

INEQUITABLE CONDUCT: A FLAWED DOCTRINE WORTH SAVING*

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A growing chorus of voices is calling for reform or even elimination of the doctrine of inequitable conduct.¹ Critics cite the high costs and unpredictability associated with litigating the issue,² and argue that innocent or even irrelevant prosecution mistakes can be met with the ultimate penalty: unenforceability of the entire patent.³

It is not surprising that reform-minded critics have turned their attention to the inequitable conduct doctrine. The remarkable level of Supreme Court attention to the patent system in recent years⁴ has no doubt encouraged patent litigants to file certiorari

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¹ Brief for Interested Patent Law Professors as Amici Curiae Supporting Panel Rehearing or Rehearing en banc, *Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.*, 525 F.3d 1334 (Fed. Cir. 2008) (No. 2007-1280), 2008 WL 2967559 (noting that a “loud call for reform from academics and practitioners shows that concern is shared both by those whose interests lie in the broader health of the patent system as well as by those immediately affected by this Court's decisions,” and that “legislative proposals show Congress is concerned about the doctrine's impact on innovation, litigation, and liquidity.”).

² Nat'l Research Council, Comm. on Intellectual Property Rights in the Knowledge-Based Economy, *A PATENT SYSTEM FOR THE 21ST CENTURY* 82-83 (2004) [hereinafter “21st Century Report”].

³ See, e.g., *The Patent Reform Act of 2007: Hearings on H.R. 1908 Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on the Judiciary*, 110th Cong. [hereinafter “Hearings on H.R. 1908”] 43-44 (2007) (statement of Kevin Sharer, CEO and Chairman of the Board of Amgen, Inc.) (“When a patent is litigated, the most innocent statements, or failures to disclose the smallest thing, can become the bases for charges of inequitable conduct.”).

⁴ The Supreme Court has decided eight patent cases during the last four terms. See *Quanta Computer, Inc. v. LG Electronics, Inc.*, 128 S.Ct. 2109, 2122 (2008) (holding that “[t]he authorized sale of an article that substantially embodies a patent exhausts the patent holder's rights and prevents the patent holder from invoking patent law to control postsale use of the article”); *Microsoft Corp. v. AT&T Corp.*, 127 S. Ct. 1746, 1751-52 (2007) (addressing the extraterritorial reach of U.S. patent law); *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1733 (2007) (revising the standard for establishing obviousness); *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 777 (2007) (expanding the availability of declaratory relief); *eBay, Inc. v. MercExchange, L.L.C.*, 126 S. Ct. 1837, 1841 (2006) (holding that district courts are to apply generally applicable equitable principles in deciding whether to grant injunctions in patent cases); *Illinois Tool Works, Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 45-46 (2006) (rejecting the premise that a patent necessarily confers market power on its owner, and holding that “in all cases involving a tying arrangement, the plaintiff must prove that the defendant has market power in the tying product.”); *Unitherm Food Sys., Inc.*

petitions and raised hopes that the Court might accept an inequitable conduct case for review. In addition, the fact that the Supreme Court has reversed or vacated eight decisions of the U.S. Court of Appeals for the Federal Circuit in the last four years might be perceived, at least, as motivation for the Federal Circuit to grant *en banc* review in an attempt to pre-empt Supreme Court review with respect to increasingly controversial patent law doctrines.⁵ Thus, parties who have lost on an issue at the Federal Circuit have reason to hope that the courts will be receptive to certiorari or rehearing petitions, and an expectation that they may be able to enlist or enjoy the support of interested amici.

Further, although none of the various comprehensive congressional patent reform proposals introduced over the last several years⁶ has yet garnered sufficient support in both houses to reach the desk of the President, it is clear that there is still significant appetite for wide-ranging reforms,⁷ and therefore a real opportunity for proponents of legislative alteration of the inequitable conduct defense.

But abrogation of the defense would be a mistake, particularly as concerns about patent quality echo in the U.S. Patent and Trademark Office (USPTO), the Congress, the courts, the practitioner's office, and the media.

This essay argues that retaining the defense will help maintain the integrity of, and continuing public confidence in, the U.S. patent system. It sets forth specific recommendations for much-needed modifications designed to better serve the doctrine's essential purposes, and to ameliorate the key problems with its current application. Although these changes can be implemented by the courts, legislative action would be more appropriate because the recommended modifications affect virtually every aspect of the doctrine, and because it is unlikely that a given case or series of cases will present appropriate facts for judicial resolution in the near future.

v. Swift-Eckrich, Inc., 546 U.S. 394, 407 (2006) (applying the requirements of Fed. R. Civ. P. 50(b) to foreclose review of the sufficiency of the evidence); Merck KGaA v. Integra LifeSciences I, Ltd., 545 U.S. 193, 208 (2005) (interpreting the patent statute's safe harbor provision relating to the development and submission of data to the Food & Drug Administration). The Court also granted certiorari in a ninth patent case during this period, but ultimately dismissed the writ of certiorari as "improvidently granted." Lab. Corp. of Am. v. Metabolite Lab., Inc., 126 S. Ct. 2921, 2921 (2006) (per curiam). Even the latter case, however, resulted in an opinion on the merits by three justices. *Id.* (Breyer, J., dissenting).

⁵ The Federal Circuit's recent *sua sponte* decision to rehear an appeal relating to statutory subject matter is one possible example. *In re Bilski*, 264 Fed.Appx. 896, 897 (Fed. Cir. 2008).

⁶ *See, e.g.*, Patent Reform Act of 2007, S. 1145, H.R. 1908, 110th Cong. (1st Sess. 2007); Patent Reform Act of 2006, S. 3818, 109th Cong. (2d Sess. 2006); Patents Depend on Quality Act of 2006, H.R. 5096, 109th Cong. (2d Sess. 2006); Patent Reform Act of 2005, H.R. 2795, 109th Cong. (1st Sess. 2005).

⁷ H.R. 1908 was approved in the House of Representatives in September 2007, and the key Senate supporters are reported to be poised to press ahead in the next Congress. *See, e.g.*, Donald Zuhn, *Senate Patent Reform Legislation – One Old Bill and One New Bill*, PATENT DOCS, Aug. 11, 2008, http://www.patentdocs.net/patent_docs/2008/08/senate-patent-r.html.

THE INEQUITABLE CONDUCT DEFENSE SHOULD BE RETAINED

Several fundamental realities militate against abrogating the doctrine of inequitable conduct. Patent quality is widely perceived as lacking. Some applicants or their representatives do engage in egregious misconduct. And other existing and proposed enforcement mechanisms are deficient or problematic.

There is a Crisis of Confidence in the U.S. Patent System

If the recent press coverage of the patent system is an accurate reflection, patent quality is the most significant problem faced by the U.S. patent system.⁸ In fact, the importance of improving patent quality may be the only patent reform-related issue on which there is widespread agreement. Concerns about patent quality emanate from scholars,⁹ members of Congress,¹⁰ policy groups,¹¹ practitioners,¹² consumer and industry

⁸ See Lisa A. Dolak & Blaine T. Bettinger, *The United States Patent System in the Media Mirror*, 58 SYR. L. REV. 459, 488 (2008) (reporting results of a study of recent major newspaper coverage of the patent system).

⁹ See, e.g., ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT 4 (2004) (“[m]any people and companies have received patents for trivial or even non-existent inventions.”); John R. Allison & Starling D. Hunter, *On the Feasibility of Improving Patent Quality One Technology at a Time: The Case of Business Methods*, 21 Berkeley Tech. L.J. 729, 789 (2006) (“[n]ot only does the PTO issue substantial numbers of low quality patents in practically all fields, but it issues many patents across all technology fields that are subsequently invalidated in litigation.”); Mark A. Lemley, Douglas Lichtman & Bhaven N. Sampat, *What to do About Bad Patents*, 28 Regulation 10 (Winter 2005-2006), <http://ssrn.com/abstract=869826> (“Bad patents are everywhere: covering obvious inventions like the crustless peanut butter and jelly sandwich, ridiculous ideas like a method of exercising a cat with a laser pointer, and impossible concepts like traveling faster than the speed of light.”); *Patent Quality Improvement: Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Prop.*, Before the H. Comm. on the Judiciary, 108th Cong. 58 (2003), http://commdocs.house.gov/committees/judiciary/hju88545.000/hju88545_0.htm (statement of John R. Thomas, Professor of Law at Georgetown University) (“[u]nfortunately, despite extraordinary efforts by the USPTO to improve patent quality, the problem [of poor patent quality] remains. Persistent accounts suggest that patent quality remains at less than optimal levels.”).

¹⁰ See, e.g., Press Release, United States Senator Patrick Leahy, *Leahy, Hatch, Berman And Smith Introduce Bicameral, Bipartisan Patent Reform Legislation*, (Apr. 18, 2007) available at <http://leahy.senate.gov/press/200704/041807a.html> (“poor patent quality has been identified as a key element of the law that needs attention”).

¹¹ See, e.g., George S. Ford, Thomas M. Koutsky & Lawrence J. Spiwak, *Quantifying the Cost of Substandard Patents: Some Preliminary Evidence* 1 (Phoenix Center for Advanced Legal & Economic Public Policy Studies Paper Number 30, 2007), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1012933 (“Under plausible assumptions, we find that the economic losses resulting from the grant of substandard patents can reach \$21 billion per year by deterring valid research with additional deadweight loss from litigation and administrative cost of \$4.5 billion annually”); 21st Century Report, *supra* note 2, at 51 (“[t]here are several reasons to suspect that more issued patents are deviating from previous or at least desirable standards of utility, novelty, and

groups,¹³ and government agencies – including the U.S. Patent and Trademark Office (USPTO).¹⁴ Even the major party presidential candidates have cited patent quality as a problem, particularly as it adversely affects innovation.¹⁵ But perhaps the most important and reliable indicator of the significance of the problem is the dissatisfaction of those who are most heavily invested in our patent system: the owners. In a 2005 survey of corporate members of the Intellectual Property Owners Association (IPO), 51.3% of responding members “rated the quality of patents issued in the U.S. today as less than satisfactory or poor . . .”¹⁶

And even if concerns about patent quality are overstated,¹⁷ it is clear, at a minimum, that quality is widely perceived as a problem. Abrogation of the inequitable

especially non-obviousness and that this problem is more pronounced in fast-moving areas of technology newly subject to patenting than in established, less rapidly changing fields.”).

¹² See, e.g., *Patent Quality Improvement Hearing*, supra note 9 (statement of Charles E. Van Horn of Finnegan, Henderson, Farabow, Garrett & Dunner LLP on behalf of the American Intellectual Property Law Association) (improving patent quality is “goal number one.”).

¹³ Brief for Public Patent Foundation, AARP, Computer & Communications Industry Association, Consumer Watchdog, Essential Action, Initiative for Medicines, Access & Knowledge, Prescription Access Litigation, Public Knowledge Research on Innovation, and Software Freedom Law center, as Amici Curie Supporting Appellants, *Tafas v. Dudas*, 541 F.Supp.2d 805 (2008) (Nos. 1:07cv846, 1:07cv1008), 2008 WL 904800 (“[f]urther, the over-patenting that results from low patent quality leads to thickets of patents that bury first inventors with countless small improvement patents claimed by others.”).

¹⁴ FED. TRADE COMM’N, *TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY* (2003), available at <http://www.ftc.gov/os/-2003/10/innovationrpt.pdf>; Press Release, U.S. Patent and Trademark Office, *USPTO to Publish Measures to Improve Patent Quality: Claims and Continuations Rules Will Improve Effectiveness and Efficiency of Patent Examination* (Aug. 20, 2007), <http://www.uspto.gov/web/offices/com/speeches/07-33.htm> (according to John Dudas, then Under Secretary of Commerce for Intellectual Property, the proposed changes would “better focus examination and will bring closure to the examination process more quickly, while ensuring quality and maintaining the right balance between flexibility for applicants and the rights of the public.”).

¹⁵ JohnMcCain.com, *Technology*, <http://www.johnmccain.com/Informing/Issues/cbcd3a48-4b0e-4864-8be1-d04561c132ea.htm> (last visited Sept. 15, 2008) (“[T]he lack of an affordable, reliable means to ensure that the Government only grants valid patents has led to overly broad, frivolous lawsuits designed to force innovative companies into big settlements.”); Barack Obama and Joe Biden, *Technology*, <http://www.barackobama.com/issues/technology/> (last visited Sept. 15, 2008) (“[G]iving the Patent and Trademark Office (PTO) the resources to improve patent quality and opening up the patent process to citizen review will reduce the uncertainty and wasteful litigation that is currently a significant drag on innovation.”).

¹⁶ Press Release, Intellectual Property Owners Association, *U.S. Patent Quality Questioned in Industry Poll: Patent Litigation Costing More* (Sept. 13, 2005), <http://www.ipo.org/AM/Template.cfm?Section=Home&Template=/CM/ContentDisplay.cfm&ContentID=1659> .

¹⁷ Some worry that the proposed reforms are unnecessary and potentially harmful. See, e.g., Douglas E. Schoen, Editorial, *Protecting U.S. Patents Should be Top Priority*, BALTIMORE SUN, Feb. 21, 2008 at 17 (“[R]ather than overhaul the system that has fostered more than 200 years of technological breakthroughs, lawmakers ought to devote their energies to strengthening U.S. patents against the threats posed by foreign

conduct doctrine would only exacerbate this perception and, in some cases, result in illegitimate patent grants.¹⁸

Inequitable Conduct Happens!

There is no question that inequitable conduct allegations drain resources and inject uncertainty into litigation. And, no doubt, the defense is overpled. But it is also undeniable that serious breaches of the duty of candor occur.¹⁹

Furthermore, the reported instances of inequitable conduct represent only a small fraction of the cases which involve credible evidence of inequitable conduct. Most such cases presumably settle before trial. Accordingly, the inequitable conduct doctrine, like other defenses to patent infringement, curtails litigation in some cases, and presumably tends to function most efficiently where the evidence is the most compelling and the allegations the most meritorious. Eliminating the defense would lead to an increase in the instances of successful enforcement of patents procured through deception, and, likely, an increase in attempts to mislead the USPTO.

counterfeiters.”); Press Release, Biotechnology Industry Organization, *Study Finds Lack of Evidence to Support Draconian Efforts to Weaken Patent Rights* (Jan. 31, 2008), http://www.bio.org/news/newsitem.asp?id=2008_0131_02 (citing study conclusions that “contrary to the assertions of the industry proponents of the pending patent reform legislation, the evidence contained in [the three reports most often relied upon] actually demonstrates that the current patent system is working well to promote innovation.”); *Chief Intellectual Property and Licensing Officer for InterDigital Communications Bernstein Testifies on Patent Reform Before Senate Judiciary Committee*, U.S. Federal News, June 6, 2007, available at 2007 WLNR 20182240 (“In InterDigital’s view, claims [of a broken patent system with poor quality patents] are grossly exaggerated and dangerous in their potential impact on our patent system.”).

¹⁸ See Christopher Cotropia, *Modernizing Patent Law's Inequitable Conduct Doctrine*, Berkeley Tech. L.J. (forthcoming 2009), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1139424 (articulating how and why the inequitable conduct doctrine affects patent quality).

¹⁹ See, e.g., *Applied Materials, Inc. v. Multimetrix, LLC*, 2008 WL 2892453 (N.D. Cal. July 22, 2008) (holding patent unenforceable for inequitable conduct based on the submission of signature forged after the inventor’s death); *Armament Systems & Procedures, Inc. v. IQ Hong Kong Ltd.*, No. 00-C-1257, 2007 WL 2154237, at *22 (E.D. Wis. July 24, 2007) (patent unenforceable for inequitable conduct after judge concluded that a drawing submitted as part of a Rule 131 declaration and dated 1997 was actually drawn in 2002); *Grefco, Inc. v. Kewanee Industries, Inc.*, 499 F. Supp. 844 (D. Del. 1980) (holding patent unenforceable as procured through fraud where the patentee misrepresented test results and told the examiner that the invention had been successfully tested when in fact it had actually failed two tests), *aff’d without publ. opinion*, 671 F.2d 495 (3d Cir. 1981).

Concerns that patent applicants might be tempted to misrepresent essential facts have motivated aspects of our patent policy for more than 100 years. See, e.g., Lisa A. Dolak, *Patents Without Paper: Proving a Date of Invention with Electronic Evidence*, 36 HOUS. L. REV. 472, 496 (1999).

Other Proposed Enforcement Mechanisms are Unsatisfactory

It is not clear how some of those who advocate abrogation of the defense²⁰ propose to deal with these consequences.²¹ Others suggest that alternative existing enforcement mechanisms and doctrines would suffice to deter misconduct and protect the integrity of the prosecution system.²² But each of the alternatives has significant limitations. Not all of the misconduct which would undermine the integrity of the patent prosecution system would qualify the affected claims for invalidation. Likewise, the potential for USPTO practitioner disciplinary action would deter/punish some, but not all, of the affirmative misrepresentations and willful omissions applicants might be tempted to make.²³ And other identified remedies – such as antitrust, unfair competition, common law fraud, and tortious interference claims²⁴ – are affirmative claims for relief which require the proof of elements beyond those required to establish the defense of inequitable conduct.

²⁰ See, e.g., John F. Lynch, “An Argument for Eliminating the Defense of Patent Unenforceability Based on Inequitable Conduct,” 16 AIPLA Q.J. 7, 10-12 (1988) (arguing that the doctrine should be eliminated because, among other articulated reasons, it is “subjective” and the concepts of materiality and intent are “vague.”).

²¹ For example, it has been argued that the doctrine “has ceased to serve a useful purpose in our patent system” because “patent applications are no longer secret.” See, e.g., Hearings on H.R. 1908, *supra* note 3 (Sharer statement). However, aside from the fact that some patent applications are still held in secrecy, for numerous reasons, patent application publication does not guarantee that misconduct will come to light. For one thing, opportunities for interested parties to challenge bad patents in the USPTO remain limited. For another, even full-blown federal court litigation may not succeed in exposing prosecution misconduct (but the threat of potential unenforceability may deter such activity).

²² See, e.g., 21st Century Report, *supra* note 2, at 122-23 (“If invalidity, disciplinary action, and reputational concerns are not sufficient deterrent to misconduct, other civil and even criminal remedies exist—antitrust, unfair competition, common law fraud, and tortious interference. Moreover, since the creation of the inequitable conduct doctrine by the courts, other safeguards have been adopted by Congress and the USPTO to support the integrity of the patent system. These include third-party- and USPTO-initiated re-examination on withheld prior art, publication of pending applications, and third-party access to pending prosecution papers and the ability to submit material information.”).

²³ The conduct of inventors and other persons associated with the patent applicant can qualify as inequitable conduct. See, e.g., *Dippin’ Dots, Inc. v. Mosey*, 476 F.3d 1337 (Fed. Cir. 2007) (inventor submitted a sworn statement that initial sales of the ice cream were in March of 1988 despite selling the product starting in July 1987); *Pharmacia Corp. v. Par Pharmaceutical, Inc.*, 417 F.3d 1369 (Fed. Cir. 2005) (inventor submitted a 37 C.F.R. § 1.132 declaration that conflicted with a paper the inventor had co-authored, but failed to bring the paper to the attention of the examiner).

A review of precedential decisions of the Federal Circuit affirming inequitable conduct determinations during the period January 2006 through August 2008 reveals that in six out of 10 cases, the court attributed at least some of the misconduct in question to someone (e.g., an inventor) other than the patent practitioner.

²⁴ See 21st Century Report, *supra* note 22.

Another proposed alternative mechanism would transfer the authority to adjudicate most inequitable conduct charges to a new tribunal within the USPTO.²⁵ However, at a time when the USPTO is under fire for how it carries out its existing responsibilities, it is not clear that creating a new enforcement bureaucracy inside the agency is advisable.²⁶ Furthermore, there is no reason to believe that the USPTO is better qualified to apply the applicable standards for evaluating alleged applicant misconduct than the federal courts.²⁷

RECOMMENDATIONS FOR REFORM

For the above reasons, elimination of the inequitable conduct doctrine would be bad policy. However, that the doctrine should be revised is just as certain. But what change is appropriate? At a minimum, the following changes should be implemented.

1. Prosecution conduct should be judged in the courts by the standards which govern applicants and practitioners inside the USPTO.

Currently, patent owners are subject to different materiality standards in the USPTO and the courts. The Federal Circuit has not only declined to adopt the “new” Rule 56 materiality standard (thus denying accused practitioners and parties the comfort of its relative clarity), but has expressly reaffirmed its 1984 decree that no “single standard” will govern materiality determinations in the court’s inequitable conduct analysis.²⁸ This decision effectively displaces the agency’s standard, except that, because of the consequences that may result from a court finding that a particular piece of withheld or omitted information was relatively more material,²⁹ it adds complexity and

²⁵ See Patent Reform Act of 2005, H.R. 2795, 109th Cong. (1st Sess. 2005).

²⁶ See, e.g., Joseph N. Hosteny, *Litigator’s Corner: The Patent Reform Act and Inequitable Conduct*, IPO (March 2006), available at <http://www.hosteny.com/archive/Hosteny%2003-06.pdf> (“The Patent Reform Act of 2005, H.R. 2795, would make major changes to how inequitable conduct is handled. But unfortunately, it wouldn’t make the changes that need to be made On the contrary, [the subject inequitable conduct provision] complicates things and adds delay.”).

²⁷ See, e.g., Steven R. Ludwig, Ted J. Ebersole & Donald J. Featherstone, *U.S. Patent Reform and the Future of Nanotechnology*, 20 THE LEGAL BACKGROUNDER 1 (2005), available at <http://www.wlf.org/upload/081205Ludwig.pdf> (“The Patent Act of 2005 would transfer determinations of inequitable conduct to the USPTO. While many companies support decreasing litigation costs, many wonder whether such a transfer of jurisdiction achieves this goal. Moreover, the USPTO may not have the resources and investigatory procedures to properly develop evidence to competently rule on these issues.”).

²⁸ *Digital Control Inc. v. Charles Machine Works*, 437 F.3d 1309, 1315 (Fed. Cir. 2006) (citing *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1363 (Fed. Cir. 1984) (“There is no reason . . . to be bound by any single standard”)).

²⁹ See *infra* notes 44-45 and accompanying text.

expense to the litigation of inequitable conduct by encouraging accused infringers and forcing patentees to litigate the issue under both standards.

Congress should redefine materiality with a standard that binds both the courts and the USPTO, and that standard should be at least as specific and objectively determinative as the current Rule 56 standard.

2. Only conduct which undermines the integrity of the prosecution process should qualify for judicial sanction.

Under current law, inequitable conduct charges can be based on information completely immaterial to patentability. For example, in *Ulead Sys., Inc. v. Lex Computer & Mgmt. Corp.*,³⁰ a split panel of the Federal Circuit held that an unjustifiable claim of entitlement to small entity status and accompanying payment of insufficient maintenance fees was material as a matter of law.³¹ And in *Gen. Electro Music Corp. v. Samick Music Corp.*³², the Federal Circuit upheld a jury finding of materiality based on a statement – found false – that a “search” had been made in a petition to make special.³³

Thus, *Ulead* and *Gen. Electro* support the general proposition that inequitable conduct can be based on gaining an advantage³⁴ before the PTO if the gain is based on a deceitful misrepresentation. Instead, the qualifying conduct should be limited to acts which undermine the *substantive* examination function of the USPTO – conduct which, objectively viewed – could reasonably have induced the USPTO to err in the application of a substantive patentability requirement, i.e., novelty, nonobviousness, utility, statutory subject matter, or compliance with the disclosure or definiteness requirements of Section 112.

3. The evidentiary standards governing intent findings should be revised.

The Federal Circuit’s inequitable conduct intent prong jurisprudence has, of late, been the target of increasing criticism.³⁵ The split panel’s decision in *Ferring B.V. v.*

³⁰ 351 F.3d 1139 (Fed. Cir. 2003).

³¹ *Id.* at 1146.

³² 19 F.3d 1405 (Fed. Cir. 1994).

³³ *Id.* at 1411.

³⁴ For example, maintenance of an issued patent (*Ulead*) or early issuance (*Gen. Electro*).

³⁵ See e.g., *Ferring B.V. v. Barr Laboratories, Inc.* 437 F.3d 1181, 1202-03 (Fed. Cir. 2006) (Newman, J., dissenting) (“[T]here is a wide gulf between a rule that intent ‘may’ be inferred by a jury upon consideration of all the circumstances, in accordance with *Kingsdown [Med. Consultants, Ltd. v. Hollister, Inc.]*, 863 F.2d 867 (Fed. Cir. 1988)], and a rule that intent ‘must’ be inferred as a matter of law against a party opposing summary judgment, based solely on a material omission, in violation of *Kingsdown* and in

*Barr Laboratories, Inc.*³⁶ is the focal point of much of the criticism,³⁷ and with good reason. In *Ferring*, the determination of inequitable conduct was based upon withheld information – itself not directly bearing on substantive patentability – which information the majority held the applicants “knew or should have known”, and which was regarded as “highly material”, thus justifying an inference of deceptive intent.³⁸ Moreover, the majority upheld the district court’s conclusion that there was no genuine issue of fact as to any of this.³⁹

Ferring thus exemplifies the type of inequitable conduct “snowball” that can result under recent Federal Circuit interpretations. Notably, the court appears to be cognizant of the problem. In its most recent⁴⁰ inequitable conduct decision, *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*,⁴¹ the panel emphasized that a “district court may infer facts supporting an intent to deceive from indirect evidence. But no inference can be drawn if there is no evidence, direct or indirect, that can support the inference.”⁴²

Admittedly, whenever subjective intent is at issue, the lines that separate reasonable inferences from conjecture are not always easy to draw. For this reason, a renewed and invigorated emphasis should be placed on carefully evaluating evidence of good faith proffered by the patentee.

violation of the rules of summary judgment.”); James E. Hanft & Stacey S. Kearns, *The Return of the Inequitable Conduct Plaque: When “I Did Not Know” Unexpectedly Becomes “You Should Have Known”*, 19 No. 2 INTEL. PROP. & TECH. L.J. 1, 3 (2007) (“Materiality and intent are separate components of inequitable conduct and require clear and convincing evidence for each. Intent to deceive can be inferred from circumstantial evidence, especially from the facts and circumstances of a knowing failure to disclose material information. While inferences may be drawn from circumstantial evidence, an inference based on a should-have-known standard given these facts is not an inference based on circumstantial evidence.”).

³⁶ 437 F.3d 1181 (Fed. Cir. 2006).

³⁷ See, e.g., Hanft, *supra* note 35, at 4 (“The interesting aspect of this case is that the court acknowledged that materiality does not presume intent, which is a separate and essential component of inequitable conduct, but then stated that ‘[i]n a case such as this, when the materiality of the undisclosed information is relatively low, there is less basis for inferring intent from materiality alone.’ The only other evidence of intent was found only ‘marginally related’ to the determination of intent to deceive. This implies that, if the court found the undisclosed information to be moderately or highly material, then intent would be inferred based on materiality alone. Such an inference, once again, does not hold up to the clear-and-convincing-evidence standard emphasized in *Kingsdown*.”).

³⁸ *Ferring B.V. v. Barr Laboratories, Inc.*, 437 F.3d at 1187-94.

³⁹ *Id.*

⁴⁰ As of this writing.

⁴¹ *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, ___ F.3d ___, ___, 2008 U.S. App. LEXIS 18160 (Fed. Cir., August 25, 2008).

⁴² *Id.* at *26 (setting aside the district court’s finding of deceptive intent).

In this regard, the most important directive in *Star Scientific* is this:

[I]nferences drawn from [less-than-clear-and-convincing evidence] cannot satisfy the deceptive intent requirement. Further, the inference must not only be based on sufficient evidence and be reasonable in light of that evidence, but *it must also be the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard.*⁴³

A firm resolve on the part of the courts to carefully observe this dictate should go a long way toward limiting erroneous deceptive intent findings and affirmances. But successful implementation of a more rigorous intent standard, whether imposed by or on⁴⁴ the Federal Circuit, would depend on the commitment of the Federal Circuit to speak with one voice. Panels must strictly observe the “Rule of Newell”⁴⁵ and resist the temptation to articulate new and different formulations of the governing standards. Non-panel members must aid their colleagues by carefully scrutinizing precedential opinions before they issue, and take steps to prevent the issuance of opinions which relax or undermine what should be a very exacting standard.

4. Courts should abandon the materiality-intent balancing inquiry.

It is black-letter law, recently reinvigorated by the Federal Circuit, that district courts must undertake an equitable balancing of the evidence of materiality and intent in a given case “to determine whether a finding that inequitable conduct occurred is warranted.”⁴⁶ On many occasions, the court has explained how that balancing can affect the ultimate conclusion on the issue of inequitable conduct, namely, that where the

⁴³ *Id.* at *19-20 (emphasis added) (citing *Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 528 F.3d 1365, 1376 (Fed. Cir. 2008) (“Whenever evidence proffered to show either materiality or intent is susceptible of multiple reasonable inferences, a district court clearly errs in overlooking one inference in favor of another equally reasonable inference.”)).

⁴⁴ I.e., by Congress.

⁴⁵ *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 765 (1988) (“This court has adopted the rule that prior decisions of a panel of the court are binding precedent on subsequent panels unless and until overturned *in banc.*”).

⁴⁶ *Novo Nordisk Pharm., Inc., v. Bio-Technology Gen. Corp.*, 424 F.3d 1347, 1359 (Fed. Cir. 2005); *see also* *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1366 (Fed. Cir. 2001) (describing the two steps of the inequitable conduct analysis as “first, a determination of whether the withheld reference meets a threshold level of materiality and intent to mislead, and second, a weighing of the materiality and intent in light of all the circumstances to determine whether the applicant’s conduct is so culpable that the patent should be held unenforceable”); *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 551 (Fed. Cir. 1990) (“A threshold showing of both materiality and intent to mislead or deceive must be first established, and then those fact-findings are balanced to make the determination whether ‘the scales tilt to a conclusion that inequitable conduct occurred.’” (quoting *J.P. Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553, 1560 (Fed. Cir. 1984))).

materiality of the omission or misrepresentation is high, a lesser showing of intent is required.⁴⁷

As a practical matter, however, because varying degrees of materiality can often be discerned, but direct evidence of deceptive intent is rarely available, this “balancing” inquiry almost exclusively serves to bolster intent findings and affirmances in certain cases. Thus, it exacerbates the problem of lax application of the intent standard.

Furthermore, balancing materiality and intent is not a necessary facet of a regime committed to drawing only the most reasonable inferences and fully crediting plausible good faith explanations. Materiality and intent should be entirely separate threshold inquiries, and remain independent of one another throughout the analysis.

Finally, de-coupling the materiality and intent prongs would not undermine the essential equitable nature of the inequitable conduct doctrine. Trial courts should continue to be authorized to use their discretion to evaluate the quality and quantity of the evidence of each to determine, on particular facts, whether a determination that inequitable conduct has occurred is warranted. Even under current law, such a determination does not necessarily follow from findings that material information was withheld or misrepresented with deceptive intent.⁴⁸ But in appropriate circumstances, where materiality and intent are independently established by clear and convincing evidence, the inherent equitable authority of the federal courts to deny relief to those who enter the court with unclean hands should be preserved and respected.

5. Trial judges should be permitted to tailor the remedy to the circumstances.

The one-size-fits-all remedy of total unenforceability deprives the courts of the ability to tailor the “punishment” to the offense. Recent reform proposals would expand the possible remedies for inequitable conduct. For example, S. 1145 would have authorized courts to impose “1 or more of” several potential remedies, including “[h]old[ing] the patent unenforceable”, “hold[ing] 1 or more claims of the patent unenforceable”, and “order[ing] that the patentee is not entitled to equitable relief and that the sole and exclusive remedy for infringement of the patent shall be a reasonable

⁴⁷ See, e.g., *Bristol-Myers Squibb Co. v. Rhone Poulenc Rorer, Inc.*, 326 F.3d 1226, 1234 (Fed. Cir. 2003); *Baxter Int’l Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1328 (1998).

⁴⁸ See, e.g., *Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A.*, 464 F.3d 1339 (Fed. Cir. 2006). In *Kemin Foods*, the jury, acting in an advisory capacity, had found that the president of the owner of one of the patents-in-suit had withheld a reference with intent to deceive the USPTO. The Federal Circuit, though, affirmed the district court’s determination that the patent was not unenforceable, on the ground that the reference “was not highly material and that the showing of deceptive intent was not compelling.” According to the court, “[e]ven when a court finds that the patentee failed to disclose material information to the [USPTO] and acted with deceptive intent, the court retains discretion to decide whether the patentee’s conduct is sufficiently culpable to render the patent unenforceable.” *Id.* at 1347.

royalty.”⁴⁹ Such flexibility would appropriately reflect the reality that some misconduct is more egregious and deleterious than other misconduct. And giving the courts the power to sanction misbehaving patentees without necessarily wiping out all of the claims of the patent at issue, would lessen the incentives for frivolous assertions of inequitable conduct, or at least undermine the leverage of those accused infringers who seek to take advantage of the distorting effects of inequitable conduct allegations in litigation.

Authorizing courts to select from a menu of potential sanctions would, of course, add its own complexity and expense to the litigation of inequitable conduct allegations. But if such flexibility were adopted in combination with other reforms, such as those discussed above, the result should be a reduction, overall, in the frequency and burdens of litigating the issue.

6. Patentees who prevail on the issue of inequitable conduct could be awarded attorney fees.

Finally, as a further deterrent to frivolous or nuisance prosecution misconduct allegations, it may make sense to implement a fee-shifting provision in favor of patentees who prevail on the issue, for example, an automatic award of inequitable conduct-related attorney fees to a plaintiff who prevails on inequitable conduct, regardless of whether the patentee wins on infringement and validity.

CONCLUSION

To the extent that calls to eliminate the inequitable conduct doctrine or strip the courts of the authority to adjudicate such allegations stem from dissatisfaction with aspects of the Federal Circuit’s jurisprudence, the appropriate solution is to hone the doctrine, by congressional dictate if necessary. Abrogation would be appropriate, on the other hand, if there were a consensus that the doctrine serves no purpose. Given that the primary impetus behind calls for elimination of the doctrine is the former, the patent system is best served by efforts aimed at achieving a well-designed, well-implemented inequitable conduct doctrine.

⁴⁹ S. 1145, 110th Cong. (1st Sess. 2007).