

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

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

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

v.

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

and

BAYER HEALTHCARE LLC,
Defendant-Appellee.

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

**ABBOTT DIABETES CARE, INC. AND ABBOTT LABORATORIES’
BRIEF ON REHEARING EN BANC**

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2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

None

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by me are:

None

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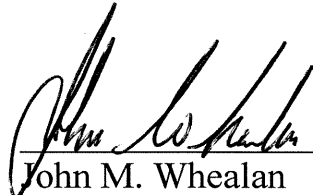
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STATEMENT OF RELATED CASES

There have been no prior appeals from the district court proceedings. All related cases except one were consolidated in this appeal. Another appeal from the same district court proceedings was decided by this Court in case numbers 2009-1009, 1010, 1034, 1035, 1036, & 1037 (consolidated) on January 25, 2010. *Therasense, Inc. (now known as Abbott Diabetes Care, Inc.) and Abbott Laboratories v. Becton, Dickinson and Company, and Nova Biomedical Corporation*, 593 F.3d 1325 (Fed. Cir. 2010) (Linn, J., Friedman & Dyk, JJ.).

Plaintiffs-Appellants Abbott Diabetes Care, Inc. and Abbott Laboratories respectfully submit this brief in response to the Court’s order of April 26, 2010.

INTRODUCTION AND SUMMARY OF ARGUMENT

The question in this case is not whether to *reform* the doctrine of inequitable conduct, but whether to *restore* it—to its origins in Supreme Court precedent; to the confines Congress intended in the 1952 Patent Act; to the standards this Court articulated *en banc* in *Kingsdown Medical Consultants v. Hollister, Inc.*, 863 F.2d 867 (Fed. Cir. 1988); and to the standards that govern in other areas of law. This Court has expanded the inequitable conduct doctrine well beyond those boundaries, and the result has been an “ongoing pandemic” of inequitable conduct charges. *Taltech Ltd. v. Esquel Enters. Ltd.*, 604 F.3d 1324, 1335 (Fed. Cir. 2010) (Gajarsa, J., dissenting). The expansion has rendered valuable patents unenforceable based on minor omissions far afield from the doctrine’s purposes. And it has converted the federal courts into roving commissions to enforce standards of conduct before the PTO without regard to whether the alleged infractions had any impact.

I. This Court and its members have recognized the “severe”—indeed, “atomic bomb”—consequences of a finding of inequitable conduct. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed Cir. 2008); *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1349 (Rader, J., dissenting). Such a finding does not merely require judgment for the defendant in

a particular case, eliminate a particular claim, or eliminate the presumption of validity. It renders the entirety of an otherwise valid patent unenforceable. It can also result in an attorney's fees award under the "exceptional" case standard of 35 U.S.C. § 285, and has potentially ruinous consequences for the reputations of those involved in the patent's prosecution. *See, e.g., Aventis*, 525 F.3d at 1349-50 (Rader, J., dissenting).

Supreme Court precedent and the legal principles embodied in the Patent Act reserve those extreme consequences for the most egregious circumstances—cases where a party “obtained its patent by fraud.” *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 175, 176 (1965). As this Court has recognized, the Supreme Court has held patents unenforceable “only in cases of ‘fraud on the Patent Office.’” *Star Scientific*, 537 F.3d at 1365-66 (quoting *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 250-51 (1944)); *see Larson Mfg. Co. of S.D., Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1343 (Fed. Cir. 2009) (Linn, J., concurring). A party seeking to invalidate a trademark or copyright based on misconduct before the agency must prove it was the product of fraud. The standard should be no less stringent here.

The PTO and the Department of Justice have ample tools to redress misconduct that falls short of that standard. Moreover, imposing the drastic consequences of unenforceability where the patent was not obtained by fraud distorts the

patent prosecution process. It encourages applicants either to overwhelm the PTO with prior art, prior pleadings, and now attorney argument in the foreign prosecution of prior art (while commenting as little as possible on those submissions), or to provide no prior art at all for fear that a selective presentation may later be challenged as misleading. And it multiplies the quantity and costs of litigation.

II. Even apart from the requirements of fraud, this Court's *en banc* decision in *Kingsdown* properly requires powerful proof of scienter: “[T]he involved *conduct*, in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability *to require a finding of intent to deceive.*” 863 F.2d at 876 (emphasis added). The required intent cannot be inferred from materiality, and deceptive intent must be “the single most reasonable inference ... from the evidence.” *Star Scientific*, 537 F.3d at 1366. Sound precedent and policy support those requirements. *Kingsdown* articulated the governing standard over 20 years ago to stem a “plague” of inequitable conduct charges. 863 F.2d at 876 n.15. A return to *Kingsdown*'s intent standard will help restore the inequitable conduct doctrine to its proper bounds.

III. “In patent cases, ‘materiality’” is most properly interpreted to require proof that, “if the Patent Office had been aware of the complete or true facts, the challenged claims would not have been allowed.” *Norton v. Curtiss*, 433 F.2d 779, 794 (C.C.P.A. 1971). That standard of but-for causation reflects Supreme Court

precedent; applies in other areas of law like trademark and copyright; and helps limit the judiciary to its proper role.

IV. This Court should eliminate the sliding-scale approach that allows stronger proof of materiality to lower the burden for proving intent, and vice-versa. That framework conflates, and thereby dilutes, *both* the intent requirement and the materiality requirement. It has produced a “should have known” standard for intent that sounds not in deceit but in negligence. It has been invoked to dilute the materiality requirement from but-for causation to a lower threshold—whether “a reasonable examiner would have considered the information important,” even where the information did not affect patentability. And it makes predictability nearly impossible to achieve. By undermining *Kingsdown* and the requirements for inequitable conduct, the sliding scale “returned” this Court “to the ‘plague’ of encouraging unwarranted charges of inequitable conduct.” *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 926 (Fed. Cir. 2007) (Newman, J., dissenting). The inequitable conduct doctrine has an important role in patent law. But it is a limited role that can be served effectively, and without destroying other important values, only if the doctrine is restored to its proper confines.

V. The multiple opinions in this case illustrate the difficulties that arise when courts infer intent from materiality, when the materiality standard itself is diluted, and when the analysis all turns on a sliding scale that is as indeterminate as

it is unsupported. The Court should restore inequitable conduct to its proper bounds and reverse the finding of inequitable conduct and resulting attorney’s fees award in this case.

ARGUMENT

I. Courts May Render a Patent Unenforceable for Inequitable Conduct Only Where the Patent Was Procured Through Conduct Tantamount to Fraud

A. Supreme Court Precedent Recognizes Inequitable Conduct Only in Cases of Egregious, Fraud-Like Conduct

1. This Court’s “inequitable conduct” doctrine originated in three Supreme Court decisions—*Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944); and *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945). In those foundational cases, the Supreme Court “refused to enforce [the] patents” at issue because “the patentees had engaged in fraud in order to procure those patents.” *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1315 (Fed. Cir. 2006). Collectively, those cases make clear that the extreme remedy of unenforceability is justified only where the patent was obtained by outright fraud or similar conduct.

In *Keystone*, for example, the applicant engaged in bribery and fraud to “suppress the evidence” of another inventor’s disqualifying prior use of the invention. 290 U.S. at 244. The patentee “had learned of [the] possible prior use”

the winter before filing his application, yet deliberately withheld evidence of it from the PTO. *Id.* at 243. When counsel advised that the “prior use . . . was sufficient to cast doubt on the validity of the patent” in pending litigation, *id.*, the patentee tried to conceal it through a “corrupt transaction”: He gave the prior user “valuable considerations” in exchange for (1) a false affidavit that his use was an “abandoned experiment” and (2) his agreement “to keep secret the details of the prior use.” *Id.* at 243-44. Invoking the doctrine of “unclean hands,” the Supreme Court denied the patentee’s request for injunctive relief because his “unconscionable act” had such an “immediate and necessary relation to the equity that he seeks in respect of the matter in litigation.” *Id.* at 245.

In *Hazel-Atlas*, the Supreme Court again addressed a “deliberately planned and carefully executed scheme to defraud not only the Patent Office but the Circuit Court of Appeals.” 322 U.S. at 245. Confronted by “apparently insurmountable Patent Office opposition” to its application, the applicant’s agents wrote an article hailing the invention as “a remarkable advance in the art.” *Id.* at 240. They then convinced Clarke—an “ostensibly disinterested expert”—to publish it as his own in a trade journal. *Id.* The article “was introduced as part of the record in support of the pending application,” which “the Patent Office granted.” *Id.* at 240-41. In infringement proceedings, the court of appeals relied heavily on the “spurious article” in holding the patent “valid and infringed.” *Id.* at 241. After judgment, the

patentee procured perjury to cover its tracks: When the alleged infringer sought to question Clarke about the article, the patentee convinced Clarke falsely to “reinforce[] his claim of authorship”; Clarke was later paid \$8,000 for doing so. *Id.* at 242, 243.

When the truth emerged in a criminal antitrust suit, the defendant sought vacatur of the judgment against it. 322 U.S. at 243-44. After recounting the misconduct, the Supreme Court concluded that the “total effect of all this *fraud*, practiced on both the Patent Office and the courts,” warranted “a complete denial of relief ... for the claimed infringement of the *patent thereby procured and enforced.*” *Id.* at 250 (emphasis added). Because the case involved “a patent obtained by fraud,” the Court encouraged the government to bring a “direct proceeding” to “vacate[] the patent so as “[t]o grant full protection to the public.” *Id.* at 251.

One year later, the Supreme Court decided *Precision Instrument*, a case in which “the history of the patents” was again “steeped in perjury and undisclosed knowledge of perjury.” 324 U.S. at 816. In that case, Larson and his company (Precision Instrument) developed a wrench using information stolen from another inventor, Zimmerman, and his employer (Automotive Maintenance). When the PTO declared an interference between Larson’s and Zimmerman’s patent applications, Larson filed a “preliminary statement in the Patent Office” in which

he “gave false dates as to the conception, disclosure, drawing, description and reduction to practice of his claimed invention,” purporting to “antedate those” in Zimmerman’s application. *Id.* at 809-10. Nine witnesses testified in support of those false priority claims. *Id.* at 810. Automotive learned of the fraud, but declined to take “the matter up with the Patent Office,” *id.* at 810, instead forcing Larson to settle the interference proceeding, *id.* at 813-14. Automotive thereby “secured the perjured Larson application” for itself, “made numerous changes and expansions as to the claims,” and “eventually secured a patent on it.” *Id.* at 819. When Automotive sued Precision Instrument for infringement, the Supreme Court held that the doctrine of unclean hands barred Automotive’s suit. *Id.* The public, the Court held, has “a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud” and “are kept within their legitimate scope.” *Id.* at 816. Because the “patent claims [were] infected with fraud,” Automotive was barred from proceeding. *Id.* at 819.

As the Supreme Court has observed, those three cases stand for the proposition that a defendant “sued for infringement can challenge the validity of the patent” on grounds of “*fraudulent procurement.*” *Walker Process*, 382 U.S. at 176 (emphasis added); *see also Star Scientific*, 537 F.3d at 1365-66 (“cases of ‘fraud on the Patent Office’”) (quoting *Hazel-Atlas*, 322 U.S. at 250-51); *Norton*, 433 F.2d at 792 n.12 (cases allow “a private party to assert that a patent has been procured by

fraud practiced on the Patent Office”). Those cases did not involve missteps in making the legally and factually complex decisions applicants regularly make (such as whether to submit marginal prior art or potentially cumulative material). Nor were they “mere” cases of fraud. They were extreme cases of blatant misconduct involving perjury, fabricated evidence, and bribery—“conduct so reprehensible” that it warranted the “severe penalt[y]” of unenforceability. *Norton*, 433 F.2d at 792-93.

2. Fraud has “indispensible elements,” including (1) a false representation of material fact; (2) made with “the *intent to deceive*” or, “at least, a state of mind so reckless as to the consequences that it is held to be *the equivalent of intent (scienter)*”; and (3) “a justifiable *reliance* upon the misrepresentation by the party deceived which *induces him to act thereon.*” *Norton*, 433 F.2d at 792-93 (emphasis added); *see also Prosser & Keeton on Torts* § 105, at 728 (5th ed. 1984); Restatement (Second) of Torts § 525 (1977) (“Restatement”). In fraud contexts, the third element—denominated “reliance,” “transaction causation,” or “but-for causation”—requires proof that, but for the deceptive act, the plaintiff would not have entered into the transaction. *See, e.g., Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341-42 (2005); Restatement § 525 (injury must result from “justifiable reliance upon the misrepresentation”).

Consistent with Supreme Court precedent, this Court should require proof that the patent was issued as a result of extreme misconduct tantamount to fraud. This Court’s predecessor “evaluate[d] the evidence” of inequitable conduct “in light of the traditional elements of . . . fraud.” *Norton*, 433 F.2d at 793; *see id.* at 794 (“considering seriatim each one of the elements of . . . ‘fraud’”).¹ In *Kingsdown*, this Court emphasized the requirement of extreme conduct manifesting fraudulent intent. Sitting *en banc*, the Court held that “the involved *conduct*, in light of all the evidence, including evidence indicative of good faith, *must indicate sufficient culpability to require a finding of intent to deceive.*” 863 F.2d at 876 (emphasis added). This Court’s predecessor invoked the but-for causation standard from fraud, *i.e.*, that the patent claims “would not have been allowed *but for* the misrepresentation.” *Norton*, 433 F.2d at 795 (emphasis added). And in *Corona Cord Tire Co. v. Dovan Chemical Corp.*, 276 U.S. 358 (1928), the Supreme Court similarly required but-for proof. Although it “appear[ed], without contradiction” that the patentee there had filed false affidavits with the PTO, the Supreme Court refused to reject even the presumption of patent validity because the false affidavits were not “the basis for” or “indispensable to the granting of the patent.” *Id.* at 373-74.

¹ *Norton* (without citation to authority) purported to recognize an “expan[ded] . . . concept of ‘fraud’” to lower the required intent, 433 F.2d at 795-96, but this Court corrected that expansion *en banc* in *Kingsdown*, *see pp.* 18-20, *infra*.

B. Trademark and Copyright Impose Similarly Exacting Requirements

The “procured by fraud” standard reflected in Supreme Court precedent is followed in connection with other forms of intellectual property, including trademark, *see In re Bose Corp.*, 580 F.3d 1240 (Fed. Cir. 2009), and copyright, *see Eckes v. Card Prices Update*, 736 F.2d 859, 861-62 (2d Cir. 1984). Patents should be treated no differently.

In *Bose*, for example, this Court held that a trademark registered with the PTO may be cancelled where the “registration was obtained fraudulently.” 580 F.3d at 1243 (quoting 15 U.S.C. § 1064(3)). “A party seeking cancellation” based on “fraudulent procurement” bears “a heavy burden”—it must prove that the “registrant knowingly ma[de] a false, material representation, with the intent to deceive the PTO.” *Id.* at 1243-45. A “[s]ubjective intent to deceive, however difficult it may be to prove, is an indispensable element.” *Id.* at 1245; *see Far Out Prods., Inc. v. Oskar*, 247 F.3d 986, 996 (9th Cir. 2001); *Meineke Discount Muffler v. Jaynes*, 999 F.2d 120, 126 (5th Cir. 1993); *The Money Store v. Harriscorp Fin., Inc.*, 689 F.2d 666, 670, 673 (7th Cir. 1982). Invalidation, moreover, results only if the misrepresentation “would have constituted grounds for denial of the registration had the truth been known” to the examiner. *Citibank, N.A. v. Citibanc Group, Inc.*, 724 F.2d 1540, 1544 (11th Cir. 1984); *see also San Juan Prods., Inc. v. San Juan Pools of Kan., Inc.*, 849 F.2d 468, 473 (10th Cir. 1988).

Likewise, a copyright may not be held unenforceable unless a “*fraud* on the copyright office” is proved. *Original Appalachian Artworks, Inc. v. Toy Loft, Inc.*, 684 F.2d 821, 828 (11th Cir. 1982) (emphasis added); *see also Urantia Found. v. Maaherra*, 114 F.3d 955, 963 (9th Cir. 1997); *Advisers, Inc. v. Wiesen-Hart, Inc.*, 238 F.2d 706, 708 (6th Cir. 1956). Scierter thus is required. *Appalachian Artworks*, 684 F.2d at 828. So too is proof that the misrepresentation was causal: “Only the knowing failure to advise the Copyright Office of facts” that would have “occasioned a rejection of the application constitutes reason for holding the registration invalid.” *Eckes*, 736 F.2d at 861-62 (quotation marks omitted). The same standard should apply here. The Supreme Court has long considered copyright the “closest analogy” to patent law, and has routinely found it “appropriate to refer” to patent law in deciding copyright issues and vice-versa “because of the[ir] historic kinship” (even when the statutes differ). *Sony Corp. of Am. v. Univ. City Studios, Inc.*, 464 U.S. 417, 439 (1984); *see, e.g., eBay Inc. v. MercExchange L.L.C.*, 547 U.S. 388, 391-93 (2006).

C. Congress Adopted the “Unenforceability” Defense Against the Backdrop of a “Fraudulent Procurement” Standard

“In suits for patent infringement, unenforceability”—including “unenforceability due to fraudulent procurement”—is “a statutory defense” set forth in 35 U.S.C. § 282. *Norton*, 423 F.2d at 793. When Congress codified that defense in the 1952 Patent Act, it did so against the immediate backdrop of the Supreme

Court’s decisions in *Keystone*, *Hazel-Atlas*, and *Precision Instrument*. As explained above, those cases held patents unenforceable in egregious cases of outright fraud—bribing witnesses, falsifying evidence, and blatant perjury—perpetrated on the PTO and the courts. Under settled canons of statutory construction, Congress is presumed to have intended to incorporate those decisions. *See, e.g., Midlantic Nat’l Bank v. N.J. Dep’t of Env’tl Prot.*, 474 U.S. 494, 501 (1986).

The 1952 Act’s predecessors, moreover, had long been construed to require “something akin to proof of common law fraud or deceit.” Robert J. Goldman, *Evolution of the Inequitable Conduct Defense in Patent Litigation*, 7 Harv. J.L. & Tech. 37, 38 (1993). Each of the five enumerated defenses set forth in § 61 of the 1870 Act were encompassed within the defenses of the 1952 Act or eliminated as surplusage in light of the new defenses. P.J. Federico, *Commentary on the New Patent Act*, 75 J. Pat. & Trademark Off. Soc’y 161, 216 (1993) (reprinted from 35 U.S.C.A. (1954 ed.)). Congress cannot lightly be presumed to have intended a radical departure from prior law when it codified the “unenforceability” defense in the 1952 Patent Act. *See Finley v. United States*, 490 U.S. 545, 554 (1989); *Ankenbrandt v. Richards*, 504 U.S. 689, 700-01 (1992).

D. Unclean-Hands Principles Support a Fraud-Based Limit Where, as Here, Important Property Rights Are at Stake

Keystone and *Precision Instrument* both indicate that the “authority to render a patent unenforceable for inequitable conduct is founded in the equitable principle

that he who comes into equity must come with clean hands.” *See Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1364 n.3 (Fed. Cir. 2003) (quotation marks omitted). Consistent with the Supreme Court’s foundational decisions, that principle requires proof of overt fraud before courts will destroy a property right like a patent. The “traditional equitable principles” governing that doctrine in other contexts, *eBay*, 547 U.S. at 393, simply will not tolerate imposing the “‘atomic bomb’ remedy of unenforceability,” except where the patent was obtained by fraud or similarly egregious conduct, *Aventis*, 525 F.3d at 1349 (Rader, J., dissenting).

Even in ordinary contexts, unclean hands is an “exceptional” defense that will “rarely” be applied to “prevent[] the grant of the relief that would otherwise be appropriate.” *Polk Bros., Inc. v. Forest City Enters., Inc.*, 776 F.2d 185, 193 (7th Cir. 1985); *see also Dream Games of Ariz., Inc. v. PC Onsite*, 561 F.3d 983, 990-91 (9th Cir. 2009) (unclean hands defense to copyright infringement “recognized only rarely”); 30A C.J.S. *Equity* § 124 (“not favored”). The aversion to applying unclean hands is heightened where, as in this context, the result “would be to work a forfeiture of [the party’s] property, something which equity is always reluctant to do.” *Shinsaku Nagano v. McGrath*, 187 F.2d 753, 759 (7th Cir. 1951). Even where the party’s offense was “serious,” the “clean-hands maxim should not be applied” if the “forfeiture which would be visited upon” the party would “be

extreme.” *W. Los Angeles Inst. for Cancer Research v. Mayer*, 366 F.2d 220, 227 (9th Cir. 1966).

As in *Precision Instrument* and *Keystone*, unclean hands requires proof of “particularly egregious conduct,” *Serdarevic v. Advanced Med. Optics, Inc.*, 532 F.3d 1352, 1361 (Fed. Cir. 2008), committed with an aggravated mental state, *Dollar Sys., Inc. v. Avcar Leasing Sys., Inc.*, 890 F.2d 165, 173 (9th Cir. 1989). There must be “fraud, deceit, unconscionability, or bad faith.” *Performance Unlimited, Inc. v. Questar Publ’rs, Inc.*, 52 F.3d 1373, 1383 (6th Cir. 1995); *see also*, e.g., *Keystone*, 290 U.S. at 245 (“some unconscionable act”); *Hot Wax, Inc. v. Turtle Wax, Inc.*, 191 F.3d 813, 826 (7th Cir. 1999) (“willful, egregious, or unconscionable conduct or bad faith”); *S&R Corp. v. Jiffy Lube Int’l, Inc.*, 968 F.2d 371, 377 n.7 (3d Cir. 1992) (similar); *Eresch v. Braecklein*, 133 F.2d 12, 14 (10th Cir. 1943) (similar); *Pace v. Wainwright*, 10 So.2d 755, 756 (Ala. 1942) (“There must also be the existence of a fraudulent intent . . .”).

Likewise, unclean hands requires proof of causation—here, that the misrepresentation was the but-for cause of the patent’s issuance and the resulting injury to the alleged infringer: ““The alleged wrongdoing of the plaintiff does not bar relief unless *the defendant can show that he has personally been injured by the plaintiff’s conduct.*”” *Dream Games*, 561 F.3d at 990 (quoting *Mitchell Bros. Film Group v. Cinema Adult Theater*, 604 F.2d 852, 863 (5th Cir. 1979)) (emphasis

added); *Serdarevic*, 532 F.3d at 1361 (party must prove “that the defendant’s misconduct was responsible for” its alleged injury). Unclean hands does not apply where “the unlawful or inequitable conduct” is “merely collateral to the . . . cause of action.” *Alcatel USA, Inc. v. DGI Techs., Inc.*, 166 F.3d 772, 797 (5th Cir. 1999). And a “misdeed is regarded as ‘collateral’ . . . when the right for which the plaintiff seeks protection in the injunction suit did not accrue to him *because of the misdeed.*” Restatement § 940 cmt.c (emphasis added). Unclean hands prevents courts from becoming “abetter[s] of iniquity” by “aid[ing] a party” who has, by “fraud[]” or “deceit,” “gained an advantage” to the direct detriment of the other party. *Keystone*, 290 U.S. at 245 (quotation marks omitted). Where the conduct did not result in the patent’s issuance, that concern is not implicated.

Moreover, general principles of equity limit severe sanctions like unenforceability to the most egregious conduct so that “the remedy imposed” is “commensurate with the violation,” *Columbus Bd. of Educ. v. Penick*, 443 U.S. 449, 465 (1979), and the relief is “no broader than necessary to cure the effects of the harm,” *Soltex Polymer Corp. v. Fortex Indus., Inc.*, 832 F.2d 1325, 1329 (2d Cir. 1987).

Just as it is inequitable to permit a patentee who obtained his patent through deliberate misrepresentations or omissions of material information to enforce the patent against others, it 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.

Star Scientific, 537 F.3d at 1366.

In the area of litigation misconduct, courts treat dismissal of a case against a *single* defendant as an “extreme” remedy that is warranted only for the most outrageous misconduct. See *Shcherbakovskiy v. Da Capo Al Fine, Ltd.*, 490 F.3d 130, 140 (2d Cir. 2007); *OFS Fitel, LLC v. Epstein, Becker & Green, P.C.*, 549 F.3d 1344, 1366 n.24 (11th Cir. 2008) (dismissal “justified only in extreme circumstances and as a last resort”); Verizon Br. as *Amicus Curiae* 6-7 n.3. Courts should not more readily impose the graver sanction of holding an entire patent forever unenforceable against all infringers for alleged misconduct before the PTO.

II. Under This Court’s *En Banc* Precedent, Inequitable Conduct Requires a Showing That the Patentee Acted With Specific Intent To Deceive the PTO into Granting the Patent

Even if this Court were to extend the doctrine of inequitable conduct beyond patents obtained by fraud—and it should not—this Court’s own *en banc* precedent in *Kingsdown* independently and properly requires clear-and-convincing proof of a specific intent to deceive. Confronted by an “absolute plague” of misconduct charges precipitated by “conflicting” intra-circuit precedent, 863 F.2d at 876 & n.15, *Kingsdown* held that inequitable conduct requires proof that the applicant engaged in misconduct “with *an intent to deceive*” the PTO, *id.* at 872 (emphasis added). Given the requirement of proof by clear-and-convincing evidence, the Court stated that “the involved conduct, viewed in light of all the evidence . . . ,

must indicate sufficient culpability *to require* a finding of intent to deceive.” *Id.* at 876 (emphasis added).

Properly applied, *Kingsdown*’s intent standard helps limit unenforceability to the egregious cases that warrant such an extreme sanction. By restoring *Kingsdown*’s intent standard, the Court can also mitigate the outbreak of inequitable conduct charges that besets this Court again today. *Larson*, 559 F.3d at 1342 (Linn, J., concurring) (calling for return to *Kingsdown* intent standard); *Aventis*, 525 F.3d at 1350-53 (Rader, J., dissenting) (same); *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1195-97 (Fed. Cir. 2006) (Newman, J., dissenting) (same).

A. This Court Should Reinvigorate *Kingsdown*’s Requirement of Specific Intent To Deceive the PTO

1. In *Kingsdown*, the applicant for a continuation patent falsely represented that its claim 43 “corresponded to allowed claim 50 in the parent application.” 863 F.2d at 870. In fact, claim 43 corresponded to an earlier, unamended version of claim 50 that “had been rejected for indefiniteness.” *Id.* at 871. The continuation patent issued nonetheless. *Id.* When *Kingsdown* brought an infringement action, the district court held the patent unenforceable. *Id.* at 869. Materiality was obvious: The language accepted as claim 43 of the continuation patent previously had been *rejected* for indefiniteness. *Id.* at 871.

The district court “inferred intent” to deceive “based on what it perceived to be *Kingsdown*’s gross negligence,” 863 F.2d at 873, and it “inferred motive to

deceive the PTO” because it thought Kingsdown might have included the broader, unamended version of claim 50 in its continuation application to improve its chances in an infringement action against its competitor, *id.* at 872, 874-75. The court found it difficult to understand “how an experienced patent attorney” could have included a *rejected* claim in a “continuation application.” *Id.* at 875.

In an opinion by Chief Judge Markey, this Court reversed. Notwithstanding the glaring error and its obvious materiality, the Court held that the rigorous requirement of specific intent to deceive had not been established. The Court explained that, “[t]o be guilty of inequitable conduct, one must have *intended* to act inequitably,” *i.e.*, the patentee must have “*intended to deceive* the PTO.” 863 F.2d at 872, 873 (quoting *FMC Corp. v. Manitowoc Co., Inc.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987)) (emphasis added). In an *en banc* section of the opinion, the Court held that “conduct that amounts to ‘gross negligence’ does not of itself justify an inference of intent to deceive.” *Id.* at 876. Instead, the “involved *conduct*, viewed in light of all the evidence, including evidence of good faith, must indicate sufficient culpability *to require a finding of intent to deceive.*” *Id.* (emphasis added). The panel refused to infer such intent from a *knowing failure to disclose* material information alone. While a “knowing failure to disclose and knowingly false statements are always difficult to understand,” by themselves they are

insufficient to show the “deceitful intent element of inequitable conduct.” *Id.* at 875.

2. Since *Kingsdown*, this Court has often invoked the clear-and-convincing, ““specific intent to deceive”” standard. *Star Scientific*, 537 F.3d at 1366 (quoting *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1181 (Fed. Cir. 1995)); see *Astrazeneca Pharms. LP v. Teva Pharms. USA, Inc.*, 583 F.3d 766, 776 (Fed. Cir. 2009); *Larson*, 559 F.3d at 1340. It is not enough to show that the patentee had an “intent to take the action or omission complained of.” *Optium Corp. v. Emcore Corp.*, 603 F.3d 1313, 1320 (Fed. Cir. 2010). Rather, the patentee must have the subjective “intent to deceive or mislead the patent examiner into granting the patent.” *Id.*; see *Dayco*, 329 F.3d at 1367 (“inequitable conduct requires not intent to withhold, but rather intent to deceive”); *Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1442-43 (Fed. Cir. 1991) (despite patentee’s “admitt[ed] awareness of the withheld references,” there was “no direct evidence that [the patentee] intended to mislead the PTO by withholding references”); *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1289, 1319 (Fed. Cir. 2010) (Linn, J., concurring in part and dissenting in part) (“‘[S]pecific intent’ denotes a subjective rather than objective standard and is generally associated with actions

deliberately and consciously taken to achieve a specific result.”), *vacated pending reh’g en banc*, 2010 WL 1655391.²

Because specific intent is a subjective standard, it must be analyzed from the perspective of the applicant confronting the situation at the time the conduct occurred—not with 20-20 hindsight. The evidence must establish that, *at the time*, the applicant (1) knew of the information, (2) knew it was material to issuance of the patent, (3) made a deliberate decision to withhold or misrepresent it, and (4) intended to *deceive* the PTO. *See Star Scientific*, 537 F.3d at 1366; *Ferring*, 437 F.3d at 1200-01 (Newman, J., dissenting). The possibility that, years after the fact, a court might “later f[i]nd” that the information not disclosed was “material” under an objective standard “cannot, by itself, satisfy the deceptive intent element.” *Star Scientific*, 537 F.3d at 1366. It is the applicant’s state of mind at the time—what he believed and understood—that matters.

“While deceptive intent can be inferred from circumstantial evidence, the circumstantial evidence must still be clear and convincing.” *Larson*, 559 F.3d at

² That requirement is consistent with this Court’s construction of the “specific intent” standard in other contexts. For example, to be liable for inducing patent infringement, the defendant must have had a “specific intent to encourage another’s infringement.” *Kyocera Wireless Corp. v. ITC*, 545 F.3d 1340, 1354 (Fed. Cir. 2008) (quotation marks omitted). In that context too, “specific intent” requires not merely “intent to cause the acts that produce direct infringement,” but also “an affirmative intent to cause direct infringement.” *Id.* at 1354 (quoting *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (*en banc* in relevant part)).

1340. That clear-and-convincing standard is not met unless deceptive intent is “the single most reasonable inference able to be drawn from the evidence.” *Star Scientific*, 537 F.3d at 1366; *see also Orion IP, LLC, v. Hyundai Motor Am.*, 605 F.3d 967, 979 (Fed. Cir. 2010) (same). “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.” *Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 528 F.3d 1365, 1376 (Fed. Cir. 2008).

Finally, “it is the ‘accused infringer’—not the patentee—who ‘must prove by clear and convincing evidence that the material information was withheld with the specific intent to deceive the PTO.’” *Larson*, 559 F.3d at 1344 (Linn, J., concurring) (quoting *Star Scientific*, 537 F.3d at 1366). Thus, a “lack of a good faith explanation” cannot “constitute clear and convincing evidence sufficient to support a determination of culpable intent.” *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*, 439 F.3d 1335, 1341 (Fed. Cir. 2006). And the existence of a sufficiently plausible explanation—even negligence or inadvertence—is enough to defeat the charge. *See Leviton Mfg. Co. v. Universal Sec. Instruments, Inc.*, 606 F.3d 1353, 1362-63 (Fed. Cir. 2010); *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1348 (Fed. Cir. 2005).

3. The “great weight of Federal Circuit authority” recognizes *Kingsdown* as the appropriate intent standard. *Optium*, 603 F.3d at 1320. Nonetheless, in the decades since *Kingsdown*, this Court’s inequitable conduct law has become inconsistent as panels have overlooked *Kingsdown*’s intent standard—often in favor of the cases *Kingsdown* expressly disapproved. See *Larson*, 559 F.3d at 1343 (Linn, J., concurring). For example, four years before *Kingsdown*, a panel in *Driscoll v. Cebalo*, 731 F.2d 878 (Fed. Cir. 1984), held that the “intent” element of inequitable conduct is satisfied if the patentee “knew, or should have known, that the withheld reference would be material to the PTO’s consideration”—a standard the panel described as “gross negligence.” *Id.* at 885 (emphasis added).³ When *Kingsdown* later rejected the “gross negligence” standard *en banc*, it explicitly overruled *Driscoll*. 863 F.2d at 876. Yet, more than a decade later, *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253 (Fed. Cir. 1997), cited *Driscoll* and applied its “should have known” standard. *Id.* at 1256. Other panels followed. See, e.g., *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1313-14 (Fed. Cir. 2008); *Ferring*, 437 F.3d at 1191.

By returning to a pre-*Kingsdown* knew-or-should-have-known standard, *Critikon* and similar cases have sown confusion and created a “resurgence” of the

³ Moreover, the *Driscoll* “should have known” standard is not even gross negligence, but rather “a simple negligence standard.” *Bose*, 580 F.3d at 1244; see also *Larson*, 559 F.3d at 1343 (Linn, J., concurring).

very “plague” of inequitable conduct charges *Kingsdown* tried to stem. *Ferring*, 437 F.3d at 1202 (Newman, J., dissenting); see *Larson*, 559 F.3d at 1342 (Linn, J., concurring). To restore order, this Court must return to *Kingsdown*—a workable intent standard that kept the “plague” in check for years and achieved just results when rigorously applied.

B. Supreme Court Precedent Supports *Kingsdown*’s “Intent To Deceive” Standard

Supreme Court precedent likewise supports the *Kingsdown* standard. That Court has held patents unenforceable in only three cases—*Keystone*, *Hazel-Atlas*, and *Precision Instrument*. Each involved clear-cut evidence that the patentee obtained and sought to enforce its patent through truly exceptional misconduct—perjury, fabricating evidence, and bribing witnesses—designed to deceive the PTO and often the courts. See *Larson*, 559 F.3d at 1343 (Linn, J., concurring) (“Supreme Court’s three inequitable conduct cases” each “involved overt fraud, not equivocal acts of omission”).

Kingsdown’s requirement of a specific “intent to deceive” the PTO—and its rejection of a lesser “gross negligence” standard—brings this Court’s cases within the realm of the “egregious acts of omission and commission that have been seen as reflecting the deceitful intent element” in the Supreme Court’s precedents. *Kingsdown*, 863 F.2d at 875. Those precedents provide no support for a doctrine that renders valuable patents unenforceable simply because the patentee may have

failed to disclose information that he “should have known” was material. *See, e.g., Praxair*, 543 F.3d at 1313-14; *Ferring*, 437 F.3d at 1191; *Critikon*, 120 F.3d at 1256. The Court should not expand the extreme remedy of unenforceability to boundaries “previously unknown.” *Grupo Mexicano de Desarrollo S.A. v. Alliance Bond Fund, Inc.*, 527 U.S. 308, 332-33 (1999).

C. *Kingsdown’s* Intent Standard Is Consistent With Other Areas of Intellectual Property Law

Kingsdown finds broad support throughout intellectual property law. For example, this Court has held that a party “seeking cancellation of a trademark registration” based on misrepresentations to the PTO may prevail “only if” it proves that “the applicant or registrant knowingly ma[de] a false, material representation *with the intent to deceive the PTO.*” *Bose*, 580 F.3d at 1243, 1245 (emphasis added). Quoting *Kingsdown*, *Bose* rejected the premise that ““gross negligence”” can ““itself justify an inference of intent to deceive.”” *Id.* at 1244 (quoting 863 F.2d at 876). And the Court explained that a “should have known” standard cannot satisfy the “subjective intent” element, because it would improperly lower that element to a “simple negligence standard.” *Id.* “[H]owever difficult it may be to prove” a “[s]ubjective intent to deceive,” the Court declared, it is “an indispensable element.” *Id.* at 1245; *see also Far Out Prods.*, 247 F.3d at 996; *Meineke*, 999 F.2d at 126; *Money Store*, 689 F.2d at 670.

It would be illogical for this Court to apply *Kingsdown*'s rigorous, subjective, specific "intent to deceive" standard faithfully in trademark cases—as *Bose* requires—yet permit a watered-down standard in the patent context that gave birth to the *Kingsdown* standard. That is especially true given that "fraudulent trademark procurement" and "inequitable conduct" concern similar misconduct before *the same agency*—the PTO.

Courts similarly refuse to enforce a copyright on grounds of "unclean hands" only where the registrant acted with "scienter" and obtained the copyright through a "fraud on the copyright office." *Appalachian Artworks*, 684 F.2d at 828; *see also Eckes*, 736 F.2d at 861-62. The requisite "intent to mislead" is absent unless there has been a "*knowing* failure to advise the copyright office of facts" that would have "occasioned a rejection of the application." *Appalachian Artworks*, 684 F.2d at 828 (emphasis added); *see Lamps Plus, Inc. v. Seattle Lighting Fixture Co.*, 345 F.3d 1140, 1144-45 (9th Cir. 2003) (refusing to apply unclean hands based on failure to identify pre-existing works where applicant subjectively "believed" its lamp "was an original sculptural work"). Patent law should not stand as the lone area of intellectual property law where the standard is lower.

D. Sound Policy Considerations Support the *Kingsdown* Standard

Kingsdown's standard, moreover, strikes the correct balance. It "properly mak[es] inequitable conduct a rare occurrence," reserving the extreme sanction of

unenforceability for cases in which the intent to deceive is inescapable. *Aventis*, 525 F.3d at 1350 (Rader, J., dissenting). It clarifies that inequitable conduct is not a proper “remedy for every mistake, blunder, or fault in the patent procurement process.” *Id.* At the same time, *Kingsdown*’s intent standard can be met for those “more egregious acts of omission [or] commission” that *should* render an entire patent unenforceable. 863 F.2d at 875; *see, e.g., Advanced Magnetic Closures, Inc. v. Rome Fastener Corp.*, 607 F.3d 817, 830-32 (Fed. Cir. 2010) (*Kingsdown* intent standard met where applicant “falsely sw[ore] that he invented a device before the PTO” and “fabricated evidence to support his claim”).

1. Before *Kingsdown*, lesser intent standards were sometimes proposed on the theory that courts should be “more critical” in evaluating the “relationship of confidence and trust” between applicants and the PTO; that the PTO “must rely” on applicants given the *ex parte* nature of the claims; or that the PTO has “limited” resources. *See, e.g., Norton*, 433 F.2d at 793-94. But precisely those same claims could be made about trademark or copyright law; yet this Court and others insist on compelling proof of intentional deception in those contexts. *See pp. 25-26, supra.* The argument also misconstrues the role of the courts. It is primarily the agency’s “responsibility to police fraud consistently with the agency’s judgment and objectives.” *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 350

(2001). A low judicial threshold diminishes the agency's discretion to calibrate the practice before it through discretionary enforcement and rules refinement.

The current low judicial threshold for finding intent to deceive, combined with the potentially drastic consequences of inequitable conduct charges, has created “an incentive [for applicants] to submit a deluge of information” the PTO “neither wants nor needs” while simultaneously denying the PTO assistance in reviewing it for fear that anything they do or say may be used against them. *Cf. Buckman*, 531 U.S. at 351. As a former PTO Director testified, inequitable conduct's “uncertain” application leads to “counterproductive behavior before the USPTO,” causing some to overload the agency with information for “fear that [courts] may unfairly punish [applicants] with draconian penalties for innocently omitting information.” *Patent Reform: The Future of American Innovation, Hearing Before the S. Comm. on the Judiciary*, 110th Cong. (2007) (statement of Jon Dudas, Director of the PTO) (“Dudas”), available at http://judiciary.senate.gov/hearings/testimony.cfm?id=2803&wit_id=6506. The phenomenon is widely recognized. See ABA Section of Intellectual Property Law, *A Section White Paper: Agenda for 21st Century Patent Reform 2* (2009) (“ABA White Paper”) (“Applicants disclose too much prior art for the PTO to meaningfully consider, and do not explain its significance, all out of fear that to do otherwise risks a claim of inequitable conduct.”); Christopher A. Cotropia, *Modernizing Patent Law's*

Inequitable Conduct Doctrine, 24 Berkeley Tech. L.J. 723, 768-71 (2009) (fear of inequitable conduct charges causes inventors and patent prosecutors to “over-comply,” submitting “everything of even remote relevance in one’s possession to the USPTO,” creating “[i]nformation overload”); H.R. Rep. No. 110-314, at 42 (2007) (“to fulfill their disclosure requirement and avoid a later charge of inequitable conduct, [applicants] send the office all the prior art references they are aware of, including those that are only vaguely relevant”).

The panel decision in this case is already contributing to the deluge: One patent prosecutor explained that he submitted more than 13,000 pages of non-patent or foreign prior art “in view of” that ruling because, even though “the prosecution history of a foreign application cannot be used to construe patent claims, it may now render them unenforceable.” Patently-O, *What Does a Patent Examiner Do with 900+ References* (Jan. 28, 2009), <http://www.patentlyo.com/patent/2010/01/what-does-a-patent-examiner-do-with-900-references.html>. Law firms are now warning clients that the “safest course is to disclose every attorney argument in every related application,” even though it may often seem “unworkable.” A. Bukoye, *et al.*, *A New and Troubling Decision for Patent Owners*, Jackson Walker I.P. e-Alert (Mar. 3, 2010), <http://images.jw.com/ealert/ip/2010/0303sm.html>.

Fear of inequitable conduct charges also interferes with the ability of applicants to assist the PTO. Four years ago, the PTO proposed requiring applicants to

identify the most relevant prior art to “[c]oncentrat[e] the patent examiner’s review” on the “most pertinent” information. 71 Fed. Reg. 38,808, 38,810 (2006). But that effort failed because applicants feared that “anything an applicant does to help the examiner focus on the most relevant information during examination [will] become[] the target of an inequitable conduct charge in court.” S. Rep. No. 111-18, at 47 (2009) (supplemental views of Sen. Hatch); *see also* 154 Cong. Rec. S9991 (daily ed. Sept. 27, 2008) (Sen. Kyl). The fear of inequitable conduct charges thus “discourages many applicants from conducting a search and leads others to be indiscriminate in the information they submit.” Dudas, *supra*.

2. Even apart from those practical consequences, constitutionally protected advocacy is at stake. *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 684 (2d Cir. 2009) (“[C]onduct in obtaining and enforcing a patent is generally protected . . . by the First Amendment.”). In a variety of contexts, courts have recognized that those seeking government action cannot be sanctioned for petitioning conduct absent extreme, intentional falsity. Litigation cannot result in antitrust liability unless it is a “sham”—both subjectively and objectively baseless. *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61 (1993); *BE&K Constr. v. NLRB*, 536 U.S. 516, 532 (2002). Legislative lobbying and petitioning administrative agencies are similarly protected. *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510

(1972); *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1071 (Fed. Cir. 1998) (no antitrust liability for obtaining patents absent clear-and-convincing proof of “the knowing assertion of a patent procured by fraud on the PTO”). The severe consequences of inequitable conduct—which renders unenforceable not just tainted claims but entire patents—should be restricted to similarly compelling proof.

3. The damage to innovation and the costs to the judicial system are incalculable. By undermining the certainty of patent enforcement, “charges of inequitable conduct [are] a disincentive to [the] technologic innovation” that the patent system was designed to foster. *Ferring*, 437 F.3d at 1196 (Newman, J., dissenting). As inequitable conduct has “taken on a new life as a litigation tactic,” it has subjected parties, district courts, and this Court to satellite litigation; disqualified patent counsel (even when they may best understand the facts and technology); and threatened reputations and careers. *See Aventis*, 525 F.3d at 1349 (Rader, J., dissenting). The ABA, the National Academy of Sciences, and the PTO’s Director agree. *See ABA White Paper, supra*, at 18-20 (doctrine’s overuse discourages meaningful disclosure to the PTO and increases the complexity and cost of litigation); National Research Council of the National Academies, *A Patent System for the 21st Century* 122-23 (Stephen A. Merrill *et al.* eds.) (2004). As the PTO’s Director has explained, such allegations impose “expensive, discovery-

heavy” litigation, but “they usually don’t get to the heart of patentability. In fact they become a high priced side show to the real issues.” David Kappos, *Remarks at George Washington Law Symposium: Building Bridges and Making Connections Across the IP System* (May 11, 2010), http://www.uspto.gov/news/speeches/2010/Kappos_GW_Law_Symposium.jsp. To mitigate those impacts, this Court must at least return to *Kingsdown*’s intent standard.

III. A Patent Should Be Unenforceable for Inequitable Conduct Only Where the Patent Would Not Have Issued Absent the Misconduct

This Court has articulated and applied at least “four tests for materiality,” a situation then-Chief Judge Michel characterized as a jurisprudential “train wreck” that “makes the problem four times harder.” James Nurton, *Chief Judge Michel Calls for Inequitable Conduct Review*, *Managing Intell. Prop.* (Oct. 18, 2009). Elsewhere, by contrast, the standards are clear. Where (as here) a party seeks to invalidate an otherwise final transaction (whether trademark or copyright, a contract, or a decree) based on misconduct, there must be proof of but-for or “transaction causation”—*i.e.*, that the result would have been different absent the misconduct. While the names for that requirement vary by context, this Court and its predecessor have characterized it as “materiality”—“that if the Patent Office had been aware of the complete or true facts, the challenged claims would not have been allowed.” *Norton*, 433 F.2d at 794. Thus, even aside from the inequitable conduct doctrine’s origins in patents procured by fraud, settled tradition in

analogous areas of law and sound policy considerations require adherence to a but-for standard of materiality here.

A. Supreme Court Precedent Requires But-For Causation

The Supreme Court decisions that form the foundation for the inequitable conduct doctrine, *see pp. 5-9, supra*, all reflect a but-for standard—a patent may be unenforceable because of misconduct only if the patent was obtained by reason of the misconduct. *See* Hon. Randall R. Rader, *Always at the Margin: Inequitable Conduct in Flux*, 59 Am. U. L. Rev. 777, 779 (2010). In *Precision Instrument*, the patent application was “admittedly based upon false data which destroyed whatever just claim [the applicant] might otherwise have had to . . . a patent.” 324 U.S. at 816. In *Hazel-Atlas*, the patentee’s application had been ““confronted with apparently insurmountable Patent Office opposition,”” 322 U.S. at 240, which was overcome only when the patentee submitted a “spurious” article applauding the purported invention (while concealing its true authorship), *id.* at 241. And in *Keystone*, the patentee suppressed a disqualifying prior use (and obtained false statements concerning it) through the “corrupt transaction” of bribery. 290 U.S. at 243-44; *see pp. 5-6, supra*.

As the Supreme Court later summarized, those cases allowed defendants to assert a defense of unenforceability where patents were “procured by” or “obtained by” the misconduct, *i.e.*, “intentional fraud.” *Walker Process*, 382 U.S. at 173, 176;

id. at 179 (Harlan, J., concurring) (“procured by knowing and willful fraud”). That “procured by” or “obtained by” standard has a long pedigree. *See Mowry v. Whitney*, 81 U.S. (14 Wall.) 434, 440 (1871); 2 William C. Robinson, *The Law of Patents for Useful Inventions* 474-75 (1890) (patents “may be . . . avoided when originally obtained by fraud”). A patent cannot be said to have been “procured by” or “obtained by” misconduct where the misconduct was not the but-for cause of its issuance. *See Bayer AG v. Housey Pharms., Inc.*, 340 F.3d 1367, 1378 (Fed. Cir. 2003) (“by” means “through the direct agency of” or “through the work or operation of”).

The Supreme Court’s decision in *Corona* likewise requires but-for proof that the patent was “secured by false evidence.” 276 U.S. at 373. In that case, it “appeared, without contradiction,” that the inventor had submitted false affidavits claiming that his vulcanization process had successfully produced “rubber goods for use” when, in fact, the process had produced only test slabs. *Id.* at 373-74. The Court acknowledged that the affidavits were “perhaps reckless.” *Id.* Because they “were not the basis for [granting the patent] or essentially material to its issue,” however, they did not warrant setting aside the “presumption of validity furnished by the grant of the patent.” *Id.*; *see id.* (affidavits not “indispensable to the granting of the patent”). *A fortiori*, misconduct that is “not indispensable to the

granting of the patent” cannot have the more draconian effect of rendering the patent wholly unenforceable.

B. But-For Causation Is Required in Related Contexts

That same requirement—proof that the result would have been different absent the misrepresentation—pervades the law. As explained above, but-for proof is required where a private party seeks to invalidate a trademark or copyright based on applicant misconduct. *Citibank*, 724 F.2d at 1544 (trademark registration invalid if misrepresentation “would have constituted grounds for denial of the registration had the truth been known”); *Eckes*, 736 F.2d at 861-62 (copyright invalid only if omitted facts would have “occasioned a rejection of the application”); pp. 11-12, 26, *supra* (additional cases).

“Unclean hands” likewise requires but-for causation. The party asserting that doctrine must show that the claimed misconduct “was responsible for” the result it seeks to avoid. *Serdarevic*, 532 F.3d at 1361. If the “right for which the plaintiff seeks protection in the injunction suit did not accrue to him *because of* the misdeed,” the “misdeed is regarded as ‘collateral’” and cannot support a claim of unclean hands. Restatement § 940 cmt.c (emphasis added); *Alcatel*, 166 F.3d at 797; *see* pp. 15-16, *supra* (citing additional authority).

Similarly, where a party seeks to rescind a contract based on misrepresentation, it must prove but-for causation by showing that it “actually relied on the

representation or concealment” in deciding to enter the contract. *Woodworker’s Supply, Inc. v. Principal Mut. Life Ins. Co.*, 170 F.3d 985, 994 (10th Cir. 1999); *see also Lyn-Lea Travel Corp. v. Am. Airlines, Inc.*, 283 F.3d 282, 290 (5th Cir. 2002) (misrepresentations must have “procured the alleged contract”). Even appeals asserting ordinary error—where a successful challenge would not result in judgment but a new proceeding—require proof of some likelihood that the error altered the outcome. 11 Wright & Miller, *Federal Practice and Procedure* § 2883 (2d ed. 1995); *Brecht v. Abrahamson*, 507 U.S. 619, 631, 637 (1993) (requiring a showing that the error “had substantial and injurious effect or influence in determining the jury’s verdict”). A causation requirement likewise must be imposed here.⁴

C. Courts Should Not Render Valuable Patents Unenforceable Based on Violations of PTO Rules Where Causation Is Unproved

1. Neither this Court nor the Supreme Court has ever considered itself bound by the definition of materiality in PTO rules. The trio of Supreme Court cases that established the basis for inequitable conduct—*Keystone*, *Hazel-Atlas*,

⁴ Requiring proof of but-for causation does not render inequitable conduct duplicative of invalidity. Inequitable conduct makes an entire patent (and potentially related patents in the same family) unenforceable, even if the conduct was the but-for cause of the PTO’s approval of only particular claims. *See Kingsdown*, 863 F.2d at 877. Inequitable conduct, moreover, is often grounds for an award of fees under the “exceptional” case standard of 35 U.S.C. § 285, as in this case; ordinary invalidity is not. In all events, inequitable conduct claims should be a rarity—not the grist of daily litigation they have become.

and *Precision Instrument*—did not mention PTO rules. The Supreme Court’s *Corona* decision, which rested on materiality, did not either. Nor did the decisions of this Court and its predecessor until *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350 (Fed. Cir. 1984). And when the PTO changed its definition of materiality, this Court held that its precedent would not follow. *See Digital Control*, 437 F.3d at 1314-16 (PTO rule changes on materiality do not “supplant or replace the case law precedent”). Congress, moreover, has deliberately limited the PTO’s authority to issuing rules that govern its *own* proceedings. The PTO thus lacks authority to issue rules interpreting § 282 for the courts. *See Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996); Duty of Disclosure, 57 Fed. Reg. 2021, 2024 (1992) (“The rules do not define . . . inequitable conduct.”). Having never before felt bound by the PTO’s standards, this Court should not reverse course now.

The PTO’s standards, moreover, serve a distinct purpose. The PTO’s rules define the duty of disclosure *ex ante* (when causation cannot be proved, because no patent has yet been issued). Such standards necessarily must be relatively broad and serve a prophylactic purpose. But they are *not* appropriate for determining whether to unwind a transaction, impose liability, or withdraw a previously granted patent. For those sorts of determinations, courts require proof of transaction

causation—that, but for the misconduct, the transaction would not have occurred. *See pp. 35-36, supra.*

2. Ironically, cementing PTO rules into place as judicial standards undermines the PTO’s flexibility, preventing it from adjusting applicant behavior by fine-tuning its standards. For example, in 1992, the PTO replaced former Rule 56’s “reasonable examiner” standard because that standard forced applicants and the Office to devote unnecessary “resources . . . to duty of disclosure issues . . . without significantly contributing to the reliability of the patents being issued.” 54 Fed. Reg. 11334 (1989); Harry F. Manbeck, Jr., *The Evolution and Issue of New Rule 56*, 20 AIPLA Q.J. 136, 139-140 (1992) (Rule 56 amended in part because prior standard led to “unjustifiable charges” of misconduct). Yet this Court continues to use former Rule 56’s reasonable-examiner standard notwithstanding its rescission. *Digital Control*, 437 F.3d at 1316. Because applicants cannot risk an inequitable conduct ruling in court under the older standard, the PTO’s efforts to mitigate the burdens of disclosure through a new standard have been ineffectual. PTO standards may be useful as a safe harbor; it cannot be misconduct to do as the agency prefers. But this Court should limit itself to holding patents unenforceable in those extreme cases where the conduct *affects the public* by causing a patent to issue improperly. Violations of PTO rules unaccompanied by any such impact are matters for the PTO, not the courts.

Indeed, rendering patents unenforceable for misrepresentations without regard to their impact improperly converts the inequitable conduct doctrine into an unauthorized regime of judicial punishment. Equitable defenses assist the injured by undoing or mitigating the effects of prior misconduct. *See* p. 16, *supra*. To the extent the misconduct did not result in the patent’s issuance, destroying the patent based on the misconduct is nothing more than punishment. But policing misconduct before the agency is the agency’s job; the patent laws do not appoint the courts or private litigants to enforce PTO rules and punish infractions.

Expanding the judicial role through broad materiality standards also has the inevitable effect of diminishing the PTO’s responsibilities. Congress’s delegation of “plenary authority over PTO practice . . . to the Office,” *Stevens v. Tamai*, 366 F.3d 1325, 1333 (Fed. Cir. 2004) (quotation marks omitted), encompasses disciplinary authority to “suspend or exclude” individuals from PTO practice for misconduct, 35 U.S.C. § 32; *e.g.*, *Bender v. Dudas*, 490 F.3d 1361, 1365 (Fed. Cir. 2007), and authority to strike applications or cancel patents for misconduct, *Norton*, 433 F.2d at 791. And the Justice Department has criminal enforcement authority over those who make false statements before the PTO and other federal agencies. *See, e.g.*, 18 U.S.C. § 1001. Yet, as this Court has expanded the inequitable conduct doctrine over the past 25 years, the PTO has pulled back. 1095 Official Gazette Pat. Off. 16 (Oct. 11, 1988) (stating that PTO would no longer

investigate and reject reissue applications under Rule 56 given enforcement of inequitable conduct by the courts). Courts should not encourage agency abdication by taking over the agency's responsibilities as their own.

3. Finally, allowing inequitable conduct to render a patent unenforceable when the conduct did not result in the patent's issuance yields absurd results that cannot be reconciled with Supreme Court precedent. In the "trilogy of U.S. Supreme Court cases that spawned the doctrine of inequitable conduct," the "applicants 'lied, cheated, and stole' to obtain a patent"—they were "clear-cut scenarios where a witness was paid to suppress or falsify information without which the applicant would not have had a chance to obtain a patent." Rader, *Always at the Margin, supra*, at 779-80. By contrast, this Court has held an entire patent unenforceable where the patentee paid discounted small entity fees when he was not entitled to do so. *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1230-33 (Fed. Cir. 2007); *Ulead Sys., Inc. v. Lex Computer & Mgmt. Corp.*, 351 F.3d 1139, 1146 (Fed. Cir. 2003). It has done so where the applicant failed to notify the examiner of activity in a co-pending application. *McKesson*, 487 F.3d at 897. And it has rendered patents unenforceable because some (but not all) of the expert declarants, while testifying entirely accurately, failed to identify their past relationship with the patentee on their resumes. *Ferring*, 437 F.3d 1181; *see also Gen. Electro Music Corp. v. Samick Music Corp.*, 19 F.3d 1405, 1410-11 (Fed. Cir. 1994) (pat-

ent unenforceable because applicant misrepresented that he had researched prior art, even though there was no evidence any prior art had escaped the examiner's review). It is improbable that the Supreme Court would have decided those cases the same way.

The inequitable conduct doctrine has expanded “to embrace any kind of perfidy, no matter how inconsequential to the grant of the patent.” Rader, *Always at the Margin, supra*, at 782. Such lesser misconduct may well warrant sanction by the PTO. But billion-dollar investments in innovative technologies should not be wiped out because of transgressions that had no causal role in the patent's issuance.

IV. The Court Should Eliminate Sliding-Scale Balancing Because It Dilutes Both the Intent and Materiality Requirements

This Court has often employed a sliding scale under which “[t]he more material the omission or misrepresentations, the less intent that must be shown to elicit a finding of inequitable conduct.” *Aventis*, 525 F.3d at 1344. That sliding scale improperly dilutes the required proof for *both* materiality and intent. It yields inconsistent and unpredictable results. And it has, in application, tended to make materiality the only requirement, effectively “read[ing] the element of intent to deceive” right out of inequitable conduct. *Taltech*, 604 F.3d at 1341 (Gajarsa, J., dissenting). It is a mode of analysis that, simply put, has “earned its retirement.” *Bell Atlantic Corp. v. Twombly*, 550 U.S. 554, 563 (2007).

1. “Inequitable conduct requires proof by clear and convincing evidence of a threshold of *both materiality and intent.*” *Allen Organ Co. v. Kimball Int’l, Inc.*, 839 F.2d 1556, 1567 (Fed. Cir. 1988) (emphasis added); *see also Kingsdown*, 863 F.2d at 872. Those two requirements should not, and logically cannot, be conflated so that one substitutes for another, even in part. “Intent” addresses the individual’s subjective mental state. *Morissette v. United States*, 342 U.S. 246, 252 (1952). By contrast, “materiality” addresses the “import[ance]” of a statement or omission to another. *Basic v. Levinson*, 485 U.S. 224, 231-32 (1988). A person who forgets or overlooks information cannot be said to have intended to deceive, regardless of how material the information. *See Ariad Pharms, Inc. v. Eli Lilly & Co.*, 560 F.3d 1366, 1379 (Fed Cir. 2009) (“There is simply no evidence of . . . ‘purposeful concealment’ no matter how material the errors might be.”), *vacated pending reh’g en banc*, 595 F.3d 1329, *reinstated in relevant part*, 598 F.3d 1336, 1358 (2010) (*en banc*). Conversely, a person’s undisputed intent to deceive cannot transform a trivial matter into something “material.”

This Court thus has repeatedly held that materiality and intent are “distinct elements [that] must be shown by clear and convincing evidence.” *Hoffman-LaRoche Inc. v. Promega Corp.*, 323 F.3d 1354, 1359 (Fed. Cir. 2003); *see also Upjohn Co. v. Mova Pharm. Corp.*, 225 F.3d 1306, 1312 (Fed. Cir. 2000); *Braun Inc. v. Dynamics Corp. of Am.*, 975 F.2d 815, 822 (Fed. Cir. 1992). “[M]ateriality

does not presume intent, which is a separate and essential component of inequitable conduct.” *Allen Organ Co.*, 39 F.2d at 1567; *see also Astrazeneca*, 583 F.3d at 770; *Optium*, 603 F.3d at 1320-21; *Ariad*, 560 F.3d at 1380; *Star Scientific*, 537 F.3d at 1366; *Braun*, 975 F.2d at 822; *Halliburton*, 925 F.2d at 1442.

The notion of a sliding scale of proof between intent and materiality entered this Court’s precedents in *American Hoist*, which incorporated the concept from *Digital Equipment Corp. v. Diamond*, 653 F.2d 701, 716 (1st Cir. 1981) (“DEC”).

Quoting *DEC*, *American Hoist* declared:

Questions of “materiality” and “culpability” are often interrelated and intertwined, so that a lesser showing of the materiality of the withheld information may suffice when an intentional scheme to defraud is established, whereas a greater showing of materiality of withheld information would necessarily create an inference that its non-disclosure was “wrongful.”

725 F.2d at 1363. As explained above, however, that is incorrect: Materiality does not prove intent. And the entire edifice of a sliding scale stands on a phantom foundation. The sole case *American Hoist* cites is *DEC*, and the sole case *DEC* cited was a then 24-year-old (now 53-year-old) district-court decision, *United States v. Standard Electric Time Co.*, 155 F. Supp. 949, 952-53 (D. Mass. 1957). But *Standard Electric* contains no suggestion of an intent-materiality balancing test.

2. This Court has sometimes stated that the sliding scale can be applied only *after* “both materiality and intent have been established” by clear-and-

convincing evidence; once “intent” and “materiality” are established at “threshold level[s],” courts *then* “balance . . . the equities” on a sliding scale to “determine if a finding of inequitable conduct is warranted.” *Optium*, 603 F.3d at 1320 (emphasis added); *see also Astrazeneca*, 583 F.3d at 776; *Star Scientific*, 537 F.3d at 1367. That, however, hardly fixes the problem, because the supposed “threshold levels” of materiality and intent have themselves been diluted by the sliding scale. This Court first adopted the “sliding scale” in *American Hoist* as the reason why it should not be “bound by any single standard of materiality,” instead incorporating four different standards, including the most lenient “reasonable examiner” test. 725 F.2d at 1363. That lower standard of materiality, however, promptly became a threshold that, once met, would in turn justify lowering the required showing of intent. *See, e.g., Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1234-40 (Fed. Cir. 2003). The sliding scale thus justified using lesser standards of materiality, which in turn justified lesser showings of intent. The resulting series of cases “emphasize materiality”—under an already relaxed standard—“almost to the exclusion of any analysis of the lofty intent requirement for inequitable conduct.” *Aventis*, 525 F.3d at 1350 (Rader, J., dissenting).

For example, notwithstanding this Court’s repeated admonition that “[i]ntent to deceive cannot be inferred from even a high degree of materiality,” *Aspex Eyewear Inc. v. Clariti Eyewear, Inc.*, 605 F.3d 1305, 1316 (Fed. Cir. 2010), courts

have held that intent to deceive may be inferred—indeed, inferred *as a matter of law*—where “(1) the applicant knew of the information; (2) the applicant knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding.” *Ferring*, 437 F.3d at 1191; *see, e.g., Praxair*, 543 F.3d at 1315, 1318; *Bristol-Myers*, 326 F.3d at 1239; *Critikon*, 120 F.3d at 1256-57. But that three-part test simply “replac[es] the need for evidence” that the applicant *intended* to deceive “with a ‘should have known’ standard of materiality, from which deceptive intent is inferred, even in the total absence of evidence.” *Ferring*, 437 F.3d at 1196 (Newman, J., dissenting). It disregards the principle that “‘materiality does not presume intent, which is a separate and essential component.’” *Larson*, 559 F.3d at 1344 (Linn, J., concurring) (quoting *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 552 (Fed. Cir. 1990)). And the “should have known,” *i.e.*, negligence, standard for materiality eviscerates *Kingsdown*, which rejected even *gross* negligence as insufficient. *Bose*, 580 F.3d at 1244; *Aventis*, 525 F.3d at 1350-51 (Rader, J., dissenting); *Larson*, 559 F.3d at 1344 (Linn, J., concurring) (“‘should have known’” is “a simple negligence standard, lower even than the ‘gross negligence’ standard that was expressly rejected in *Kingsdown*”).

Proof that the patentee knew of the information (prong one), together with evidence that it should have known the information was material (prong two),

simply is not “evidence of deceptive intent.” *Larson*, 559 F.3d at 1344 (Linn, J., concurring). “The first is evidence of materiality; the second is evidence of negligence. These two prongs are therefore insufficient as a matter of law to establish a clear and convincing ‘threshold level’ of deceptive intent before the third prong can ever properly come into play.” *Id.*; see *Halliburton*, 925 F.2d at 1443 (“Gross negligence cannot elevate itself by its figurative boot-straps to an intent to mislead based on the identical factors used to establish gross negligence in the first instance unless all the facts and circumstances indicate sufficient culpability.”).

The third prong, which requires a “‘credible explanation’” whenever the patentee knew of the information and should have known of its materiality, “effectively shifts the burden to the patentee to prove a negative: that it did not intend to deceive the PTO.” *Larson*, 559 F.3d at 1344 (Linn, J., concurring). “But it is the ‘accused infringer’—not the patentee—who ‘must prove by clear and convincing evidence that the material information was withheld with the specific intent to deceive the PTO.’” *Id.* (quoting *Star Scientific*, 537 F.3d at 1366). That burden-shifting is inconsistent with the rule “that ‘[t]he patentee need not offer any good faith explanation unless the accused infringer first carried his burden to prove a threshold level of intent to deceive by clear and convincing evidence.’” *Id.* (quoting *Star Scientific*, 537 F.3d at 1368). No court has explained why two facts

that do not themselves show intent to deceive—knowledge of the information and negligent failure to recognize its materiality—should saddle the patentee with the burden of disproving intent.

Finally, a sliding scale is necessarily subjective; one cannot articulate a rule regarding the particular quantum of proof of one element that is necessary to lower the requisite proof of another element (or by how much). The subjectivity inherent in applying the sliding scale yields unpredictable results—and has been responsible in part for the unusual number of dissenting opinions in this context. Especially where the consequences are so severe, the required proof should not vary so dramatically and so often with the eye of the beholder.

This Court simply cannot allow district courts “to balance” “relatively weak evidence of intent” with “strong evidence that [the] omission was highly material” and “find that on balance, inequitable conduct had occurred.” *Dippin’ Dots, Inc. v. Mosey*, 476 F.3d 1337, 1346 (Fed. Cir. 2007). Where the evidence of intent to deceive is “relatively weak,” it by definition cannot satisfy the “clear and convincing” standard, no matter how strong the evidence of materiality. And by contrast, where intent and materiality *have* been independently proved by clear-and-convincing evidence, there would seem to be little “balancing” left for the district court to perform—a finding of inequitable conduct would seem warranted. The

sliding scale should therefore be rejected to restore clarity and predictability to this area of law.

V. This Case Illustrates Why This Court Must Revitalize Inequitable Conduct Standards

This case illustrates how diluted inequitable conduct's requirements have become. There is no dispute that Abbott presented the examiner with the relevant prior art. The claim of inequitable conduct arises solely from the failure of a U.S. patent attorney (Pope) and a company scientist (Sanghera) to disclose a few sentences of *argument* characterizing that prior art in two legal briefs submitted by a German patent attorney (Dost) to the EPO in proceedings about a different patent family two years earlier. The district court interpreted Dost's arguments to be inconsistent with Abbott's position before the PTO; Pope and Sanghera explained without contradiction that they read Dost's arguments differently. *See, e.g.*, JA2982; JA3010-11. This case thus involves nothing like the conduct (*e.g.*, bribing witnesses and falsifying evidence) at issue in the foundational Supreme Court precedents of *Keystone*, *Hazel-Atlas*, and *Precision Instrument*. Rather, it concerns judgments—weighing what should be submitted from volumes of documents concerning already-disclosed prior art—that applicants and counsel routinely must make. Moreover, as Judge Linn explained in his dissent, Pope and Sanghera's reading of Dost's arguments *in context* was “equally reasonable (if not more reasonable)” than the alternative. 593 F.3d at 1313 (Linn, J., dissenting).

Certainly, this is not a case where the “involved conduct . . . *require[s]* a finding of intent to deceive.” *Kingsdown*, 863 F.2d at 876 (emphasis added).

A. The Panel Opinion Improperly Substitutes Materiality for Proof of Intent Under a Diluted Standard

The technology at issue here involves devices for measuring glucose in blood and interstitial bodily fluids using electrochemical sensors. In 1981, Medisense filed the '382 patent (its European counterpart is the '636 patent) (“the '382/'636 patent”) as an advance over prior art, including a reference identified as D1. D1 described a sensor that required a “diffusion limiting” membrane to slow glucose passage to avoid overwhelming the sensor. JA2742. The '382/'636 invention eliminated the “diffusion limiting” membrane. JA3002-03. But it still needed, or at least “preferably” employed, a “protective” membrane when used with blood. That protective membrane was *permeable* to glucose; it was needed only to prevent larger blood particles from reaching and “fouling” the sensor. JA2733; JA2738.

This case concerns a patent from a separate family—the '551—that Medisense filed but the PTO initially rejected as obvious over the '382/'636. In 1997, after Abbott acquired Medisense, Pope assumed the prosecution of the '551. He worked with Sanghera to determine whether there were patentable claims in the application, and filed claims for a sensor that measured glucose in whole blood without *any* membrane. JA2976. They claimed that, while the '382/'636 patent

required a “protective” membrane for whole blood (but not other fluids), the ’551 invention made that protective membrane unnecessary even for whole blood. The charges of inequitable conduct arise from the failure to disclose Dost’s arguments, in EPO in proceedings unrelated to the ’551 patent, explaining the difference between the D1 and ’382/’636 membranes. JA6530-31; JA6584-86.

The district court and panel majority identified no document, no memorandum, no e-mail, no note, no statement—no documentary evidence of any sort—indicating that Pope and Sanghera believed Dost’s statements were damaging and withheld them for that reason. Instead, as summarized by the panel majority, the district court found intent to deceive based on 5 determinations:

- (1) that the statements made to the PTO concerning the prior art ’382 patent were absolutely critical in overcoming the examiner’s earlier rejections . . . ;
- (2) that [Dost’s] EPO statements would have been very important to an examiner because they contradicted the representations made to the PTO;
- (3) that Pope and Dr. Sanghera both knew of the EPO statements and consciously withheld them from the PTO;
- (4) that neither Pope nor Dr. Sanghera provided a credible explanation for failing to submit the EPO documents to the PTO; and
- (5) that Pope’s and Dr. Sanghera’s explanations for withholding the EPO documents were so incredible that they suggested intent to deceive.

593 F.3d at 1306.

That reasoning illustrates how *Kingsdown*'s formerly rigorous standard has been diluted. The first two findings are not about intent. They address materiality. The third reflects the fact that Pope and Sanghera knew of Dost's statements and failed to disclose them. But "intent to take the action or omission complained of" is not proof of "intent to deceive or mislead the patent examiner into granting the patent." *Optium*, 603 F.3d at 1320 (emphasis added); p. 20, *supra*. The fourth factor—the supposed failure to give a credible explanation—does not show intent to deceive. Instead, it *inverts* the burden of proof. Because the party charging inequitable conduct must prove intent to deceive by clear-and-convincing evidence, the patentee need not offer any explanation if the evidence does not otherwise establish intent. *See* pp. 22, 45-47, *supra*.

Finally, the district court's claim that the explanations given were so incredible as to create an inference of intentional deception builds on that burden-shift, and adds another improper inference: "[D]iscredited testimony is not [normally] considered a sufficient basis for drawing a contrary conclusion." *Bose Corp. v. Consumers Union*, 466 U.S. 485, 512-13 (1984). More important, the only stated basis for rejecting Pope and Sanghera's explanation was the district court's disagreement with their interpretation of Dost's legal briefs. JA92-94. Thus, the only evidence of intent was the fact that Pope and Sanghera disagreed with the district court on the issue of materiality. If that were all that was

necessary for a finding of intent, the requirement would be eliminated whenever an applicant disputed the materiality of a withheld reference.

B. Pope and Sanghera’s Interpretation of Dost’s Arguments Was at Least Reasonable

In fact, looking at Dost’s arguments in context, Pope and Sanghera’s understanding of Dost’s arguments was “equally reasonable (if not more reasonable)” than the alternative. 593 F.3d at 1313 (Linn, J., dissenting).

The ’382/’636 patent presented a difficulty for prosecuting the ’551: While the ’551 claimed to be an advance because it required *no* protective membrane when used with blood, the ’382/’636 specification provided for a protective membrane “[o]ptionally, but preferably when being used on live blood.” That language could be (and ultimately was) read to mean that the ’382/’636 patent did not require the membrane for use on blood either. But each instance of use in blood in the ’382/’636 patent referenced a membrane. *See* 593 F.3d at 1296-97 & n.5. (Indeed, Dost had pointed that out to the EPO: “For use on human blood the sensor of Example 7 was provided with a protective membrane.” JA6586, ¶5.) The PTO Examiner agreed that the *teaching* of the ’382/’636 was that it *required* a membrane for blood—it was not merely a preference—and requested an affidavit that those reasonably skilled in the art would have so believed. JA2977; JA7639. Sanghera submitted a declaration so stating. JA2999; JA7636-37. Pope’s legal

remarks similarly explained that “[t]here is no teaching or suggestion of unprotected active electrodes for use with whole blood.” JA7643-46.

The panel in this case held the ’551 obvious, in part because ’382/’636’s specification states that its membrane was “preferabl[e] with” live blood, which the panel understood to mean that it was *not* required. 593 F.3d at 1295-96. But the panel also ruled that Pope and Sanghera intended to deceive the PTO into believing the membrane was required when they failed to disclose Dost’s arguments in EPO proceedings about the ’382/’636 patent. As Pope and Sanghera explained, however, they understood Dost’s arguments to address not whether a membrane *was needed* for blood, but whether the membrane *used for blood was different* from the membrane used by D1, making the ’382/’636 patent different from that prior art. JA2990; 593 F.3d at 1316 n.9 (Linn, J., dissenting).

That understanding was consistent with the issue before the EPO, which was whether the ’382/’636 patent used the *diffusion-limiting* membrane that the D1 reference required to slow glucose passage to the sensor. JA6525-39. Urging that it did not, Dost observed that the ’382/’636 patent sometimes used a *protective* membrane that blocked red blood cells that would foul the sensor but was *permeable* to glucose molecules (which are smaller than red blood cells). To illustrate the point, Dost quoted the portion of the ’382/’636 specification that stated: “Optionally, but *preferably when being used on live blood*, a *protective* membrane

surrounds both the enzyme and the mediator layers, *permeable to water and glucose molecules.*” JA6585 (emphasis added). He explained that the ’382/’636 specification was explicit that the membrane’s purpose was to filter blood, not to affect glucose:

It is submitted that this disclosure is unequivocally clear. The protective membrane is optional, however, it is preferred *when used on live blood in order to prevent the larger constituents of the blood, in particular erythrocytes from interfering with the electrode sensor.* Furthermore it is said, that said *protective membrane should not prevent the glucose molecules from penetration, the membrane is “permeable” to glucose molecules.*

JA6585 (emphasis added); *see also* JA6531. Dost’s point was not whether the membrane was “required” for blood. His point was that the ’382/’636 did not use a glucose-limiting membrane but instead a membrane that filtered only blood cells.

EPO’s Appeal Board understood Dost’s point the same way Pope and Sanghera did—that *use* of a protective membrane in ’382/’636 for a “filtering function” showed that ’382/’636 did not have a glucose-diffusion-limiting membrane:

Common sense dictates moreover that the optional *presence* of a protective membrane *would be unnecessary if a diffusion controlling membrane was present* The distinction [that] the sensor electrode according to the patent in suit does not have a substrate diffusion controlling membrane is . . . seen as valid.

JA6571 (emphasis added). In other words, the *presence* of a filtering “protective membrane” in certain contexts, such as when working with blood, proved the

'382/'636 was *different* from prior art: It demonstrated that the '382/'636 did not use a “diffusion-controlling membrane” (to limit smaller glucose molecules) because, if one were present, it could exclude “larger blood constituents” as well, making the “protective membrane” mentioned in the '382/'636 “unnecessary.”

In making those arguments, Dost did *repeat* the '382/'636 specification's problematic statement that the protective membrane was “optional but preferable with live blood.” But that is cumulative of the specification and thus, by definition, immaterial. *Larson*, 559 F.3d at 1327; *Star Scientific*, 537 F.3d at 1371. Indeed, this Court invalidated the patent as obvious without referring to Dost's argument, relying instead on the specification itself. 593 F.3d at 1293-1300. The panel read Dost's arguments as also urging that the *membrane is “optional”* or *unnecessary for blood*. *Id.* at 1302-03. But Dost *never* said that. No such statement exists. Dost at most paraphrases the already-disclosed specification that the membrane is “optional,” albeit “preferred” with live blood.⁵ Despite the myriad technical experts in this case, not one—no expert in electrochemical sensors or membranes—testified that they disagreed with Pope and Sanghera's

⁵ The statement that the membrane was generally “optional,” moreover, hardly forecloses it from being required in some contexts. That helmets are “optional” when skiing does not foreclose specific contexts—racing, jumping, competition—where helmets are required. Even saying helmets are “preferred” for racing does not foreclose the possibility that those learned in the art might understand that, in practice, no one will allow you to race without one. But even if that is wrong, it surely is not so clearly wrong that intent to deceive can be inferred.

understanding that Dost was *not* arguing that the membrane was “optional” for blood but rather arguing about the “type” of membrane used with blood.

Dost’s argument itself also belies intent to deceive because it “bolster[s], rather than refute[s], Abbott’s argument to the PTO that a protective membrane was thought . . . to be required for use in blood.” 593 F.3d at 1314 (Linn, J., dissenting). Dost’s argument emphasizes the *presence* of the “protective” membrane when testing live blood: Dost argued that there would be no reason for a “protective” membrane in ’382/’636 to keep out larger particles when dealing with blood if the ’382/’636 already used a glucose-diffusion-limiting membrane like D1, as the diffusion-limiting membrane would serve that same purpose. *See pp. 53-55, supra.* As the EPO explained, the “protective membrane *would be unnecessary if a diffusion-controlling membrane was present.*” JA6571 (emphasis added). Dost’s point was “the fact that the ’382/’636 patent even discloses *the use* of a protective membrane” in blood showed “that no diffusion-limiting membrane was present in the ’382/’636 patent,” distinguishing it from D1. 593 F.3d at 1317 (Linn, J., dissenting) (emphasis added). “If a [diffusion-limiting membrane] were present, then the diffusion-limiting membrane would itself block larger blood constituents, thus rendering a protective membrane entirely redundant and unnecessary.” *Id.*

The inequitable conduct claim thus comes down to the assertion that Pope and Sanghera wanted to trick the PTO into believing that the '382/'636 *needed* a protective membrane to handle whole and live blood. To achieve that goal, they allegedly refused to give the PTO an attorney's argument in which he not only emphasized the *presence* of the protective membrane for live blood to prove his point, but also explained a *purpose*—"to prevent the larger constituents of the blood, in particular erythrocytes from interfering with the electrode sensor," JA6585—that exists for *all* whole blood and *all* live blood. To state the contention is to refute it.

Dost did also state that the '382/'636 specification was "unequivocally clear." *See* 593 F.3d at 1304. But the notion that failing to disclose such lawyer-hyperbole should destroy a patent illustrates how far current doctrine has strayed from Supreme Court precedent. Besides, Dost did not say that the word "preferably" is "unequivocal" in precluding the membrane from being necessary in some contexts. Instead, as the next sentences clarify, Dost claimed that the specification was "unequivocally clear" in specifying the membrane's functions ("protective," not diffusion-limiting) to exclude "larger blood constituents" (not to slow glucose). *See* 593 F.3d at 1317-18 (Linn, J., dissenting). The notion that Dost was disclaiming any ambiguity of any sort—and ascribing a specific meaning to "preferably" instead—seems strained. But surely the argument is not so clear as to "require" an

inference that Pope and Sanghera intended to deceive the PTO rather than that they understood the sentence differently. *Kingsdown*, 863 F.2d at 876.

C. The Panel Decision Abrogates the Rule That Lawyer-Argument Is Not Material

For over 20 years, this Court has held that attorney arguments characterizing prior art are not material. *Akzo N.V. v. U.S. Int’l Trade Comm’n*, 808 F.2d 1471, 1482 (Fed. Cir. 1986); *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1349 (Fed. Cir. 2007); *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1379 (Fed. Cir. 2008). That is true even if the argument characterizing prior art is in an affidavit. *Akzo*, 808 F.2d at 1482.

The panel in this case tried to distinguish that unbroken line of cases on two grounds; neither withstands scrutiny. The panel asserted that the “representations” to the PTO here “were not merely lawyer argument; they were factual assertions as to the views of those skilled in the art.” 593 F.3d at 1305. But the question here is not whether Sanghera’s *affidavit* was material. It is whether the *omitted* materials—the *arguments* German *counsel* made to the EPO—were material. And applicants regularly argue about what a person of ordinary skill in the art would understand, because that is a legal standard that resonates through patent law. If arguments on that issue were exempt, the rule that lawyer argument is not material would become meaningless.

The panel also stated that the prior cases could be distinguished because they involved affirmative lawyer-arguments made to the PTO, not lawyer-argument in other proceedings that was withheld from the PTO. 593 F.3d at 1305. But argument about the meaning of prior art is not material because the Examiner—with the prior art before him—is “free to reach his own conclusions.” *Lumenis*, 492 F.3d at 1349. To say lawyer-arguments are immaterial when made to the PTO, but material when made elsewhere and withheld from the PTO, thus makes no sense. Such a rule, moreover, would encourage applicants to submit all pleadings, briefs, and arguments regarding prior art *en masse* to the PTO for fear of being accused of selective disclosure. That is precisely the impact the panel majority’s holding has had. *See* pp. 29-30, *supra*. Until this case, this Court had never found a lawyer’s characterizations of prior art, whether in argument or affidavit, material. It should not start now.

CONCLUSION

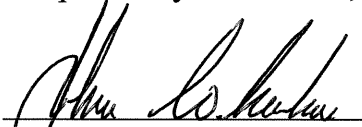
For the foregoing reasons and those stated in Abbott’s briefs before the panel, this Court should reverse the panel’s finding of inequitable conduct, the “exceptional” case determination, and the attorney’s fees award.

July 26, 2010

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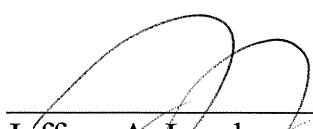
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