

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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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

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

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.

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.

