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 & 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 , CONSOLIDATED CASE NOS. 04-CV-2123, 04-CV-3327, AND 04-CV-3732, JUDGE WILLIAM H. ALSUP

BRIEF OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION AS *AMICUS CURIAE* IN SUPPORT OF NEITHER PARTY

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August 2, 2010

CERTIFICATE OF INTEREST

Counsel for the amicus curiae Biotechnology Industry Organization certifies the following:

1. The full name of the amicus that we represent is:

BIOTECHNOLOGY INDUSTRY ORGANIZATION

2. The name of the real party in interest that we represent is:

BIOTECHNOLOGY INDUSTRY ORGANIZATION

3. All parent corporations and publicly held companies that own 10 percent or more of the stock of the amicus curiae that we represent are:

None

4. The names of all firms and partners or associates that appeared for the amicus curiae now or are expected to appear in this Court are:

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H. Sauer

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I. INTEREST OF BIOTECHNOLOGY INDUSTRY ORGANIZATION

Amicus curiae Biotechnology Industry Organization (BIO) is the principal trade association of the U.S. biotechnology industry, with over 1,150 corporate, academic, and non-profit members. The vast majority of BIO's corporate members are small or mid-size businesses that have yet to bring a product to market and attain profitability. Approximately 90% have annual revenues under $ 25 million. These businesses invest heavily in research on biologic medicines and diagnostic products, next-generation crops, and a host of scientific solutions for society's mounting energy and environmental needs. The biotechnology industry has more than 400 drug products and vaccines currently in clinical trials being studied to treat more than 200 diseases.

Biotechnology products today treat heart disease, cancer, AIDS, stroke, septic shock, diabetes, anemia, cystic fibrosis, multiple sclerosis, lupus, kidney disease, rheumatoid arthritis, and liver disease. Modern biotechnology crops increase farm productivity, conserve arable land, and reduce pesticide and herbicide use. Many more inventions, however, have yet to make the transition from foundational knowledge to practical and safe solutions for health, nutrition, and energy needs.

Businesses that engage in such research operate in an environment of rapidly-evolving science, high rates of publication, and vibrant scientific and

public discourse. Aware of their duty of disclosure, biotechnology applicants face difficult choices about which information to cite to the PTO, and the risk of misstatements and omissions is significant.

Valid patents procured after complex prosecution are among a biotechnology company's most valuable business assets. Many years later, the complexity that drove the procurement of such patents opens the door to hindsight-driven charges of prosecution misconduct, allegedly committed by applicants "under pressure" to obtain patent protection.

The power of hindsight is particularly evident in the biopharmaceutical area, where product development times are lengthy, and development costs are large. Developing a single biotechnology therapy requires an average investment of $1.2 billion, and the clinical testing period alone consumes more than 8 years on average. Joseph A. Di Masi and Henry G. Grabowski, The Cost of Biopharmaceutical R & D: Is Biotech Different? *Manage. Decis. Econ.* 28: 469-479 (2007). Such investment is risky. For every successful biopharmaceutical product, thousands of candidates are designed, screened, and rejected after large investments have been made. Only a small minority even advance to human clinical trials, and most of those fail to obtain FDA approval. The chances that a biopharmaceutical medicine will advance from the laboratory bench to the hospital

bedside are approximately one in 5,000. Secretary of Health and Human Services Thompson, *Remarks at the Milken Institute's Global Conference* (Apr. 26, 2004), http://www.hhs.gov/news/speech/2004/040426.html.

In the rare instances where this long-term investment comes to fruition in the form of high-value products, litigation over the underlying patents will almost certainly occur. It has become commonplace for such litigation to include charges of prosecution misconduct, and this practice is believed to be fostered by actual or perceived ambiguities in the current inequitable conduct jurisprudence and inconsistencies in its application. While litigating allegations of misconduct increases the cost and complexity of such litigation, the greater harm of the doctrine lies elsewhere: The doctrine today impairs the ability of biotechnology patent applicants to engage in high-quality patent prosecution, and undermines the reliance on patents that is critical to investment and product development decisions in biotechnology. For these reasons, BIO urges this Court to set aside its prior legal framework on which the inequitable conduct defense presently rests and adopt a more certain framework, as proposed below.

The parties to this appeal are members of BIO. BIO takes no position on the merits of this case and has no interest in the ultimate disposition of this litigation. No party has contributed to or participated in the preparation of this brief.

II. SUMMARY OF THE ARGUMENT

In the interest of strengthening the U.S. patent system and protecting the public interest in the issuance of strong, valid patents, BIO urges this Court to abandon its present legal framework for determining inequitable conduct and adopt a framework that requires clear and convincing evidence of (1) the misrepresentation or omission of a material fact, (2) with a specific intent to deceive the PTO, and (3) PTO reasonable reliance on the misrepresentation or omission, to the public's detriment, in issuing an invalid claim. BIO submits that its proposed framework for determining inequitable conduct will increase certainty in the analysis and cure the "plague" that has infected the system since this Court's creation in 1982.[1]

III. ARGUMENT

While the original purpose of the inequitable conduct defense – encouraging full disclosure of relevant information to the PTO -- may have been a laudatory one, its net impact has been damaging to the U.S. patent system, including the

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[1] The framework proposed here concerns the defense of inequitable conduct as a basis for holding a granted patent unenforceable. This brief does not address the legitimate interests of the PTO in establishing, through appropriate rulemaking, standards of conduct of registered practitioners and others who appear before it. *See infra* section III.F.

PTO. For more than 25 years, this Court has attempted to apply the law on inequitable conduct in a fair and uniform manner but without much success. Nonuniformity and unpredictability are as much a problem today as in 1970, when this Court's predecessor first expanded the bases for inequitable conduct beyond those for traditional fraud, thereby inviting the PTO to do the same. *Norton v. Curtiss*, 433 F.2d 779, 791-93 (CCPA 1970) (noting "this is the first occasion on which this court has been asked to review an action of the Patent Office dealing with charges of fraud" and holding that "'fraud' on the Patent Office . . . encompasses not only . . . 'technical' fraud, but also a wider range of 'inequitable' conduct found to justify holding a patent unenforceable").

BIO believes that this Court's lack of success is at least in part attributable to the nonuniform foundation from which the doctrine has developed. This court has strained to synthesize a uniform body of law from Supreme Court precedent concerned about patent "monopolies," disparate lower court precedent, including that of a CCPA preoccupied with industrial era patent prosecution in a postwar PTO, and rules designed to aid the PTO in conducting its business. Lack of uniform goals underlying these bases has resulted in an unworkable and outdated framework for deciding inequitable conduct cases.

In 1988, this Court decided *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867 (Fed. Cir. 1988) (*en banc* in relevant part). The Court sought to bring greater clarity to its own conflicting body of precedent and address a rising tide of inequitable conduct allegations. Yet, by instituting an abuse of discretion standard for reviewing a lower court's "balancing," this Court made uniformity of this determination virtually impossible.

This Court should take its first opportunity in over 20 years to eliminate the current inequitable conduct framework and replace it with a new approach -- one providing more certainty while protecting the public's interest in valid patents. Sitting *en banc*, this Court is not confined by prior CCPA or Federal Circuit precedent, or by PTO rules earlier adopted by this Court. And, while this Court cannot overrule Supreme Court precedent applying equitable "unclean hands" defenses, the approach outlined below is not inconsistent with that precedent.

BIO addresses the Court's six issues as follows:

A. This Court's Present Framework For Inequitable Conduct Should Be Replaced With A More Certain Approach

BIO respectfully submits that the modern inequitable conduct doctrine creates more harm than good for the U.S. patent system. In the PTO, the doctrine hinders rather than promotes candid interactions between applicants and patent

examiners. For example, it creates frequent pressure on applicants to make prophylactic submissions of large amounts of information that examiners neither want nor consider material, resulting in a disclosure burden that is without parallel in the industrialized world.[2] Voluminous information disclosure statements (IDSs) are common in the biomedical arts. Other applicants forego prior art searching and IDS submissions altogether. *See, e.g.,* Statement of USPTO Director Dudas before the U.S. Senate Judiciary Committee, June 6, 2007, http://www.uspto.gov/news/speeches/2007/2007jun06.jsp ("It discourages many applicants from conducting a search and leads others to be indiscriminate in the information they submit."). *See also* Letter of Commerce Secretary Gutierrez to Senate Judiciary Committee Chairman Leahy, April 3, 2008, http://www.ogc.doc.gov/ogc/legreg/letters/110/S1145Apr0308.pdf (explaining that applicant quality standards and inequitable conduct reform are inextricably linked).

Under the current framework, applicants are commonly forced to adopt a "no-comment" approach to patent prosecution as the most prudent course of action. Examiners who may have 10 hours or less to prepare a first Office action (including searching and IDS review) can expect little help from wary applicants

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[2] See, e.g., U.S. Patent 7,754,697, which has 18 pages of cited references including 5 pages listing references to claims, office actions, declarations, amendments, interview summaries, and other communications in related applications in the PTO.

concerned about future allegations of concealment or misrepresentation. Incipient patent practitioners are taught to attack the sufficiency of Office Actions on legal grounds only, and to reserve discussions (if any) about the merits of prior art for examiner interviews that leave essentially no trace in the prosecution history. And the submission of affidavits or expert declarations, however helpful they may be to examiners, is deemed fraught with litigation risk. At a time of historically high backlogs, when the PTO is faced with patent applications more numerous and more complex than ever before, this policy outcome is unsustainable.

Evidence of the doctrine's negative impact can be found also in the courts. Inequitable conduct is today pled with very high frequency. For example, patent litigation statistics compiled by the University of Houston Law Center show that federal courts issued no less than 334 reported inequitable conduct dispositions during 2005-2009. Remarkably, the frequency at which inequitable conduct is raised and decided appears to be on par with obviousness under 35 U.S.C. § 103 (364 dispositions). *See* U.S. Patent Litigation Statistics, http://www.patstats.org/Patstats2.html.

Inequitable conduct allegations are particularly frequent in cases involving high-value therapeutic and other biomedical products. By 2006, 42% of all post-*Kingsdown* appeals to the Federal Circuit on the issue of inequitable conduct

involved patents on biologics, drugs, medical devices, diagnostics, or agricultural biotechnology products. Brief, Biotechnology Industry Organization as Amicus Curiae supporting Petition for Cert. in *Ferring B.V. v. Barr Labs.*, 437 F.3d 1181 (Fed. Cir. 2006), *cert. denied*, 549 U.S. 1015 (2006)(No. 06-372), at 15; available at: bio.org/ip/amicus/ferring.pdf. This trend appears to continue unabated. BIO's analysis of decisions listed in the patstats.org database for 2007-2009 indicates that fully 35% of all inequitable conduct dispositions, overwhelmingly at the district court level, involved biotechnology, drug, or medical device patents.

Absent an assumption that fraud and deceit in patent procurement are somehow unusually prevalent in the life sciences industry, such a high proportion of biomedical patents can only be explained by an over-inclusive legal standard that lends itself well to attacking the enforceability of biotech patents, combined with a high incentive to make such assertions. Indeed, there are some aspects of biotechnology patent practice and business reality that make the invocation of the inequitable conduct defense particularly attractive.

Biotechnology patent prosecution commonly takes place against a backdrop of fast-moving science and competing business needs that make it virtually impossible for a patent attorney to "keep an eye" on all potentially relevant information that is circulating into and out of a company. For example, company

scientists present their findings at professional meetings, write scientific publications, and constantly exchange information with outside colleagues without first seeking the advice of patent practitioners. Large numbers of references are collected by research departments and become "known" to scientists who often feel that pending patent applications, while important, are "someone else's job." Regulatory affairs employees who rarely interact with patent attorneys make representations about data to regulatory agencies. Other employees charged with business development or investor relations may tout the benefits and advantages of the company's technology over that of competitors or over older technology.

Much of this potentially relevant information may at some point or flicker across the computer screen of a patent practitioner. Even more may become known to scientists or administrators who may be deemed subject to the duty of disclosure, yet have no familiarity with patent practice. In addition, patent practitioners face difficult choices about the disclosures they *do* control: the selection of prior art for submission in light of shifting legal standards; the inclusion of experimental data to ensure an adequate representation of data to support enablement and best mode; the parsing of foreign office actions for references and examiner commentary; the coordination of opposition proceedings abroad; the disclosure of professional relationships with scientific experts; communications to U.S. and foreign examiners in related applications; and the like.

Against this backdrop, it will almost certainly be possible to find statements that an effective advocate can portray as inconsistent with representations made to the PTO, or uncited prior art that can be recast as material to examination.

At the time biotech patents are commercialized and litigated, such complex patent prosecution often lies in the remote past. With typical biotechnology product development times in the 10-year range, patentees can be particularly hard-pressed to explain ambiguities about distant patent prosecution, or inconsistent statements from various parts of one or more companies that were discovered only after extensive document production.

This problem has an even greater impact on good faith assignees and licensees who had no involvement in the prosecution of the allegedly wrongly procured patents. Because the cost and risk of product development cannot usually be borne by a single entity, biotechnology development and commercialization depends on an active licensing marketplace for development-stage products and their associated intellectual property. Licensing transactions commonly take place to advance inventions out of research universities, through commercial development and regulatory approval, into medical or commercial practice. During in-licensing due diligence, companies can develop a reasonable level of confidence about the validity of such patents. But possible misrepresentations and omissions

during prosecution are hard to detect, and licensees can never have the same confidence that their patents are not just valid but also enforceable. In this way, the inequitable conduct doctrine creates business uncertainty that is not conducive to the kind of investment and technology transfer that biotechnology needs to flourish.

The fact that inequitable conduct is pled significantly more often than it succeeds supports the proposition that the law is too uncertain. For 2007-2009, inequitable conduct in cases involving medical or agricultural biotechnology, drugs, or medical device patents were decided in favor of the patentee approximately 85% of the time (data analyzed from patstats.org collection, http://www.patstats.org/cumulative_caselist_thru_1q10.xls). When it is found, inequitable conduct is more likely to influence the ultimate disposition of the litigation because of its deep impact on the patent-in-suit and the patentee's business,[3] and a less-than-encouraging prospect of appellate reversal under a deferential clear error/abuse of discretion standard.

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[3] An adverse inequitable conduct finding extinguishes the property right in any unasserted claims, and raises the possibility of "infectious unenforceability," findings to make the case exceptional, demands for fees and costs, and follow-on litigation for damages by the defendant and unrelated third parties.

At the outset of biotech product development, the perceived risk that a valid patent could eventually be held unenforceable is thus far from negligible, given the magnitude of an investment decision that typically exceeds several hundred million dollars. After a decade of investment, all could be lost. For example, the Federal Circuit's reversal of its own inequitable conduct holding in *Purdue Pharma L.P. v. Endo Pharms. Inc,* 410 F.3d 690 (Fed. Cir. 2005), *vacated*, 438 F.3d 1123 (Fed. Cir. 2006) came too late to avoid irreparable harm to all those involved.[4]

Immediate launch of infringing products after initial appellate affirmance of unenforceability eroded the market for the patented product, and resulted in $114 million in infringing sales during the following seven months alone. Robert T. Rhoad, The OxyContin® Settlement: A Signpost on the Road to a Consumer-Friendly Policy for Generic Competition, ABA Health eSource Vol. 3 (2) 2006, http://www.abanet.org/health/esource/Volume3/02/rhoad.html. Meanwhile, the patentee continued to defend dozens of follow-on lawsuits by third parties seeking damages for harm caused by its allegedly fraudulently procured patents and its alleged sham litigation for their enforcement. *In re Oxycontin Antitrust Litigation*, 314 F.Supp.2d 1388 (Jud. Pan. Mult. Lit. 2004) (identifying 3 actions and 41 potential tag-along actions). After this Court reversed and remanded the case,

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[4] Purdue Pharma L.P. is not a member of BIO.

multiple infringers faced serious business uncertainty and the possibility of substantial damages liability. Confusion ensued among health plans, wholesalers, pharmacists, doctors, and patients. But most significantly, vacatur came too late to avoid layoff of half the patentee's R&D workforce. Dan Strempel, Patent Ruling Yields Deep Cuts at Purdue Pharma, Fairfield County Business Journal, Jun. 20, 2005, http://www.allbusiness.com/legal/intellectual-property-patent/977872-1.html.

Ultimately, permanent harm to biomedical innovation was the real outcome. Such examples have taught the industry a grim lesson that no company, however diligent, is immune from the risk of eventually suffering the profound consequences of an inequitable conduct holding, and nobody, not even accused infringers, benefits from the doctrine's unclear and shifting contours.

Biotechnology innovators understand that eventual litigation over their most valuable patents is a strong likelihood, especially in light of abbreviated regulatory approval pathways that facilitate entry of competing biosimilar or generic products. Such products can be developed and approved at vastly reduced cost, because they rely on clinical data earlier generated for an innovator product. The comparatively low barriers to generic or biosimilar entry also create systematic litigation pressure

on the innovator's patents, which often remain as the only obstacle to market access.

The high commercial stakes on both sides of such litigation ensure that the patent will be challenged by any means possible. At the high rate at which inequitable conduct is pleaded, an eventual holding of unenforceability is only a matter of time. Thus, lingering uncertainty about the doctrine impairs the ability of biotechnology companies to rely on valid patents for investment decisions that will come to fruition only in the far future. Otherwise valid and infringed patents are tainted, and the innovations protected by such patents are left idle. Nothing in the doctrine's historic roots compels such an outcome.

B. The Present Legal Framework For Inequitable Conduct Should Bbe Replaced With A New, More Certain Standard

BIO submits that this Court should develop a new, more certain standard that would better serve our patent system and the public interest and reduce the frequency at which inequitable conduct is pled.

Under the standard proposed by BIO, inequitable conduct would require proof of three elements:

(1) A misrepresentation or omission of material fact;

(2) A specific intent to deceive; and

(3) PTO reasonable reliance on the misrepresentation or omission, to the public's detriment, in issuing at least one invalid claim.

Under BIO's proposed standard, an alleged infringer would have to establish these three elements by clear and convincing evidence. The focus of the standard is the public interest, rooted in the Constitution: To "promote the Progress of ... useful Arts, by securing for limited Times to ... Inventors the exclusive Right to their... Discoveries." Art. I, § 8, cl. 8. The patent laws promote this progress by supporting the issuance of patents that are "presumed valid." 35 U.S.C. § 282.

BIO's proposed standard borrows from the doctrine of common law fraud, but should not be confused with it. Common law fraud is a tort that has its clearest contours when applied by courts of law, and that is less clear, and its application less structured, when invoked as a defense in equity. *See generally*, *Sec. & Exch. Comm'n v. Capital Gains Research Bureau*, 375 U.S. 180, 193 (1963) (quoting Hanbury, Modern Equity (8th ed. 1962), 643) ("'Law has come to regard fraud . . . as primarily a tort, and hedged about with stringent requirements, the chief of which was a strong moral, or rather immoral element, while equity regarded it, as it had all along regarded it, as a conveniently comprehensive word for the expression of a lapse from the high standard of conscientiousness that it exacted from any party occupying a certain contractual or fiduciary relation toward another party.'"). *See also* Prosser and Keeton on Torts 731-32 (W. Page Keeton

ed., West 1984) (1941) (explaining that modern procedure codes have very largely "obliterated" the distinction between law and equity and as a result, there is a great deal of uncertainty concerning the "equitable" defense of fraud -- with some courts regarding it as a form of rescission in equity and others considering it analogous to the tort action of deceit).

Even less clear is the doctrine of "unclean hands" (also a doctrine developed by courts in equity). The Supreme Court cases suggest that a pattern of very egregious conduct in both the PTO and the courts is necessary to invoke the doctrine. *See, e.g., Precision Instr. Mfg. Co. v. Auto Maint. Mach. Co.*, 324 U.S. 806 (1945); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944), overruled on other grounds, 429 U.S. 17 (1976); *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240 (1933). Beyond discussing the type of conduct needed to invoke the doctrine, the Court has given no clear guidance on when the maxim should be applied. This leaves courts with a wide range of discretion in determining whether or not to aid either party. *See,* e.g., *Keystone*, 290 U.S. at 245-46 ("A court of equity acts only when and as conscience commands, and if the conduct of the plaintiff be offensive to the dictates of natural justice . . . then he will be held remediless in a court of equity. . . . [The court] is not bound by formula or restrained by any limitation that tends to trammel the free and just

exercise of discretion."). Thus, the unclean hands doctrine is not helpful to establish clear standards of conduct in the PTO.

Under Supreme Court law, common law fraud and unclean hands will remain viable as separate defenses in very limited circumstances, for example, when the "conduct [is] so reprehensible that it could alone form the basis of an actionable wrong (e.g., the common law action for deceit)." *Norton v. Curtiss*, 433 F.2d at 792. However, these defenses have very little to do with this Court's present inequitable conduct law. Given their lack of clarity and applicability, BIO believes that their transposition outside their original context would insufficiently account for the public reliance interest in clear, valid patent rights, and thus neither should be used to police prosecution misconduct.

When it has addressed remedies for misconduct in the procurement and enforcement of patents in the separate contexts of unclean hands or antitrust law, the Supreme Court repeatedly has emphasized the primacy of the public interest over that of private litigants. *See, e.g., Precision Instru.*, 324 U.S. at 816, *Walker Process Equip. v. Food Mach. & Chem. Corp.*, 382 U.S. 176-77 (1965). By proposing its new standard, BIO likewise asks this Court to refocus the inequitable conduct defense on the public interest. Specifically, BIO's proposed standard applies in instances where unenforceability may be justified to remedy public

harm. In instances in which misconduct has occurred, but the public has not been harmed (e.g., the misconduct did not result in the issuance of an invalid claim), administrative or criminal sanctions can serve as adequate deterrence without destroying the patent right. Striking down valid patents should be avoided because it causes more public harm than good.

Bad-faith applicants who deceive the PTO into issuing invalid claims indeed cause public harm. The public is entitled to rely on, and does rely on, the presumptive validity of patents. Wrongful procurement of invalid patents is likely to cause wrong commercial decision-making in the marketplace that leads to inefficiencies and misallocation of resources on many levels. Fraud or deceit in the procurement of such patents thus causes the kind of public harm for which an unenforceability remedy may be appropriate.

But the public interest works both ways, and is not necessarily advanced if *valid* patents are held unenforceable. Commercial reliance on valid patents takes many forms. Start-up biotechnology companies are formed around such patents, and investors invest in them in reliance on their patents' presumptive validity. Patents bring order to the competition for scarce clinical resources, scientific expertise, and regulatory agency time that is so characteristic of biotechnology development. Competing businesses may delay market entry of infringing

products, use their resources to develop design-arounds, or redirect their business into a different market altogether. Other businesses may take expensive licenses under such patents, often only after procuring favorable validity opinions from independent counsel. Whole companies are bought and sold on the value of their patents. Every such decision is based on a patent's presumptive validity and cannot be undone. And indeed, every such decision is the right one to make if the patent is valid. To affirm the validity of such patents in litigation - and then hold them unenforceable – undoes years of correct commercial decisionmaking and sends a message that businesses cannot rely on patents, be it their own or their competitors, regardless of their validity. Such an outcome in no way promotes the progress of the useful arts, and causes more public harm than good. To protect the public reliance interest in valid and clear patent rights, BIO's proposed standard therefore requires that the applicant must have caused the PTO to issue at least one invalid claim.

This Court's present inequitable conduct doctrine is based primarily on CCPA law, specifically *Norton v. Curtiss*, and the PTO's Rule 56 (as adopted by the PTO in 1977).[5] Neither CCPA law nor PTO rules bind this Court. Thus, BIO

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[5] Prior to 1977, the title of Rule 56 was "Improper applications," and its scope was quite limited and based on "fraud": "Any application signed or sworn to in blank or without actual inspection . . . [and] any application fraudulently filed or in

respectfully submits the Court should overrule *Norton v. Curtiss* (to the extent *Kingsdown* did not do so), and adopt the above-proposed standard, as elaborated below.

C. The Materiality Standard Should Require That "But-For" The Misrepresentation Or Omission, At Least One Asserted Claim Would Not Have Issued

Material information should be defined as facts that establish invalidity of at least one issued claim, in other words, "but for" materiality. Other information, such as attorney argument (if just that), past relationships with declarants, or noncompliance with small entity fee requirements, that does not impact validity should not constitute material information. Materiality should be measured at the time of trial. Doing so best comports with the interests of the public, who have

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connection with which any fraud is practiced or attempted on the Patent Office, may be stricken from the files." (pre-1977 versions). The rule was amended in 1977 to incorporate the "reasonable examiner" standard and was embellished in the Manual of Patent Examining Procedure ("MPEP") in 1980, the first time a "Duty of Disclosure" section was included in it. See MPEP, Ch. 2000 (Apr. 1980) (relying heavily on *Norton v. Curtiss*). The number of times inequitable conduct has been mentioned by a federal court has exploded since 1980, even after 1988 when *Kingsdown* was decided. *See* Patently-O, Measuring the Plague of Inequitable Conduct (June 2, 2010), http://www.patentlyo.com/patent/2010/06/measuring-the-plague-of-inequitable-conduct.html (citing Mammen, "Controlling the 'Plague': Reforming the Doctrine of Inequitable Conduct," 24 Berkeley Tech. L.J. 1329 (2010)).

relied on the presumptive validity of the issued claim. It also simplifies the analysis and conserves judicial resources by obviating the need for certain discovery about what would have happened at some point in the distant past. Measuring materiality at the time of trial also means that all information of record can be taken into account, including for example, rebuttal evidence that was not of record in the PTO or not known at the time of prosecution.

A trial court, prior to hearing evidence of specific intent, should be required to make a determination that an individual having a duty of disclosure engaged in misconduct that would have caused the PTO, acting reasonably, to issue at least one invalid claim. In this way, the burden on the court and the parties will be reduced in cases in which materiality has not been proven. In fact, given that discovery on the issue of intent is typically very extensive, some courts may permit parties to forego such discovery until materiality is established.

The proposed "but for" materiality standard further best comports with the principle of detrimental reliance. Proof of inequitable conduct should require a misrepresentation or omission of a material fact that was reasonably relied upon by the PTO in issuing an invalid claim, to the public's detriment. As explained above, injury to the public is greatest where the applicant's misconduct caused the PTO to issue an invalid claim. On the other hand, if there was misconduct in procuring a

valid claim, detrimental reliance does not follow, and the remedy should not be unenforceability.

A materiality standard that is tied to a defect in the validity of the patent-in-suit would not be inconsistent with instances where the Supreme Court has, outside the unclean hands context, sustained claims that relied to some extent on allegations of patent prosecution misconduct. *See United States v. Am. Bell Tel. Co.*, 128 U.S. 315, 355-56 (1888) (allegation that inventor knowingly misrepresented priority of inventorship, constituting an "essential element" that was "absolutely necessary" and indispensable to the patent right, was sufficient to sustain claim of fraudulent patent procurement); *see also Walker Process Equip. v. Food Mach. & Chem. Corp.,* 382 U.S. 176-77 (1965) (allegation that patentee knowingly concealed invalidating prior use to which it was a party, if proven, would be sufficient to remove exemption from antitrust laws, but good-faith mistake as to effect of prior use "on patentability" would furnish complete defense).

Nothing in these and other Supreme Court cases *demands* that this Court continue to apply a broad and inclusive materiality standard. Accordingly, this Court is free to adopt a test which would evaluate misrepresentations or omissions during patent prosecution according to their effect on the validity of the patent-in-

suit. Doing so would refocus the inquiry on the primary public interest in clarity and validity of patent rights, and give effect to Chief Judge Markey's warning in *Kingsdown*:

> It is well to be reminded of what actually occurred in this case--a ministerial act involving two claims, which, because both claims contained allowable subject matter, *did not result in the patenting of anything anticipated or rendered obvious by anything in the prior art and thus took nothing from the public domain.* [*Kingsdown,* 863 F.2d at 873 (emphasis added).]

D. Intent Should Be Specific And Treated As A Separate Inquiry: Under No Circumstances Should Intent Be Inferred From Materiality Alone, Or From Gross Negligence

This Court in *Kingsdown* made clear that *both* materiality and intent must be independently proven and that gross negligence is *not sufficient* to establish intent. *Id.* at 872, 876 (*en banc*). In spite of these en banc holdings, the present inequitable conduct standard permits deceptive intent to be

> inferred from findings: (1) that the [withheld information] was highly material to the prosecution ... , (2) that the applicants knew of [the withheld information] and knew or should have known of its materiality, and (3) that the patentee has failed to come forward with any credible good faith explanation for the applicants' failure to disclose [the withheld information].

Praxair, Inc. v. ATMI, Inc., 543 F.3d 1306, 1315 (Fed. Cir. 2008), *cited with disapproval in Larson Mfg. Co. v. Aluminart Prods., Ltd.*, 559 F.3d 1317, 1342 (Fed. Cir. 2009) (Linn, J., concurring "because our precedent so requires").

Consistent with *Kingsdown,* BIO's proposed standard would set aside the present standard and require "independent and clear evidence" of deceptive intent. *Nobelpharma AB v. Implant Innovations*, 141 F.3d 1059, 1070-71 (Fed. Cir. 1998).

Under the proposed standard, intent would have to be specific. *See, e.g., United States v. Sloan*, 492 F.3d 884, 891 (7th Cir. 2007) (while "[d]irect evidence of an intent to defraud is rare; a specific intent to defraud may be shown, however, by circumstantial evidence and inferences drawn from the scheme itself that show that the scheme was reasonably calculated to deceive individuals of ordinary prudence and comprehension"). This means the evidence would have to show that the individual charged with inequitable conduct not only intended to make the representation or to withhold material information but that he or she intended to deceive the PTO. Thus, actual knowledge of the falsehood would be required. Further, with respect to nondisclosure, such nondisclosure would have to occur under circumstances that make it "equivalent to a false representation." *Stewart v. Wyoming Cattle Ranch Co.,* 128 U.S. 383, 388-89 (1888).

While specific intent may be inferred under the proposed standard, it could not be inferred based on a finding of a high level of materiality alone or on gross negligence (or on a combination of these two findings). Deception is of a different character and requires evidence of culpability, not ignorance. While not knowing something that one "should have known" may be evidence of gross negligence or incompetence, it does not evidence the state of mind needed for deception. More should be required and, in fact, would be required under BIO's proposed three element standard.

During the past 22 years since *Kingsdown* was decided, many valid patents have fallen under the uncertain inequitable conduct standard applied by this Court. These include a number of cases decided quite recently, including *Praxair*, 543 F.3d at 1313-14; *McKesson Info. Sol'ns v. Bridge Med, Inc.*, 487 F.3d 897, 909 (Fed. Cir. 2007) (aff'ing district court finding of intent based in part on a finding that applicant "certainly should not have missed" the materiality of a reference); *Ferring B.V. v. Barr Labs.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006) (affirming district court intent finding and noting a high level of materiality and "clear proof that it knew or should have known of that materiality," making it "difficult to establish 'subjective good faith'"); *Bruno Indep. Living Aids v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1354-55 (Fed. Cir. 2005) (affirming district court

intent finding based on "high materiality" of the withheld prior art coupled with the lack of "a credible explanation for the nondisclosure").

Amicus BIO urges this Court to adopt the above-proposed standard as its basis for judging when patents have been obtained through inequitable conduct in the PTO, including the standard's specific intent element. That element would require direct or circumstantial evidence that the actor had a state of mind consistent with intentional deception, not just ignorance or gross negligence.

E. The Balancing Inquiry Should Be Abandoned As It Has Contributed To Uncertainty In The Law of Inequitable Conduct

Balancing should be eliminated. Balancing on a sliding scale of culpability under which a high level of materiality can offset a low level of intent, or vice versa, has further muddied the present inequitable conduct analysis and contributed to the high costs involved in either alleging inequitable conduct or defending against such allegations. Perhaps most damaging, it invites the parties (and the court) to place significant weight on the materiality prong of the analysis, in effect ignoring the need for evidence of intent. *See, e.g., Praxair*, 543 F.3d at 1315, 1318; *Ferring*, 437 F.3d at 1191. *See also Ferring*, 437 F.3d at 1196 (Newman, J., dissenting). Further, a lower court's balancing is subject to review under the deferential abuse of discretion standard, making correction of mistakes quite

difficult and contributing to lack of uniformity in the application of inequitable conduct law.

Balancing is not dictated by Supreme Court law or any other law. In fact, BIO is unaware of cases applying balancing to the equation until 1981. *Digital Equip. Corp. v. Diamond*, 653 F.2d 701, 716 (1st Cir. 1981), adopted by *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362 (Fed. Cir. 1984).

BIO's proposed standard would eliminate balancing and require both materiality (unpatentability of at least one claim) and intent to be proven, as explained above. Once each element is proven, a conclusion of inequitable conduct would follow.[6]

Returning to an approach that does not entail a "sliding scale" of culpability would involve fewer variables than the modern materiality-intent-balancing framework. It would also place meaningful review back in the hands of the

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[6] Of course, a trial court would still have discretion to consider intervening equities when deciding whether the patentee's inequitable conduct warrants the severe sanction of unenforceability. Possible factors may include, for example, the litigant's relationship to the individual who engaged in wrongdoing before the PTO (e.g. as employee, outside counsel, assignor or licensor); the patentee's efforts to engage in full disclosure and to avoid omissions or misrepresentations by those who prosecute patents on its behalf; efforts to remedy after-discovered defects; or a patentee's candid decision to disclaim or forego all efforts at enforcing claims that may be affected by a possible misrepresentation or omission.

Federal Circuit, resulting in more uniformity in the law of inequitable conduct. Instead of a free-floating three-step inquiry that involves determining the level of materiality, the level of deceptive intent, and then balancing these levels, courts could tether the inquiry to an objective patentability defect which establishes culpability if caused deliberately and in bad faith, without resort to "balancing." Elimination of the balancing step would lead to a simpler, more objective inquiry.

F. The Current Materiality Standard Should Not Interfere With the PTO's Ability To Govern The Conduct of Proceedings Before It, But Judicial Adoption Of The PTO's Or Other Administrative Materiality Standards Is Not Warranted

Congress has vested the PTO with "plenary authority" over its own administrative practice. *Stevens v. Tamai*, 366 F.3d 1325, 1333 (Fed. Cir. 2004). Within this limited delegation of authority, the Office must balance a number of policy objectives to achieve its mission: It must examine patent applications timely and accurately; review prior art found by examiners, applicants, or third parties; seek efficient interactions with patent applicants; promote candor and good faith in dealing with the Office, and sanction wrongdoing by registered practitioners.[7]

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[7] The provisions at 35 U.S.C. § 2 (b)(2) empower the PTO to "establish regulations, not inconsistent with law" in order to "govern the conduct of proceedings in the Office," 35 U.S.C. § 2(b)(2)(A); to "facilitate and expedite the

To balance these sometimes competing objectives, the PTO has at its disposal a number of regulatory and statutory enforcement mechanisms. The Office defines applicants' obligations of candor and good faith, and the information it regards as material to examination. It specifies the procedures for the submission of such information. It authorizes its examiners to request additional information from applicants when necessary, and to consider references submitted by members of the public during prosecution or reexamination. In cases where fraud on the Office was attempted or perpetrated, or disclosure obligations violated, the Office reserves the power to refuse the grant or reissue of a patent and may, at its enforcement discretion, investigate and sanction individuals registered to practice before the Office.

These and other provisions provide the PTO with a flexible framework of requirements, incentives and sanctions under which it must advance its policy goal of timely, efficient and quality examination by incentivizing the submission of the most relevant information patent applicants regard as material. Increasingly, however, courts are applying the inequitable conduct doctrine in ways that directly regulate the amount and kinds of information that must be disclosed to the agency, and the penalties for noncompliance, thereby interfering in ways not contemplated

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processing of patent applications," 35 U.S.C. § 2(b)(2)(C); and to govern the conduct of persons practicing before it, 35 U.S.C. § 2(b)(2)(D).

by Congress with the PTO's ability to exercise its "plenary authority" over PTO practice.

Within its delegated authority, the PTO is free to adopt and enforce a materiality standard that best meets its administrative needs. To be consistent with modern principles of administrative law, the judicial standard should be crafted in ways that avoid intrusion into the operation of the agency. But it is important to remember that the judicial materiality standard serves a different purpose. The court's role is not to enforce administrative disclosure requirements in private actions to which the PTO is not a party, but to balance the interests of private litigants and protect the "paramount" interest of the public.

On the other hand, PTO's Rule 56 standard necessarily takes into account the efficiency of the agency's administrative processes as well as other institutional interests that don't predominate in actions between private litigants. This standard could be more inclusive than the judicial standard if necessary for the operation of the agency. Much confusion in this area has arisen from an assumption that the administrative and the judicial materiality standards somehow have to be the same. They do not. Problems only arise when conduct that is lawful under the agency's regulations is later found unlawful in private actions. *See, e.g., Digital Control v. Charles Mach. Works,* 437 F.3d 1309, 1315-16 (Fed. Cir. 2006) (complying with

Rule 56 provides no assurance that patent will not be held unenforceable under court's materiality standard). This is precisely what is occurring today, which alone would be good reason to raise the Court's threshold for finding materiality.

But nothing in the foregoing requires this Court's adoption of the current administrative Rule 56, or abject deference to the PTO's views on materiality. Judicial resolution of inequitable conduct charges in private actions implicates a broader set of interests, the public's being the most important. Accordingly, the Court is free to adopt a standard under which some instances of noncompliance with a PTO regulation could be deemed immaterial for adjudicating a private litigant's allegation of inequitable conduct. Noninterference, not identicality, should be the guiding principle.

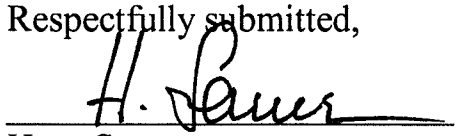
Agency law is designed to serve the purposes of administrative agencies, not the courts. Adopting a standard based on changing agency law, and enforcing it in private actions to which the agency is not a party, will only lead to problems similar to those that face this Court today. Instead, this Court should maintain its autonomy and craft a materiality standard that is applicable in such actions with reference not to the PTO's, but to the public's interests. However much these two may coincide, the former is no substitute for the latter.

IV. CONCLUSION

For the above reasons, BIO respectfully requests this Court to replace its present inequitable conduct law with that proposed above, unfettered by the doctrines of common law fraud or unclean hands and not influenced by PTO or other agency regulations.

August 2, 2010

Respectfully submitted,



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CERTIFICATE OF SERVICE

The undersigned hereby certifies that two (2) copies of the foregoing **BRIEF OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION AS AMICUS CURIAE IN SUPPORT OF NEITHER PARTY** were served this 2nd day of August, 2010, by overnight courier, to the following counsel of record:

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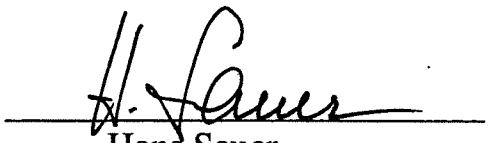
Amicus Curiae Biotechnology Industry Organization ("BIO") submits its brief under Rules 32(a)(6)(A) and 32(a)(7)(B) of the Federal Rules of Appellate Procedure. Thus, I hereby certify that *Amicus Curiae* BIO's brief complies with the type-volume limitation therein provided, and I further certify that the foregoing Brief for *Amicus Curiae BIO* was prepared with Microsoft Word 2003 using a proportional spaced typeface using 14-point Times New Roman, and contains 6,648 words, excluding the Table of Contents and Table of Authorities, as determined by Microsoft Word 2003, including footnotes, excluding the table of contents, table of authorities and certificates of counsel.



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