

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

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**United States Court of Appeals  
for the Federal Circuit**

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

*Plaintiffs-Appellants,*

v.

BECTON, DICKINSON AND COMPANY,  
and NOVA BIOMEDICAL CORPORATION,

*Defendants-Appellees,*

*and*

BAYER HEALTHCARE LLC,

*Defendant-Appellee.*

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

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**BRIEF OF *AMICI CURIAE* JOHNSON & JOHNSON AND THE PROCTER  
& GAMBLE COMPANY IN SUPPORT OF NEITHER PARTY**

Roddy M. Bullock  
THE PROCTER & GAMBLE CO.  
299 E. Sixth Street  
Cincinnati, Ohio 45202  
(513) 983-6482

*Counsel for The Procter & Gamble Co.*

Gregory L. Diskant  
Eugene M. Gelernter  
Charles D. Hoffmann  
PATTERSON BELKNAP WEBB  
& TYLER LLP  
1133 Avenue of the Americas  
New York, NY 10036-6710  
(212) 336-7635

Philip S. Johnson  
Eric I. Harris  
Henry S. Hadad  
JOHNSON & JOHNSON  
Johnson & Johnson Plaza  
New Brunswick, New Jersey 08933  
(732) 524-2368

*Counsel for Johnson & Johnson*

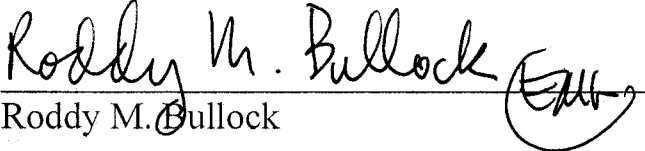
August 2, 2010

**Certificate of Interest**

Counsel for *Amicus Curiae* The Procter & Gamble Co.:

1. The full name of every party or amicus represented by me: The Procter & Gamble Co.
2. The name of the real party in interest (if the party named in the caption is not the real party in interest): The Procter & Gamble Co.
3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus represented by me: None.
4. The names of all law firms and partners or associates that appeared for the party or amicus represented by me in the trial court or agency or are expected to appear in this Court:

THE PROCTER & GAMBLE CO.: Roddy M. Bullock

  
Roddy M. Bullock

**Certificate of Interest**

Counsel for *Amicus Curiae* Johnson & Johnson certifies as follows:

1. The full name of every party or amicus represented by me: Johnson & Johnson.
2. The name of the real party in interest (if the party named in the caption is not the real party in interest): Johnson & Johnson.
3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus represented by me: None.
4. The names of all law firms and partners or associates that appeared for the party or amicus represented by me in the trial court or agency or are expected to appear in this Court:

PATTERSON, BELKNAP, WEBB & TYLER LLP: Gregory L. Diskant,  
Eugene M. Gelernter, Charles Hoffmann

JOHNSON & JOHNSON: Philip S. Johnson, Eric I. Harris, Henry Hadad



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Eugene M. Gelernter

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## I. INTEREST OF THE *AMICI CURIAE*

*Amici* Johnson & Johnson and The Procter & Gamble Company submit this brief *amicus curiae* in support of neither party pursuant to Fed. R. App. P. 29 and Federal Circuit Rule 29, with the consent of all parties.

The *Amici* have been leaders in America's technological innovation for over 100 years. Their patent portfolios protect their enormous investments in research and development, and they regularly rank near the top of the annual list of United States patent recipients. As patent holders and as defendants in patent litigation, the *Amici* have a strong interest in clear and predictable patent laws, which have been essential to the continued vitality of the country's economy. The *Amici* welcome this Court's decision to reconsider the law of inequitable conduct *en banc*. They submit this *amicus* brief to set forth their views on the subject.

When *Amici* have brought suits for infringement, they have faced inequitable conduct challenges even when the patent's validity is beyond legitimate dispute. Patent challengers have learned that it is impossible for large research and development ("R&D") teams to cite all arguably relevant prior art to the PTO, and they can always find some un-cited information to cast in hindsight as both material and having been "withheld" with sinister intent. Once made, inequitable conduct claims are difficult and expensive to defend, especially



because they turn on the subjective intent of an inventor or prosecuting attorney involving events that took place years earlier.

The *Amici* believe that this Court's current inequitable conduct doctrine goes beyond existing Supreme Court precedent, and in so doing violates the separation of powers. In the *Amici*'s view, the courts role should be limited to imposing sanctions for litigation misconduct. The primary responsibility for policing misconduct before the Patent Office should rest with the Patent Office. In keeping with Supreme Court precedent, only when such misconduct rises to the level of unclean hands in the judicial proceeding should courts consider whether the denial of relief is appropriate.

*Amicus* Johnson & Johnson is an innovator of therapeutic biologics, drugs, diagnostics, medical devices, and consumer healthcare products. In reliance on the patent system, Johnson & Johnson's companies spend over \$7 billion annually on R&D and own over 8,000 U.S. patents.

*Amicus* The Procter & Gamble Company, founded in 1837, is the largest consumer products company in the world. It markets over 300 products, including 22 brands with one billion dollars or more in sales, in 140 countries. Research and product development are central to Procter & Gamble's success, as reflected by approximately \$1.8 billion in annual R&D spending and over 40,000 patents worldwide.

**A. This Court's Inequitable Conduct Jurisprudence Impedes Innovation**

In addition to their own R&D efforts, the *Amici* look to R&D initiated by third parties as an important source of ideas for innovative products. The *Amici* invest billions of dollars annually on these efforts – in acquiring or licensing patents, in funding R&D programs by technology-based companies and in corporate acquisitions.

Like other major companies, the *Amici* conduct extensive due diligence before making these investments. In conducting this review, the *Amici* have sometimes discovered potential issues relating to the prosecution of innovative patents. Small companies often lack the experience and resources needed to prosecute their patent applications in a way that will minimize their vulnerability to inequitable conduct challenges. The scientists and managers at these companies usually focus more on describing their inventions than on defensive patenting strategies. Acting in good faith, they often take a common sense approach to disclosing information, failing to realize that self-interested infringers will later seize on almost any omission as material and intentional. Nor do they realize that by the time these issues are raised in the courts, a decade or more will have passed, present recollections will be lost, and the matter will be judged on the basis of a fragmentary documentary record that likely will be susceptible to mischaracterization.

When the *Amici* discover such issues in the course of their due diligence, they raise immediate red flags. It does not matter how innovative the invention may be. Novelty is unrelated to inequitable conduct. Rather, the issue becomes whether the *Amici* will invest the substantial sums needed to turn an innovative idea into a commercial product.

Because there is no administrative procedure to verify the enforceability of issued patents, much less to “purge” issued patents of latent inequitable conduct, the *Amici* and other companies must evaluate potential projects on the assumption that any unenforceability issue will be resolved only long *after* their full investment has been spent. The result of such additional, long-term uncertainty is that otherwise promising and beneficial new products often are not developed. The uncertainty and risk introduced by this Court’s inequitable conduct jurisprudence thus inhibits innovation.

**B. This Court’s Inequitable Conduct Jurisprudence Imposes Penalties That Are Disproportionate to Any Harm**

A particularly disturbing aspect of this Court’s inequitable conduct precedent is that, practically speaking, it threatens only *valid* patents. This is because invalid patents, including those that were procured by outright fraud on the PTO, may be successfully challenged using other, conventional defenses. Inequitable conduct issues become case-determinative only when the challenged conduct involved information that was not sufficiently material to independently

invalidate the claims at issue. The (unintended) consequence of the current inequitable conduct doctrine is thus to deny patent protection *only* to patentees whose contributions deserving of patent protection. Rendering a patent unenforceable for conduct committed before the PTO is, almost by definition, a punishment that is unrelated to the crime, and is usually vastly disproportionate to it.

The broad scope of the inequitable conduct doctrine makes this lack of proportionality particularly apparent. Even if the alleged wrongdoing did not affect any claim that is being asserted, unenforceability is still the penalty.

“[W]hen inequitable conduct occurs in relation to one claim the entire patent is unenforceable.” *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988); *see also Baxter Int’l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1333 (Fed. Cir. 1998) (same). Even if the wrongdoing did not cause the patent’s issuance, the penalty remains the same. *See Digital Control Inc. v. Charles Machine Works*, 437 F.3d 1309, 1315-16 (Fed. Cir. 2006) (a misrepresentation need not be a “but-for” cause of the patent’s issuance to be “material”). Even if the misrepresentations are unrelated to the requirements for patentability, the result is still a finding of unenforceability. *See, e.g., Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1231 (Fed. Cir. 2007) (a finding of unenforceability can result from “inequitable conduct in misrepresenting one’s status as justifying small entity

maintenance payments”), citing *Ulead Sys., Inc. v. Lex Computer & Mgmt. Corp.*, 351 F.3d 1139, 1146 (Fed. Cir. 2003).

Even more dramatically, the punishment of rendering a valuable patent unenforceable can be, and frequently is, imposed on wholly innocent parties. In some cases, the patent owner or exclusive licensee may have acquired its interest in the patent long after patent prosecution ended and without knowledge of any misrepresentations or omissions during patent prosecution. In other cases, a misrepresentation or omission may have been made by an outside attorney whom the patent owner hired in good faith to prosecute its patents and of whose errors the patent owner was unaware.<sup>1</sup> In still other cases, an employee of the patent owner may have made a misrepresentation or omission in disregard of company policy.

In all of these situations, the party that owns the patent or is its exclusive licensee is innocent of any wrongdoing. The penalty for inequitable conduct is not imposed on the wrongdoer – it is suffered by the blameless patent owner or exclusive licensee. That is particularly unfair where – as is often the case – the patent owner has invested heavily in acquiring its patent rights and/or in commercializing the invention, with the expectation that its investment will be protected.

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<sup>1</sup> *E.g., General Electro Music Corp. v. Samick Music Corp.*, 19 F.3d 1405, 1410 (Fed. Cir. 1994) (patent attorney falsely indicated that he conducted a “careful and thorough” prior art review in a declaration to support expedited review).

These outcomes are the result of a court-mandated system lacking in subtlety. Rather than allowing an administrative agency to tailor an appropriate punishment – such as admonition or censure, a financial penalty that is modest or substantial, a suspension from practice from a short time or a long time, disbarment, referral to the Department of Justice for prosecution, etc. – this Court has fashioned a one-size-fits-all remedy. Inequitable conduct renders valuable property rights worthless, even if they are the property rights of innocent third parties, in order to affect the behavior of altogether different persons, who are not before the court, who may not necessarily be heard from and who may not even learn of the court’s ruling. The rules of no other administrative agency are enforced in this fashion.

**C. Current Conduct Jurisprudence Unfairly Focuses On Antiquated Events Where Proof Is Difficult To Obtain and Thereby Diminishes the Standard of Wrongful Conduct**

Allegations of inequitable conduct are raised only after a patent has issued, and typically, well after the patentee’s product has been developed and marketed. As a result, allegations of inequitable conduct litigation often focus on events from the distant past. Due to inherent litigation delays, it is not unusual for these issues to be tried more than a decade after the alleged misconduct took place.

Delays of these lengths are especially problematic because of the highly subjective nature of the intent element of the inequitable conduct defense.

It is a rare witness who remembers what they did as part of their routine research or legal duties a decade or more ago, much less one who can recall the facts and events that could establish that their actions were undertaken in complete good faith. As a result, consideration of the intent issue has become more of an exercise in speculation than of true fact-finding. And when the challenged conduct is not an act but an omission, the accused is put in the impossible position of proving one or more negatives: Why was a piece of prior art *not* submitted to the PTO? Why were data *not* submitted to the PTO? Why didn't the accused appreciate the materiality of an undisclosed reference? Why doesn't the accused remember what he or she *thought* about it?

In most if not all cases, these questions cannot be answered accurately. Yet under this Court's jurisprudence, intent is half the inquiry and may all too readily be inferred. *See Larson Mfg Co. v. Aluminart Prods Ltd.*, 559 F.3d 1317, 1343-44 (Fed. Cir. 2009) (Linn, J. concurring) (noting that "the test for inferring deceptive intent . . . falls short of the standard 'need[ed] to strictly enforce the burden of proof and elevated standard of proof in the inequitable conduct context'" (quoting *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008))).

Meanwhile, the standard of materiality keeps changing over time. This Court and the PTO have offered various definitions over the years, even while

this Court has declined to defer to the PTO's definition. *See Digital Control Inc. v. Charles Machine Works*, 437 F.3d 1309, 1316 (Fed. Cir. 2006) (describing shifting tests for materiality). Should a co-pending application be disclosed? Should a European office action be disclosed? Actions, or inactions, taken 10 or 20 years earlier are constantly being second-guessed under new standards of materiality.

In other contexts, statutes of limitation provide protection against claims based on long-ago events.<sup>2</sup> Such statutes provide protection from charges that “may be obscured by the passage of time and to minimize the danger of official punishment because of acts in the far distant past.”<sup>3</sup>

As was said of the statute of limitations by Mr. Justice Story (*Bell v. Morrison*, 1 Pet. 351, 360): “It is a wise and beneficial law . . . to afford security from stale demands, after the true state of the transaction may have been forgotten, or be incapable of explanation, by reason of the death or removal of the witnesses.”

*Campbell v. City of Haverhill*, 155 U.S. 610, 616-17 (1895) (“This language is peculiarly applicable to patent cases,” especially for issues that “are required to be proved to the satisfaction of the court by something more than a mere preponderance of evidence.”). Although inequitable conduct charges present the

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<sup>2</sup> *See, e.g.*, 18 U.S.C. § 3282 and 18 U.S.C. § 3293 (five- or ten-year statute of limitations for mail and wire fraud); 28 U.S.C. § 1658 (two- or five-year statute of limitations for civil securities fraud); *see also* 28 U.S.C. § 2462 (five-year limitations statute for government actions to enforce administratively assessed penalties).

<sup>3</sup> Statute of Limitations in Federal Criminal Cases: An Overview, CRS Report for Congress (April 9, 2007).



same serious concerns, they are not meaningfully subject to any statute of limitations because it is the act of enforcing the patent – even if decades after the alleged misconduct – that gives rise to the claim.

These concerns should have led to the constraints on applying the doctrine of inequitable conduct based on antiquated events. Instead, this Court’s jurisprudence has evolved to *reduce* the standard of proof and thus accommodate a perceived need to permit the defense to be established – and sanctions imposed – in the absence of an actual understanding of the facts. *E.g., Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1313-14 (Fed. Cir. 2008). In the criminal justice system, prosecutors do not bring charges of fraud without serious evidence – documentary and testimonial – to support them. Even claims of civil fraud require proof of fraud.

But in this Court’s jurisprudence, common law fraud based on proven facts has been replaced by the vague and less demanding concept of “inequitable conduct,” a concept that does *not* require proof of fraud. *Dippin’ Dots, Inc. v. Mosey*, 476 F.3d 1337, 1347 (Fed. Cir. 2007) (“The difference in breadth between inequitable conduct and *Walker Process* fraud admits the possibility of a close case whose facts reach the level of inequitable conduct, but not of fraud before the PTO. This is such a case.”). In this world, in a strange nod to the impossibility of fairly

understanding long distant facts, there is no need to “prove deceptive intent independently.” *Dippin’ Dots*, 476 F.3d 1337 at 1348.

Since there is frequently no evidence at all relating to long-ago acts – other than the acts themselves – the absence of evidence is trumpeted as “suspicious” and presumptions replace actual proof of wrongdoing. A material reference is found in the patent owner’s twenty-year old file, but it was not submitted to the PTO. With no explanation available, a criminal prosecutor would walk away. But under existing precedent, the absence of “a credible explanation for the withholding” has been pointed to as proof of wrongdoing. *Praxair*, 543 F.3d at 1313-14.

A system that is based on ferreting out distant wrongs based on forgotten events and that encourages the prosecution and resolution of serious charges based on presumptions and without evidence tends over time to diminish itself. Rather than sanctioning serious misconduct, the system instead devalues the notion of intentional wrongdoing. Thus, courts are encouraged to create new “should have known” standards to replace evidence of actual wrongdoing.<sup>4</sup>

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<sup>4</sup> See *Larson Mfg. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1344 (Fed. Cir. 2009) (Linn, J., concurring) (“The . . . ‘should have known’ prong sets forth a simple negligence standard, lower even than the ‘gross negligence’ standard that was expressly rejected in *Kingsdown*.”); *Ferring B.V. v. Barr Labs Inc.*, 437 F.3d 1181, 1201 (Fed. Cir. 2006) (Newman, J., dissenting) (The majority’s holding “that clear and convincing evidence of deceptive intent may be inferred on summary judgment where the record establishes that the applicant ‘knew or should have known’ that omitted information was material . . . is directly contrary to

Current inequitable conduct jurisprudence has led the courts far away from common law fraud and has encouraged, as a matter of routine, penetrating inquiries into long-ago events about which no proof is typically available and no explanation is possible. This diminishes respect for the judicial system even while it imposes impossible burdens on patent owners.

The goal of deterring wrongful conduct in the PTO could be better served by an administrative process that operates closer in time to the conduct in question and is directed at persons who engaged in that conduct, rather than on parties who were not involved in it.

**D. Pervasive Inequitable Conduct Allegations Unjustly Tarnish the Reputations of Skilled Scientists and Attorneys**

The *Amici* have no interest in protecting genuine wrongdoers from punishment. But the nature of the Court's inequitable conduct doctrine is to generate such charges against all comers without serious regard to their veracity. A government agency, such as the PTO, can be trusted to pursue such allegations when they are warranted. But allowing such allegations to be brought by accused infringers, who have an interest in generating defenses, creates an incentive to raise even spurious charges in the hope they might prevail. This tarnishes the judicial system – and the reputations of innocent scientists and attorneys.

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*Kingsdown*, which held that even gross negligence may not establish deceptive intent.”).

The reputation of a scientist or attorney is his or her most valuable professional asset. Honest scientists and reputable attorneys should not routinely be subjected to allegations that they are liars and cheats. Sadly, under existing inequitable conduct precedent, that is the norm. These smears take a destructive personal toll on the lives of the individuals involved.

No matter how meritless these charges may be, they cause stress and sleepless nights, and distract from productive activity. Often, charges of inequitable conduct are leveled against researchers whose most important professional contribution was an important invention that is the subject of the case. After years of research, the scientist's work has culminated not only in a patent, but also in a useful and often successful product. This is a pivotal moment in the life and career of a scientist, and one that should serve as a tribute to the patent system in its finest hour. It should be an event to be savored with friends, colleagues, family and the public at large. It is simply wrong to allow such moments of pride, pleasure and achievement routinely to be tarred by spurious allegations of fraud.

Attorneys who are the subject of inequitable conduct allegations also find their reputations tarnished in public, and have no right to intervene in these actions. *See, e.g., Therasense, Inc. v. Becton Dickinson*, No. 2008-1511 (Fed. Cir. Oct. 23, 2008) (denying attorney's motion to intervene in appeal of inequitable

conduct finding based in part on the attorney's conduct). Such charges are known to prospective employers and potential clients, often with devastating professional consequences for the attorneys involved.

When the Founders sought to promote the useful arts by creating a patent system, they did not envision a system that would impose such destructive effects on the nation's scientists and professionals. There is no good reason to perpetuate such a system.

**E. Pervasive Inequitable Conduct Allegations Are a Drain on the Judicial System**

Inequitable conduct allegations are still a "plague on the system."

*Dickson Indus., Inc. v. Patent Enforcement Team, L.L.C.*, 333 Fed. Appx. 514 (Fed. Cir. 2009); *Larson Mfg. Co. v. Aluminart Prods. Ltd.*, 559 F.3d 1317 (Fed. Cir. 2009) (Linn, J. concurring). There is no empirical basis to believe that scientists and attorneys routinely engage in misconduct. But allegations of inequitable conduct remain the norm. See Randall R. Rader, *Always at the Margin: Inequitable Conduct in Flux*, 59 Am. U. L. Rev. 777, 779 (2010) (number of appeals involving inequitable conduct issues from 2004 to 2008, citing M.A. Lemley & J.H. Walker, *Intellectual Property Litigation Clearinghouse: Data Overview* (Stanford Pub. Law Working Paper No. 1024032, Nov. 2, 2007), available at <http://ssrn.com/abstract=1024032>). The chance of rendering a valid patent unenforceable – thereby avoiding a possible injunction and damages that

can run to millions of dollars – is a temptation that too many accused infringers cannot resist.

The consequence is that challengers and patent owners alike spend many millions of dollars litigating over antiquated facts in an attempt to reconstruct activities that no one remembers. Alleged infringers make hyperbolic claims. Busy district courts that, at best, have a limited understanding of the realities of patent prosecution hold unnecessary hearings. And in the end, most claims of inequitable conduct are rejected. Surely the courts have better ways to spend their time.

**F. Current Inequitable Conduct Jurisprudence Imposes An Undue Burden on the Patent System**

Finally, and perhaps worst of all, current inequitable conduct jurisprudence places an undue burden on the Patent Office. To avoid charges of inequitable conduct, applicants routinely disclose far more information than the PTO reasonably needs to review, especially when the patent is potentially valuable. The fear of being accused of having withheld information becomes a key consideration in deciding what to disclose.

There is, of course, nothing improper about submitting arguably relevant information and patent owners are now compelled to do by the need to practice defensively. Given the relatively few hours that examiners spend on

average in examining a patent,<sup>5</sup> a system that encourages applicants to inundate the PTO with numerous references is harmful – not helpful. Instead of furthering meaningful examination, this practice reduces the PTO’s ability to focus on the most important references. Yet current jurisprudence – and the risk that a valuable valid patent will be subject to challenge based on a misstep in the PTO – encourages this result.

Nor can the PTO expect patent professionals to focus examiners on the more important aspects of the prior art, when any comments will be parsed years later for allegations of misinformation, misdirection or conflict with some other public statement in related or foreign prosecution. The inevitable result is that patent applicants say as little as possible, while disclosing as much as possible. This is exactly the opposite of what should be. Current inequitable conduct jurisprudence is detrimental to the PTO examination process and ultimately to the overall quality of patents being litigated in the district courts.

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Having experienced unfounded allegations of inequitable conduct over the years, the *Amici* believe that the doctrine of inequitable conduct is ill-conceived and should be sharply curtailed. Courts should adjudicate allegations of misconduct only when misconduct is thrust upon the courts by the litigants’ actions

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<sup>5</sup> As of 2004, examiners spent an average of only 18 cumulative hours per patent application. <http://www.whitehouse.gov/omb/budget/fy2004/pma/patents.pdf>. Last accessed on August 2, 2010.

in the course of litigation. Otherwise these issues should be left to the PTO to resolve as administrative matters.

## II. ARGUMENT

This Court's inequitable conduct doctrine, which has evolved from *Norton v. Curtiss*, 433 F.2d 779 (C.C.P.A. 1970), now reaches beyond Supreme Court precedent. While this doctrine reflects the well-intentioned objective of protecting the integrity of the PTO's administrative process, its unintended impacts, as discussed above, now stand as greater tribute to the wisdom of judicial restraint mandated by controlling Supreme Court cases that gave rise to the defense.

This Court should confine the role of federal courts in such cases to what the Supreme Court permits – application of the unclean hands doctrine to litigations who attempt to perpetuate a fraud on the PTO by engaging in subsequent litigation misconduct. In contrast, as now applied, the inequitable conduct doctrine violates the separation of powers and established doctrines of administrative law by improperly involving Article III courts in what should properly be a purely administrative issue for the PTO: governing the standard of conduct before it. In addition, by allowing a private party to ask a court to extinguish the property right in a patent allegedly obtained by fraud, this Court's



decisions are contrary to Supreme Court precedent holding that only the United States may bring such an action.

**A. The PTO, Not This Court, Should Define and Enforce Inequitable Conduct Committed Before the PTO**

As Professor John F. Duffy has observed, other than in this Court's jurisprudence, there is no basis in administrative law for the courts, rather than the appropriate administrative agency, to define either the standards for conduct before the agency or the sanctions that will be levied for noncompliance. A private litigant cannot bring a claim to invalidate the action of a government agency on the ground of fraud – let alone inequitable conduct – except under this Court's precedent.

The reasons are straightforward. The Administrative Procedure Act, 5 U.S.C. § 553, *et seq.*, leaves it to the administrative agencies to set rules of behavior for regulated parties. This principle is an “outgrowth of the congressional determination that administrative agencies and administrators will be familiar with the industries which they regulate and will be in a better position than federal courts or Congress itself to design procedural rules adapted to the peculiarities of the industry and the tasks of the agency involved.” *F.C.C. v. Schreiber*, 381 U.S. 279, 290 (1965). “Even apart from the Administrative Procedure Act [the Supreme Court] has ... emphasized that the formulation of procedures was basically to be left in the discretion of the agencies to which Congress has confided

the responsibility for substantive judgments.” *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.*, 435 U.S. 519, 524 (1978).

As a consequence, absent arbitrariness or capriciousness, federal courts defer to agency decisions about their procedures and the sanctions for violations. For example, in *ABF Freight System, Inc. v. National Labor Relations Board*, 510 U.S. 317 (1994), a discharged employee gave false testimony to the NLRB in support of an otherwise valid claim for reinstatement. Despite detecting the perjury, the NLRB decided to “rely on ‘other civil and criminal remedies’ for false testimony,” *id.* at 325, rather than denying the former employee’s claim.

The Supreme Court recognized that this was not an issue for the courts to second-guess. “We recognize that the Board might have decided that such misconduct disqualified Manso from profiting from the proceeding, or it might even had adopted a flat rule precluding reinstatement when an employee so testifies. As the case comes to us, however, the issue is not whether the Board *might* adopt such rule, but whether it *must* do so.” *Id.* at 323 (emphasis in original). While the Court decried the employee’s false testimony as “intolerable,” it nonetheless noted that Congress had “delegate[d] to the Board the primary responsibility for making remedial decisions that best effectuate the policies of the Act.” *Id.* at 323-24. Accordingly, the Court found that it “must give the agency’s decision controlling weight” unless the decision were arbitrary or capricious. *Id.*

Similarly, in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Supreme Court rejected an effort to litigate “fraud-on-the-FDA claims” under state tort law. Plaintiffs contended that false representations had been made to the FDA, leading to the approval of devices that ultimately led to plaintiffs’ injuries. In a comment fully applicable to the unintended effects of this Court’s inequitable conduct jurisprudence, the Court expressed concern that permitting judges around the country to decide such 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.” *Id.* at 351. It stated: “Applicants would then have an incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA’s evaluation of an application.” *Id.* The Court also noted that the “federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration.” *Id.* at 348. The FDA administrative scheme included both “disclosure requirements” and “various provisions aimed at detecting, deterring and punishing false statements made during this and related approval processes.” *Id.* at 349.

The PTO has established standards of disclosure and, like the FDA and the NLRB, has the ability to rely on “civil and criminal penalties” for applicant misconduct. The PTO requires that inventors submit their declarations under oath,

subject to the penalty of perjury. It requires that persons practicing before the PTO pass the PTO bar exam and subject themselves to discipline like the members of any other bar. Willful false statements to the PTO are subject to prosecution under 18 U.S.C. § 1001. Yet, rather than defer to PTO regulations, this Court has held that they do “not supplant or replace our case law.” *Digital Control, Inc. v. Charles Machine Works*, 437 F.3d 1309, 1316 (Fed. Cir. 2006).

This Court’s inequitable conduct doctrine usurps the role of the PTO in violation of the Administrative Procedures Act. It involves the federal courts in regulating behavior before an executive branch agency, in violation of the separation of powers. It is not only unlawful but perverse. The administrative agency can suit the punishment to the crime, and can punish the wrongdoer rather than the innocent. Surely that is preferable to a rule that has only one remedy – effectively, a death sentence for the patent – for conduct found to be “inequitable.” This Court should reconsider its precedents and let the PTO, not the courts, take the primary role in governing the conduct of those appearing before it.

**B. Only the United States May Sue to Invalidate a Patent for Fraud**

Under English common law, only the king had the right to invalidate a patent for fraud, utilizing the ancient writ of *scire facias*. In *Mowry v. Whitney*, 81 U.S. 434 (1871), the Supreme Court adopted the same rule in this country. The Supreme Court found that the Patent Act of 1836 limited private suits to annul

patents to disputes based upon conflicting claims (a modern interference). Where fraud (and *a fortiori* inequitable conduct) is alleged, “no one but the government . . . can institute judicial proceedings for the purpose of vacating or rescinding the patent which the government has issued.” *Id.* at 439.

The reasons to limit such action to the government are obvious: “The fraud, if one exists, has been practiced on the government, and as the party injured, it is the appropriate party to assert the remedy or seek relief.” *Id.* at 441.

Moreover, if a private party could challenge a patent as fraudulently issued, “[t]he patentee would or might be subjected to innumerable vexatious suits to set aside his patent, since a decree in his favor in one suit would be no bar to a suit by another party.” *Id.*

*Mowry* made clear that it would be wrong to allow private litigants to invalidate a patent on the ground of fraud. “It would seriously impair the value of the title which the government grants after regular proceedings before officers appointed for the purpose, if the validity of the instrument by which the grant is made, can be impeached by anyone whose interest may be affected by it, and would tend to discredit the authority of the government in such matters.” *Id.*

A few years later, the Supreme Court explained that the effect of such a suit by the government was not limited to parties before the Court (unlike the then-rule for the effects of private litigation). “[T]he suit of the government, if

successful, declares the patent void, sets it aside as of no force, vacates it or recalls it, and puts an end to all suits which the patentee can bring against anybody. It opens to the entire world the use of the invention or discovery in regard to which the patentee has asserted a monopoly.” *United States v. Am. Bell Tel. Co.*, 128 U.S. 315, 372 (1888).

*Mowry* remains good law in the Supreme Court. The Supreme Court cited *Mowry* with approval as recently as 1965, in allowing antitrust cases to be brought based upon fraud before the PTO, and acknowledged “the rule that *only the United States may sue to cancel or annul a patent.*” *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 175 (1965) (emphasis added). The Court noted that a private-litigant *Walker Process* claim “does not directly seek the patent’s annulment.” *Id.* at 176.

This Court has called its doctrine of inequitable conduct the “contemporary analog” of the writ of *scire facias*. *In re Lockwood*, 50 F.3d 966, 974 n.9 (Fed. Cir.), *vacated on other grounds*, 515 U.S. 1182 (1995). Yet it has never seriously come to grips with the fact that when *Mowry* adopted that doctrine it explicitly *precluded* the private-party lawsuits that this Court *permits*. See *Norton*, 433 F.2d at 792 n.12. Indeed, as this Court has recognized, it is “[t]his court’s doctrines of inequitable conduct” – *not* Supreme Court precedent – that

permit private litigants to “render the patent itself unenforceable.”<sup>6</sup> *Aptix Corp. v. Quickturn Design Sys., Inc.*, 269 F.3d 1369, 1376 (Fed. Cir. 2001). That may be the “contemporary analog” of *scire facias*, but it is squarely in conflict with *Mowry* and at odds with Supreme Court case law.

There is no reason to believe that the Supreme Court would look favorably on this Court’s rule that permits private litigants to invalidate lawful actions by government agencies and thereby invalidate the property rights of innocent parties. *Mowry* stands for the opposite proposition. Because this Court’s inequitable conduct doctrine allows private parties to invalidate patents contrary to *Mowry*, it should be reconsidered.

### **C. The Proper Role of the Courts Is to Enforce the Unclean Hands Doctrine**

There is no statutory or Supreme Court authority for this Court’s current inequitable conduct doctrine. At the time of *Mowry*, 19th-century statutory law permitted individual litigants to assert fraud on the PTO as a defense to an infringement action. See Rev. Stat. § 4920, 35 U.S.C. § 69, cited in *United States v. Am. Bell Tel. Co.*, 128 U.S. 315, 371 (1888). This was “a more limited form of relief” – not binding on any other litigant – than “the power of the government of

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<sup>6</sup> Any difference between rendering a patent “unenforceable,” rather than “void” or “rescinded,” is only one of nomenclature. Like a suit to invalidate a patent for fraud, a declaration of unenforceability applies to the entire patent, regardless of the number of claims or the relationship between the alleged fraud and any particular claim. See *Kingsdown*, 863 F.2d at 876.

the United States to get rid of a patent obtained it from it by fraud and deceit.” *Am. Bell Tel.*, 128 U.S. at 373. By the 20th century, this “limited right” had disappeared from the statute books.

There is no statutory basis to allow a private party to have a patent declared unenforceable even against it, let alone against the entire world. There is no decision by the Supreme Court rendering a patent unenforceable in private litigation based on the allegations that a patent was obtained by fraud on the Patent Office.

Instead, the Supreme Court cases that have addressed applicant misconduct before the PTO have allowed such conduct to be relied upon only as part of an unclean hands defense based on subsequent litigation misconduct, with the benefit attaching only to the private litigant who is forced to defend itself against such misconduct. “[T]he remedies for litigation conduct bar the malfasant who committed the misconduct. The property right itself remains independent of the conduct of a litigant.” *Aptix*, 269 F.3d at 1375. There is no Supreme Court case vacating a patent for fraud at the behest of a private party, nor one denying relief to a patentee who has obtained a patent by fraud, except where the patentee has engaged in misconduct before the court.

Thus, in *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933), the patent owner obtained both a false affidavit and false deposition



testimony in return for payment. The Court found this “corrupt transaction” to be “highly reprehensible.” *Id.* at 244. But it recognized that courts “do not close their doors because of plaintiff’s misconduct, whatever its character, that has no relation to anything involved in the suit, but only for such violations of conscience as in some measure affect the equitable relations between the parties *in respect of* something brought before the court for adjudication.” *Id.* at 245 (emphasis added). On the facts before it, the Court found the “corruption” of the witness and the plaintiff’s use of the false testimony to “fairly be deemed” connected to the federal-court action. *Id.* at 246.

Likewise, in *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945), the Court considered whether the plaintiff “possessed ‘such unclean hands’ as to foreclose its right to enforce the patents and the contracts.” *Id.* at 807-08. “[T]he history of the patents . . . steeped in perjury and undisclosed knowledge of perjury,” *id.* at 816, included false testimony by Larson (the patentee) in an interference proceeding, the discovery of Larson’s perjury by Automotive (the eventual plaintiff in the patent action) and threats to report him to the district attorney, and the eventual collusive agreement between Larson and Automotive to assign Larson’s false application to Automotive. “[I]nequitable conduct impregnated Automotive’s entire cause of

action” and therefore “justified dismissal by resort to the unclean hands doctrine.”  
*Id.* at 819 (citing *Keystone, supra*).

Finally, *Hazel-Atlas Glass Co. v. Hartford Empire Co.*, 322 U.S. 238 (1944), *overruled on other grounds by Standard Oil v. United States*, 429 U.S. 17 (1976), involved the after-the-fact grant of “equitable relief against [a] fraudulent judgment[.]” *Id.* at 248. There, the patentee had paid “an ostensibly disinterested expert” to write an article describing the claimed invention as a “remarkable advance in the art.” *Id.* at 240. This fraudulent article was submitted to the PTO, resulting in the grant of the patent, and then knowingly relied upon in the Court of Appeals. Thereafter, the purported author was paid to submit a false affidavit. This “sordid story,” *id.* at 243, “a deliberately planned and carefully executed scheme to defraud not only the Patent Office but the Circuit Court of Appeals,” *id.* at 245, came out only after judgment had been entered. Based upon “settled equitable principles,” the Court ordered the judgment set aside. *Id.* at 247. But the Court did not – and could not – declare the patent void or unenforceable.

These three – and only these three – Supreme Court cases deny enforcement of a patent on the ground of unclean hands. They deny enforcement not because the patentee defrauded the PTO, but because he had come to court with unclean hands and attempted to perpetuate the fraud in federal court. They

grant relief only against the litigant, not the patent. And they make clear that only the government, not a private litigant, can invalidate a patent obtained by fraud:

To grant full protection to the public against a patent obtained by fraud, that patent must be vacated. *It has previously been decided that such a remedy is not available in infringement proceedings, but can only be accomplished in a direct proceeding brought by the government.*

*Hazel-Atlas*, 322 U.S. at 251 (emphasis added) (citing *Am. Bell Tel.*, 128 U.S. at 373).

#### **D. Toward a Proper Rule**

This Court should reconsider its precedents and limit judicial consideration of applicant misconduct before the PTO to the unclean hands doctrine. The PTO, and not this Court, should set and enforce the rules for practice before the PTO. There is no basis to allow a private litigant to challenge a patent as obtained by fraud and to render it unenforceable in violation of the rule of *Mowry*. Instead, this Court, and the federal district courts, should limit themselves to applying the unclean hands doctrine when necessary to prevent a fraud on the court. In such cases, and only in such cases, fraud on the Patent Office may appropriately be considered when it is shown to be coupled with an effort to perpetuate the fraud in court.

The PTO – like other administrative agencies – is in a far better position to set policies that govern appropriate conduct during the prosecution

process than the district courts, and to set appropriate penalties where individuals engage in misconduct. Indeed, the PTO may decide to set a higher standard of practice than fraud. Patent professionals, inventors and affiants would continue to practice at the highest standards of conduct and would be able to have a far more frank and constructive dialogue with PTO during the patent prosecution process. This is because these individuals would know their actions would be judged by professional conduct rules promulgated by the PTO, which has the appropriate expertise to determine whether there was misconduct, and not be a product of the litigation tactics that have distorted the current inequitable conduct doctrine.


In addition, leaving the PTO to set and enforce remedies for impropriety in patent prosecution, while leaving courts to enforce sanctions for litigation misconduct, would help restore proportionality between wrong-doing and the remedy for that wrong-doing. Where an individual commits misconduct in prosecuting an otherwise valid patent, then that individual should be punished – not an innocent patent owner. Similarly, if a patent owner acts with unclean hands in litigation, then courts may impose an appropriate sanction. Public policy is served in both instances, with the additional benefits that the PTO and the judicial system run more efficiently and apply justice more fairly.

## CONCLUSION

For the foregoing reasons, the *Amici* urge this Court to reconsider – and sharply curtail – the doctrine of inequitable conduct.

Dated: August 2, 2010

Respectfully submitted,

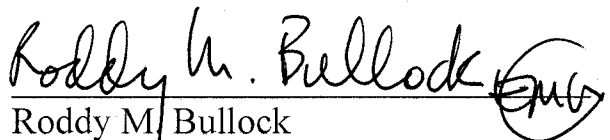


Gregory L. Diskant  
Eugene M. Gelernter  
Charles Hoffmann  
PATTERSON BELKNAP WEBB &  
TYLER LLP  
1133 Avenue of the Americas  
New York, NY 10036  
(212) 336-2000

*Attorneys for Amicus Curiae  
Johnson & Johnson*

*Of Counsel for Johnson & Johnson:*

Philip S. Johnson  
Eric I. Harris  
Henry Hadad  
JOHNSON & JOHNSON  
Johnson & Johnson Plaza  
New Brunswick, NJ 08933  
(732) 524-2368



Roddy M. Bullock  
THE PROCTER & GAMBLE CO.  
299 E. Sixth Street  
Cincinnati, OH 45202  
(513) 983-6482

*Attorney for Amicus Curiae  
The Procter & Gamble Co.*

**United States Court of Appeals  
for the Federal Circuit**

*Therasense v Becton*, 2008-1511, -1512, -1513, -1514, -1595

**CERTIFICATE OF SERVICE**

I, Elissa Matias, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by PATTERSON BELKNAP WEBB & TYLER LLP, Attorneys for Amici Curiae, to print this document. I am an employee of Counsel Press.

On the **2nd Day of August, 2010**, I served the within **Brief of Amici Curiae Johnson & Johnson and the Procter & Gamble Company in Support of Neither Party** upon:

Rachel Krevans  
Morrison & Foerster LLP  
425 Market Street  
San Francisco, CA 94105-2482  
(415) 268-7178  
Counsel for Bayer HealthCare LLC

Bradford J. Badke  
Ropes & Gray LLP  
1211 Avenue of the Americas  
New York, NY 10036-8704  
(212) 596-9000  
Counsel for Becton, Dickinson  
and Company, et al.

Rohit K. Singla  
Munger, Tolles & Olson, LLP  
560 Mission Street, 27th Floor, San  
Francisco, CA 94105  
(415) 512-4000  
Counsel for Abbott Laboratories and  
TheraSense, Inc.

**via Federal Express**, by causing 2 true copies of each to be deposited, enclosed in a properly addressed wrapper, in an official depository of Federal Express.

Unless otherwise noted, the 31 copies have been filed with the Court on the same and in the same manner as above.

August 2, 2010

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## CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B)(i), because it contains 6,853 words, calculated by the word processing system used in its preparation, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman 14 point font.

Dated: August 2, 2010



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Eugene M. Gelernter  
*Counsel for Amicus Curiae Johnson &  
Johnson*