

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.

On Appeal from the United States District Court
for the Northern District of California
in Nos. 04-2123, 04-3327, 04-3732, and 05-3117
Judge William H. Alsup

**BRIEF FOR SANOFI-AVENTIS AND MICROSOFT CORPORATION
AS AMICI CURIAE SUPPORTING APPELLANTS AND REVERSAL**

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CERTIFICATE OF INTEREST

Counsel for Amicus Curiae Sanofi-Aventis and Microsoft Corporation certifies the following:

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

Sanofi-Aventis

Microsoft Corporation

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:

N/A

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

Sanofi-Aventis is publicly traded on the New York Stock Exchange under the ticker symbol SNY. No public company currently owns 10% or more of Sanofi-Aventis stock.

Microsoft Corporation is publicly traded on the NASDAQ Stock Market under the ticker symbol MSFT. No public company currently owns 10% or more of Microsoft Corporation stock.

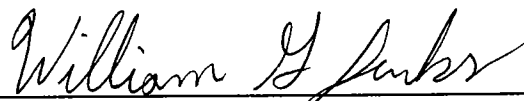
4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

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INTEREST OF AMICI CURIAE

Sanofi-Aventis and Microsoft Corporation respectfully submit that the intent element of the inequitable conduct doctrine has become unmoored from the common-law principles from which it arose. *See Aventis Pharma SA v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting), *cert. denied*, 129 S. Ct. 2053 (2009). Sanofi-Aventis is one of the largest pharmaceutical companies in the world, making innovative and life-enhancing drug products available to doctors and patients. Microsoft is one of the largest software companies in the world, providing innovative productivity solutions and other services to businesses and individuals.

It is sometimes said that “[t]he pharmaceutical industry . . . needs a different approach to patents than do software companies.” L. Gordon Crovitz, *Government Drops the Ball on Patents*, Wall St. J., July 19, 2010, at A15. In this case, however, leading participants in both industries come together to urge the Court to clarify the standard for specific intent, regardless of its particular application, based on common-law principles. *Amici* each hold thousands of patents, and are frequent parties to patent litigation—both as patent holders and as accused infringers. They have both asserted inequitable conduct as a defense and had the doctrine raised against them. *Amici* have a keen interest in clear standards in all areas of patent

law, particularly when (as here) confusion regarding the appropriate standard can drive and prolong litigation.

Amici have authority to file this brief under the Court's April 26, 2010 Order authorizing the filing of amicus briefs without leave of court. In addition, pursuant to rule, "all parties have consented to its filing." Fed. R. App. P. 29(a).

ISSUE ADDRESSED BY AMICI CURIAE

Whether the specific intent element of the inequitable conduct doctrine is properly derived from the common law.

ARGUMENT

Reconciling patent-law doctrines with legal principles of general applicability has become a recurring theme in both the Supreme Court (*e.g.*, *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437 (2007); *eBay Inc. v. MercExchange LLC*, 547 U.S. 388 (2006)) and this Court, particularly when it sits *en banc* (*e.g.*, *In re Seagate Tech., LLC*, 497 F.3d 1360 (Fed. Cir. 2007) (*en banc*), *cert. denied*, 522 U.S. 1230 (2008); *Knorr-Bremse v. Dana Corp.*, 383 F.3d 1337 (Fed. Cir. 2004) (*en banc*)). This case presents the *en banc* Court with the opportunity to ensure that the common-law concept of specific intent has the same contours within patent law as it does in other contexts.

Patent infringement sounds in tort. *Schillinger v. United States*, 155 U.S. 163, 169 (1894). Ordinary patent infringement is a tort of strict liability and re-

quires no showing of intent. *Seagate*, 497 F.3d at 1368. An actor's state of mind only becomes relevant in extraordinary situations, such as when a person is being called to account for another's actions. *See, e.g., Kyocera Wireless Corp. v. ITC*, 545 F.3d 1340, 1353-54 (Fed. Cir. 2008). Where mental state *is* relevant in patent law, as where induced infringement is alleged, the actor must usually have acted with *specific intent*. *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006) (*en banc*).

Specific intent is “[t]he intent to accomplish the precise act with which one has been charged.” *Black’s Law Dictionary* 328 (pocket ed. 1996); *see also Black’s Law Dictionary* 1399 (6th ed. 1990) (“The mental purpose to accomplish a specific act prohibited by law”). This is a common-law principle incorporated into tort law from the criminal law. *See Ratzlaf v. United States*, 510 U.S. 135, 141 (1994); *Nye & Nissen v. United States*, 336 U.S. 613, 619 (1949). It requires that the accused wrongdoer have knowledge of the unlawful consequences of its acts or omissions and the intention to bring about those same consequences. *See Cent. Bank of Denver v. First Interstate Bank of Denver*, 511 U.S. 164, 181 (1994). That is the appropriate measure of the intent element of the inequitable conduct doctrine.

1. Inequitable conduct is a judicially created doctrine designed to address misconduct during the prosecution or enforcement of a patent. *Abbott Labs v.*

Sandoz, Inc., 544 F.3d 1341, 1357-58 (Fed. Cir. 2008). But the Supreme Court decisions that gave life to the doctrine make clear that only *intentional* misconduct—that is, wrongdoing committed with the specific intent to mislead the PTO or a district court—warrants this exceptional treatment.

In three (and only three) cases, has the Supreme Court held a patent unenforceable for inequitable conduct in its prosecution or enforcement. Each involved extreme circumstances of “deliberate,” “corrupt,” “sordid,” and “highly reprehensible” conduct committed by the patent holder during prosecution or enforcement of the patent with the specific intent of misleading government officials regarding the validity of the patent.

In *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933), the Court faced a “corrupt transaction” that was “highly reprehensible.” Keystone, the patent owner, obtained, in exchange for “valuable considerations,” both a false affidavit and false deposition testimony “to keep secret the details of [a] prior use” which would have “cast doubt upon the validity of the patent.” *Id.* at 243-44. Thus, Keystone acted with the specific intent to suppress material evidence in order to preserve the patent. *Id.* at 244 (“his purpose was to keep Clutter silent”).

In *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 245 (1944), Hartford, the patentee, engaged in a “deliberately planned and carefully executed scheme to defraud” both the Patent Office and the Circuit Court of Appeals. Hart-

ford wrote an article describing the claimed invention as a “revolutionary device[],” then falsely published it with an “ostensibly disinterested” leader in the field as author. The patentee then submitted the publication to the Patent Office to obtain the patent, and later relied on it in the court of appeals to reverse an unfavorable district court ruling. *Id.* at 240, 248. Hartford also paid the purported author for claiming true authorship, when questioned by Hazel’s investigator. *Id.* at 242-43. This “sordid story,” *id.* at 243, came out nine years after judgment had been entered, *id.* at 239. Hazel-Atlas then moved to set aside the judgment based on fraud. *Id.* “Every element of the fraud” disclosed demanded that the Court exercise the historic power of equity to set aside the “fraudulently begotten judgments.” *Id.* at 245.

In *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945), “the history of the patents” was “steeped in perjury and undisclosed knowledge of perjury,” *id.* at 816, including false testimony by Larson (one patentee) in an interference proceeding, *id.* at 810. Larson’s opponent in the interference proceeding, Automotive, discovered Larson’s perjury and used that information to blackmail Larson into assigning his patent rights to Automotive and agreeing never to contest the resulting patent. *Id.* at 819. The Court barred the suit, because the patent claims were “infected with fraud and perjury.” *Id.*

In each of these cases, the specific intent of the patent holder to deceive the Patent Office or the courts was central to the judicial decision to render the patent unenforceable.

Equally illuminating is the Supreme Court's leading precedent *refusing* to hold a patent unenforceable without evidence of intentional wrongdoing. In *United States v. American Bell Telephone Co.*, 167 U.S. 224, 239-40 (1897), the Court derived from land patent cases a high standard for those who seek to challenge a patent for inequitable conduct:

The dignity and character of a patent from the United States is such that the holder of it cannot be called upon to prove that everything has been done that is usual in the proceedings had in the land department before its issue, nor can he be called upon to explain every irregularity *or even impropriety* in the process by which the patent is procured.

Id. at 242 (emphasis added) (quoting *United States v. Marshall Mining Co.*, 129 U.S. 579, 589 (1889)).

Applying this standard, the Court refused to cancel Bell Telephone's patent based on circumstantial evidence surrounding an extreme delay in the patent's issuance. The Court rejected the government's theory, which "assumes the existence of a knowledge which no one had; of an intention which is not shown." *Id.* at 259; *see also Corona Cord Tire Co. v. Dovan Chem. Corp.*, 276 U.S. 358, 373-74 (1928) (false, "perhaps reckless," affidavits insufficient to render patent unenforceable).

2. The roots of the inequitable conduct doctrine are thus deeply planted in the common law, including its strict requirement of specific intent. And absent congressional directive to the contrary, courts apply the common law. *See Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 343-45 (2005); *Neder v. United States*, 527 U.S. 1, 21 (1999).

Common law authorities establish that “intent” is not satisfied by a showing of “volition” or “knowledge” of one’s acts. The accused wrongdoer must have desired or purposefully sought not just its actions but also the wrongful *consequences* of the actions taken. Restatement (Second) of Torts § 8A (1965); *Ratzlaf*, 510 U.S. at 141. It is the intention to cause unlawful consequences that separates specific intent from negligence and recklessness. Thus, the Supreme Court has expressly rejected theories of “intent” predicated only on negligence or gross negligence. *See Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 191 n.7, 197, 201, 215 (1976).

Specific intent is a necessary element of common-law fraud, but the concept is by no means limited to fraud cases. At common law, the specific intent crimes included conspiracy; in civil cases, specific intent is an element of secondary liability theories (such as aiding and abetting), in addition to being required for certain individual torts. *See Prosser and Keeton on the Law of Torts* 322-24 (5th ed. 1984); *see also* Restatement (Second) of Torts § 876(b). In patent and copyright law, induced infringement liability—*i.e.*, secondary liability for another’s direct

infringement—likewise requires specific intent. *See Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, 545 U.S. 913, 935-36 (2005) (discussing common law and requiring “affirmative intent”); *DSU Med.*, 471 F.3d at 1305 (requiring “specific intent”). In all contexts, the accused wrongdoer must have intended the unlawful consequences of its acts, not merely intended to perform the acts themselves. *Kyocera*, 545 F.3d at 1354 (the specific intent necessary to induce infringement “requires more than just intent to cause the acts that produce direct infringement ... the inducer must have an affirmative intent to cause direct infringement”) (quoting *DSU Med.*, 471 F.3d at 1306). Where specific intent is required in the patent law—as the Supreme Court has required it in finding inequitable conduct—the common-law standard should apply. *Cf. eBay*, 547 U.S. at 391-92.

Specific intent is an element of common-law fraud, the tort that most resembles the inequitable conduct doctrine. *See* Restatement (Second) of Torts § 525. For more than two centuries the Supreme Court has repeatedly reiterated that “[f]raud means an intention to deceive.” *Lord v. Goddard*, 54 U.S. (13 How.) 198, 211 (1851); *see also Wiscart v. D’Auchy*, 3 U.S. (3 Dall.) 321, 330 (1796) (“fraud must always principally depend upon the *quo animo*,” *i.e.*, on animus or bad faith); *Moss v. Riddle & Co.*, 9 U.S. (5 Cranch) 351, 357 (1809) (stating that “[f]raud consists in the intention”); *Magee v. Manhattan Life Ins. Co.*, 92 U.S. 93, 98-99 (1875) (“To constitute fraud, the intent to deceive must clearly appear. The concealment

must be willful and intentional”) (citation omitted); *Reilly v. Pinkus*, 338 U.S. 269, 275 (1949) (findings of fraud are justified by representations “made with intent to deceive”); *Madigan v. Telemarketing Assocs., Inc.*, 538 U.S. 600, 621 (2003) (“the gravamen of the fraud action . . . is particular representations made with intent to mislead”).

For example, a patent “procured by intentional fraud” enjoys no immunity under the antitrust laws. *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 176 (1965). *Walker-Process* fraud is “common law fraud,” and thus requires the showing of specific intent that applies in fraud actions throughout the law; “mere failure to cite a reference to the PTO will not suffice.” *Dippin’ Dots, Inc. v. Mosey*, 476 F.3d 1337, 1346-47 (Fed. Cir. 2007) (internal quotation marks omitted). Indeed, the Supreme Court equated *Walker-Process* fraud with the fraudulent procurement exemplified by *Precision Instrument, Hazel-Atlas*, and *Keystone*. *Walker Process*, 382 U.S. at 176-77 (citing all three cases).

Courts likewise bar copyright infringement actions if the registration holder defrauded the Copyright Office. *Whimsicality Inc. v. Rubie’s Costume Co.*, 891 F.2d 452 (2d Cir. 1989). But a copyright will not be held unenforceable “[a]bsent intent to defraud.” *S.O.S., Inc. v. Payday, Inc.*, 886 F.2d 1081, 1086 (9th Cir. 1989) (internal quotation marks omitted); *see also Lennon v. Seaman*, 84 F. Supp. 2d 522, 525 (S.D.N.Y. 2000) (and cases cited therein); *see Nimmer on Copyright*

§ 7.20 [B][2] (2010) (noting that 17 U.S.C. § 411(b) codified the pre-2008 judicial standard).

No less than *Walker-Process* fraud or copyright fraud, inequitable conduct—*i.e.*, fraud in the prosecution or enforcement of a patent—requires proof of specific intent. There is no reason for patent law to diverge from the general law (or the antitrust or copyright laws in particular) on this most important question; wherever common-law principles govern they must do so uniformly such that intent carries the same definition in patent law as it does in securities law or elsewhere in the civil law. *Cf. eBay*, 547 U.S. at 391-92. And, indeed, this Court recognized as much two decades ago when it held that negligence, even gross negligence, is not enough to warrant invocation of the inequitable conduct doctrine. *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (*en banc*). Rather, specific intent to deceive is required. *Cf. Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 319, 324 (2007) (securities fraud requires “intent to deceive, manipulate or defraud”; and complaint must create a strong “inference of scienter” that is “at least as compelling as any opposing inference of non-fraudulent intent”).

3. Yet, in recent years, decisions of this Court have departed from the common-law standard of specific intent by holding that intent to deceive may be inferred from the materiality of a misrepresentation when “(1) highly material infor-

mation is withheld; (2) the applicant knew of the information and knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding.” *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1313-14 (Fed. Cir. 2008) (internal punctuation omitted). This line of cases is wrongly decided and the *en banc* Court should take this opportunity to clarify that materiality and intent are separate requirements that must each be proved independently under the inequitable conduct doctrine, as in common-law fraud cases. *See, e.g., Cheney Bros., Inc. v. Batesville Casket Co.*, 47 F.3d 111, 114 (4th Cir. 1995) (“The evidence of each [element of fraud] must be ‘clear, cogent, and convincing,’ and failure to prove any one element is fatal to the plaintiff’s cause of action”); *Mellon Bank Corp. v. First Union Real Estate Equity & Mortg. Invs.*, 951 F.2d 1399, 1409 (3d Cir. 1991).

The so-called sliding scale applied in some inequitable conduct cases is flawed at each of its steps: Step one of the analysis inserts materiality into the test for intent. Once materiality is established, step two examines whether the patentee “should have known” it was material—a mere negligence standard. *In re Bose*, 580 F.3d 1240, 1244 (Fed. Cir. 2009). Finally, step three shifts the burden to the patentee to proffer some “credible explanation,” effectively requiring applicants to disprove intent based on materiality and negligence. *See Larson Mfg. Co. of S.D. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1343-44 (Fed. Cir. 2009) (Linn, J., con-

curing). Thus, a highly material omission can satisfy both the materiality test and the intent test—so long as the applicant should have known of the materiality. This approach has no footing in the common law, and has never been sanctioned by the Supreme Court. *Cf. Ernst & Ernst*, 425 U.S. at 208.

Materiality is not proof of intent. Mere materiality coupled with negligence cannot be reconciled with the purposely wrongful conduct required by the Supreme Court's precedent or this Court's own decision in *Kingsdown*. *Aventis*, 525 F.3d at 1350 (Rader, J., dissenting) (“Merging intent and materiality at levels far below the *Kingsdown* rule has revived the inequitable conduct tactic”). The historical precedents limit the inequitable conduct doctrine to deliberate schemes to mislead. *Larson*, 559 F.3d at 1343 (Linn, J., concurring) (the “Supreme Court’s three inequitable conduct cases involved overt fraud”). Outright perjury (*Precision Instrument*), or intentionally false and fabricated evidence and testimony (*Hazel-Atlas* and *Keystone*) show intent to deceive—the mere negligent failure to disclose something material does not. *Aventis*, 525 F.3d at 1352 (Rader, J., dissenting). Indeed, the Supreme Court has said that a patentee need not explain every irregularity or “even impropriety” in the process. *Am. Bell Tel. Co.*, 167 U.S. at 242.

4. Inequitable conduct has become “a rather automatic assertion in every infringement case.” *Advanced Magnetic Closures, Inc., v. Rome Fastener Corp.*, 607 F.3d 817, 835 (Fed. Cir. 2010) (Rader, C.J., concurring). This unfortunate re-

ality is in no small part due to an unduly permissive view of the intent element taken by some decisions. *See Praxair*, 543 F.3d at 1329 (Lourie, J., concurring); *Larson*, 559 F.3d at 1344 (Linn, J., concurring). Ultimately, this has adverse effects across patent law.

A lax standard for inequitable conduct not only encourages unwarranted litigation, it may interfere with the ability of the PTO to effectively examine patent applications. The proliferation of inequitable conduct charges gives patent applicants strong incentives to inundate the PTO with information in the hopes of forestalling a later inequitable conduct charge. Ironically, this may decrease patent quality if applicants disclose too much prior art for the PTO to meaningfully consider. *Cf. Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 351 (2001).

The consequences of perpetuating the “plague” of “inequitable conduct as a litigation strategy,” *Aventis*, 525 F.3d at 1350 (Rader, J., dissenting), would be severe in the pharmaceutical industry, on which the American public depends for disease-curing, lifesaving innovations, and in the computer industry, which has been a major engine of American economic growth since before the first microprocessor. This Court should not condone any measure of inequitable conduct that could produce a chilling effect on the “Progress of . . . useful Arts” that a properly functioning patent system is meant to promote. U.S. Const. art. I, § 8, cl. 8; *cf. Phila. Newspapers, Inc. v. Hepps*, 475 U.S. 767, 778 (1986). Indeed, every con-

ceivable policy counsels against allowing inequitable conduct claims to proceed in any but the most extreme cases of fraud and deception.

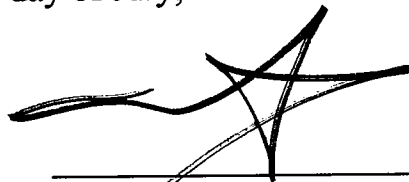
The inequitable conduct doctrine can and should be shaped by the Court to conform to the broader policies of the Progress Clause and the Patent Act, as well as the general run of federal law. Indeed, an important aspect of the Supreme Court's recent patent decisions is that patent cases should generally be decided according to the customs of other commercial litigation in our federal courts. *See, e.g., KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007); *MedImmune, Inc., v. Genentech, Inc.*, 549 U.S. 118, 132 (2007). The inequitable conduct doctrine is no exception.

Specific intent, in patent law as in the general law, requires a showing that the actor—whether patentee or accused infringer—purposefully desired to cause the consequences of its action. *See Grokster*, 545 U.S. at 935-36. Specific intent is a high standard because in every instance in which it is required, the intentional acts at issue (if proved) carry dire consequences. By acknowledging that these areas of heightened liability require specific intent—as expressed in the common law—the Court can reconcile this area of patent law with long-standing principles of general applicability.

CONCLUSION

The judgment of the district court should be reversed, and the Court should adopt the common-law standard of specific intent—"the intent to accomplish the precise act with which one has been charged"—as an indispensable and undilutable element of the inequitable conduct doctrine.

Respectfully submitted this 30th day of July, 2010.



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