 322 U.S. at 260. But, as presently applied, inequitable conduct acts as an inflexible weapon

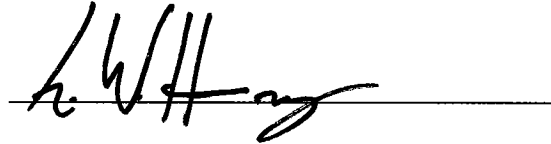
yielded by accused infringers to attack and potentially bar a patentee's cause-of-action before the Court even considers the accused infringer's conduct. While such a result is appropriate where Section 288 applies (*i.e.*, where the inequitable conduct procured allowance of an invalid claim), otherwise foreclosing relief to the patentee can serve to reward egregious conduct of an accused infringer. In such cases, the inequitable-conduct doctrine runs counter to basic notions of equity by abetting the more unconscionable party and providing an undeserved windfall. Proper application of unclean-hands standards avoids such inequitable results.

CONCLUSION

The inequitable-conduct doctrine has proved devastating to numerous parties who have, at worst, committed prosecutorial missteps having no bearing whatsoever on allowance of the patent rights asserted in litigation. In such cases, the applicant plainly has no motive for deception, yet this Court often affirms (*e.g.*, as in *Osram*, and, initially, in this case) deceptive-intent findings solely on grounds of tenuous materiality determinations coupled with discredited explanations of good faith. Such manifestly inequitable results reduce the value to society of the patent bargain by introducing substantial risks to obtaining and enforcing patents that are unrelated to the laudable goal of excising unworthy patents. This Court should provide certainty and reduce risk by grounding its inequitable-conduct jurisprudence on more doctrinally sound bases and in within Article III limitations

on judicial power. *Amici* therefore respectfully urge the Court to reform the inequitable-conduct doctrine as set forth herein.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "L. W. Hutchinson, Jr.", is written over a solid horizontal line.

Leland W. Hutchinson, Jr.

Attorney of Record

Jonathan Hill

David L. Ter Molen

Matthew J. Kramer

FREEBORN & PETERS LLP

311 South Wacker Drive

Suite 3000

Chicago, Illinois 60606-6677

Tel: (312) 360-6000

Attorneys for Amici Curiae

Ole K. Nilssen and Geo Foundation, Ltd.

July 30, 2010

CERTIFICATE OF SERVICE

The undersigned, an attorney, certifies that on July 30, 2010, he caused the foregoing **Brief of Amici Curiae Ole K. Nilssen and Geo Foundation, Ltd.** to be dispatched to a Federal Express carrier for next-business-day delivery to the Clerk of the Court for the United States Court of Appeals for the Federal Circuit, at the below address, and that two (2) true and correct copies of the same were served on all counsel of record as set forth below via next-business-day delivery.

Clerk of the Court
United States Court of Appeals for the Federal Circuit
717 Madison Place, N.W.
Washington, DC 20439

Rohit K. Singla
Jason Rantanen
Peter A. Detre
MUNGER, TOLLES & OLSON LLP
560 Mission Street, 27th Floor
San Francisco, CA 94105

Andrew W. Song
Fred A. Rowley, Jr.
Donald W. Ward
MUNGER, TOLLES & OLSON LLP
355 South Grand Avenue, Suite 3500
Los Angeles, CA 90071

Jeffrey A. Lamken
Michael G. Pattillo, Jr.
MOLOLAMKEN LLP
600 New Hampshire Ave., N.W.,
Washington, DC 20037

*Counsel for Plaintiffs-Appellants
Abbott Diabetes Care, Inc. and Abbott Laboratories*

Rachel Krevans
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, CA 94105

Morton Amster
Kenneth P. George
Joseph M. Casino
AMSTER ROTHSTEIN & EBENSTEIN LLP 90 Park Avenue
New York, NY 10016

Brian M. Kramer
Gregory Walter Reilly
MORRISON & FOERSTER LLP
12531 High Bluff Drive, Suite 100
San Diego, CA 92130

Parisa Jorjani
Wesley E. Overson
Jason R. Bartlett
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, CA 94105

Counsel for Defendant-Appellee Bayer HealthCare LLC

Bradford J. Badke
Sona De
Gabrielle M. Ciuffreda
ROPES & GRAY LLP
1211 Avenue of the Americas
New York, NY 11036-8704

Counsel for Defendant-Appellee Becton, Dickinson and Company

Carolyn B. Lamm, President
American Bar Association
321 North Clark Street
Chicago, IL 60654

Michael A. Valek
William L. LaFuze
VINSON & ELKINS LLP
2801 Via Fortuna, Suite 100
Austin, TX 78746

Counsel for Amicus Curiae American Bar Association

Cameron Keith Weiffenbach
MILES & STOCKBRIDGE, P.C.
1751 Pinnacle Drive, Suite 500
McLean, VA 22102

*Counsel for Amicus Curiae The Hon. Bruce A. Lehman and International
Intellectual Property Institute*

Christian E. Mammen
UC-Hastings College of Law
200 McAllister Street
San Francisco, CA 94102

Counsel for Amici Curiae Nine Law Professors

David Hricik
Mercer University School of Law
1021 Georgia Avenue
Macon, GA 31201

Counsel for Amicus Curiae David C. Hricik

John L. Cooper
Deepak Gupta
Robert H. Sloss
FARELLA BRAUN & MARTEL LLP
235 Montgomery Street, 30th Floor
San Francisco, CA 94104

Counsel for Amicus Curiae Dolby Laboratories, Inc.

Richard G. Taranto
FARR & TARANTO
1150 18th Street, NW, SUITE 1030
Washington DC 20036

John Thorne
1515 North Courthouse Road, Fifth Floor
Arlington, VA 22201

Gail F. Levine
1320 Courthouse Road
Arlington, VA 22201

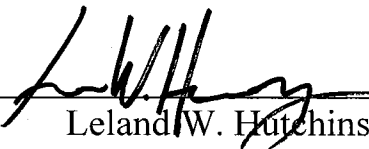
Counsel for Amicus Curiae Verizon Communications, Inc.

Richard Samp
Daniel J. Popeo
Washington Legal Foundation
2009 Massachusetts Avenue, N.W.
Washington, DC 20036

Counsel for Amicus Curiae Washington Legal Foundation


Charles Lee Thomason
SPALDING & THOMASON
106 N. 4th Street
Bardstown, KY 40004

*Counsel for Amicus Curiae
University of Kentucky Intellectual Property Law Society*


Leland W. Hutchinson, Jr.

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B). The brief contains 6,725 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).
2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word 2003 and 14-point Time New Roman font.



Leland W. Hutchinson, Jr.
Counsel for Amici Curiae
Ole K. Nilssen and Geo Foundation, Ltd.

July 30, 2010