

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

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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

v.

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

and

BAYER HEALTHCARE LLC,
Defendant-Appellee.

Appeals from the United States Court for the Northern District of California in
consolidated case nos.

04-CV-2123, 04-CV-3327, 04-CV-3732, and 05-CV-3117

Judge William H. Alsup

BRIEF OF *AMICI CURIAE* THE HONORABLE BRUCE A. LEHMAN AND
THE INTERNATIONAL INTELLECTUAL PROPERTY INSTITUTE IN
SUPPORT OF PLAINTIFFS-APPELLANTS'
PETITION FOR REHEARING *EN BANC*

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CERTIFICATE OF INTEREST

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

The International Intellectual Property Institute, and
The Honorable Bruce A. Lehman, Commissioner of Patents & Trademarks
1993-1998.

2. The name of the real parties in interest represented by me are:

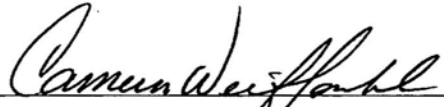
The International Intellectual Property Institute, and
The Honorable Bruce A. Lehman, Commissioner of Patents & Trademarks
1993-1998

3. There are no parent corporations or any publicly held companies that own 10 percent or more of the stock of the parties or *amicus curiae* represented by me.

4. The name of the attorney that appeared for the parties or *amicus curiae* now represented by me in the trial court or agency or expected to appear in this court is:

MILES & STOCKBRIDGE, Cameron K. Weiffenbach

March 10, 2010



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STATEMENT OF IDENTITY AND INTEREST OF *AMICUS CURIAE*

The International Intellectual Property Institute (IIPI) is a not-for-profit corporation located in Washington, DC. It was founded in 1998 as an international development organization and think tank.

Bruce A. Lehman is the president and board chairman of the International Intellectual Property Institute. From August 1993 through December 1998 Mr. Lehman served as assistant secretary of commerce and U.S. Commissioner of Patents and Trademarks. In that capacity he was responsible for advising the President and his administration on all policy matters involving the intellectual property system, domestically and internationally.

For 10 years prior to joining the Clinton administration, Mr. Lehman was a partner in the Washington, D.C., law firm of Swindler & Berlin. There he represented individuals, companies and trade associations in the areas of intellectual property rights.

Prior to entering private practice, Mr. Lehman worked for nine years in the U.S. House of Representatives as counsel to the Committee on the Judiciary and chief counsel to the Subcommittee on Courts, Civil Liberties, and the Administration of Justice. He was the Committee's principal legal adviser in the drafting of the 1976 Copyright Act, the 1980 Computer Software Amendments and the 1982 Amendments to the Patent Laws.

IIPi and Bruce Lehman, in his personal capacity, respectfully submit this brief *amicus curiae* in support of Appellants' petition for rehearing *en banc*. The Panel's opinion in this case will impose a new and confusing standard of disclosure on applicants in the course of patent prosecution. It also will create an unreasonable fear of committing inequitable conduct on the part of patent practitioners, causing them to make needlessly large submissions of information to the USPTO. Such overbroad submissions will greatly decrease the ability of patent examiners to dispose of patent applications in a timely manner, thereby threatening the ability of the USPTO to carry out its mission of issuing patents as an incentive for innovation and economic growth in the United States.

Neither IIPi nor Bruce Lehman has any financial interest in the outcome of this matter. However, both *amici* consider the need for clear rules of patent prosecution conduct to be of utmost importance to both current and future patent applicants. Accordingly, IIPi submits this brief in conjunction with a Motion to Leave to File pursuant to Fed. R. App. P. 29(b).

SUMMARY OF ARGUMENT

The purpose of the doctrine of inequitable conduct is to assure that USPTO examiners have access to information in the possession of an applicant that enables them to efficiently and accurately examine claims made in patent applications. This purpose is not served when – out of fear of being found to have committed

inequitable conduct – patent applicants, their agents and attorneys dump large quantities of information on the patent examiner, which are not necessary for an accurate examination and impede the timely disposal of cases by examiners.

Needlessly increasing the workload of examiners by submitting excessive documentation contributes to rising patent pendency and threatens the mission of the patent office, a mission that is essential to national competitiveness.

The Panel opinion in this case expands the doctrine of inequitable conduct to include attorney characterizations of the prior art. Such characterizations are not helpful to examiners who are expected to make their own, independent determinations about the relevance of prior art. It will result in submission of large quantities of information not relevant to the examination of patents needlessly adding to the burden of already overworked examiners.

ARGUMENT

I. THE PROPER ROLE OF DISCLOSURE OF INFORMATION BY AN APPLICANT DURING THE COURSE OF PATENT PROSECUTION

The doctrine of inequitable conduct is embodied in 37 CFR § 1.56, a regulation promulgated by the Director of the USPTO for the purpose of assuring that examiners have access to information in the possession of the applicant that would enable efficient and accurate consideration of the claims made in a patent application. Claims of inequitable conduct have become boilerplate in nearly

every defense to a patent infringement case. As Judge Rader had observed in *Aventis Pharma S.A. v. Amphastar Pharms., Inc.* 525 F. 3d 1334, 1349-50 (Fed. Cir. 2008), “[t]he allegation of inequitable conduct opens new avenues of discovery” in patent litigation. When inequitable conduct is asserted as a defense a huge volume of information – far exceeding that found in the USPTO’s prosecution file in any particular application – is made available to the defendant. This often enables him to begin a game of “gotcha” with the patentee asserting his or her rights. Therefore, it is frequently the case that at least some information can be found that was not submitted to the examiner that may be asserted by a defendant as material to the application, but not disclosed.

The purpose of 37 CFR § 1.56 is to encourage applicants to provide information known to them that would materially aid in the examination and that might not ordinarily, as a matter of course, come to the attention of the examiner. This enables the examiner to be more efficient by not having to search for such information if it is readily available to the applicant. When this rule is interpreted too broadly it becomes counterproductive to its purpose. Too broad an interpretation burdens the examination process because it causes patent applicants to submit extraneous or duplicative information to be sifted through by the examiner, adding unnecessary time to the examination process and to patent pendency. The Panel’s majority opinion in this case is such an overly broad

interpretation that it would result in applicants deluging a patent examiner with a volume of information, making it extremely difficult to complete the examination of an applicant's claims in a timely manner.

II. THE PANEL MAJORITY'S OPINION CREATES A CLIMATE OF FEAR AMONG PROSECUTORS AND THREATENS TO OVERBURDEN THE USPTO

A finding of inequitable conduct carries serious consequences not only for patentees, but also for individual patent practitioners. They may be sued for malpractice, face disciplinary action before the bar or the USPTO, and never recover their professional reputation. These penalties are so severe that they can induce patentees and patent practitioners to "submit everything of even remote relevance in one's possession to the PTO." *See* Christopher A. Cotropia, *Modernizing Patent Law's Inequitable Conduct Doctrine*, 24 Berkeley Tech. L.J. 723, 768 (2009). Many practitioners believe that under the current inequitable conduct standards, the safer course is to disclose information even if they believe "references . . . are cumulative or less material than those already before the Examiner." Edwin S. Flores & Sanford E. Warren, Jr., *Inequitable Conduct, Fraud, and Your License to Practice Before the United States Patent & Trademark Office*, 8 Tex. Intell. Prop. L.J. 299, 308 (2000). Congress has also recognized that "less than clear guidance" concerning inequitable conduct leads patentees to

“‘dump’ everything they have on the USPTO.” S. Rep. No. 110-259, at 32 & n.152 (2008).

The Panel’s decision exacerbates this problem in two ways. First, the decision significantly expands the kind of information that might be considered “material.” Patent practitioners who read the opinion will now feel compelled to disclose legal briefs in their files characterizing prior art, even if these briefs were submitted in an unrelated foreign prosecution and the prior art itself is already before the examiner who is trained to, and should, evaluate the prior art directly.

Second, with the Panel majority’s further eroding of the intent standard, the safest course of action for practitioners will now be to disclose information even if they honestly believe it is immaterial because a court could later disagree and subjectively find that the prosecutor “should have known” it was material. That will encompass an enormous amount of information that will overload the examiner with unnecessary information, and *also make the critical prior art more difficult to identify*. Further, the subjective nature of interpreting a practitioner’s asserted interpretation of the prior art will discourage patent attorneys and patent agents (patent practitioners) from taking any explicit position on the prior art. The climate of fear that the Panel majority’s opinion will create in the patent bar will result in the dumping of every conceivable reference on the examiner and further threaten the quality of patents issued by an already overburdened USPTO.

III. THE DECISION WILL MAKE IT DIFFICULT FOR THE USPTO TO ACCOMPLISH ITS STATUTORY MISSION OF PATENT EXAMINATION

This is the worst possible time for the Court to impose unnecessary burdens on the USPTO. The USPTO is currently operating under “almost \$200 million in budget reductions” and has been trying to accomplish its mission with a declining number of examiners as the result of a hiring freeze put into effect because of those budget reductions. *See, USPTO, Performance and Accountability Report: Fiscal Year 2009*, at 45. This report notes that the “backlog [is] growing, processing times increasing, and the number of patents issued flattening.” *Id.* at 103. This is a problem that goes far beyond its impact on an ordinary government bureaucracy. The USPTO has a constitutional mission which is critical to the nation in a time of fierce global competition. Judicial interpretations of the law that create confusing rules for patent prosecution and result in patent examiners being deluged with unmanageable amounts of needless documentation will threaten the ability of the USPTO to carry out its critical mission.

IV. THE PANEL UNDERMINES THE BRIGHT LINE RULE THAT CHARACTERIZATIONS OF PRIOR ART CANNOT BE MATERIAL

The Panel’s opinion affirming a finding of inequitable conduct does not rest on withheld prior art or technical data. Rather, it rests on attorney *characterizations* of the prior art. This undermines the bright line rule established in a series of cases

holding that characterizations of prior art – even supposedly false ones or those directly contrary to characterizations being advanced before the USPTO – cannot be considered material when the prior art itself is disclosed to the examiner. *See, e.g. Innogenetics N.V. v. Abbott Labs.*, 512 F. 3d 1363, 1378-79 (Fed. Cir. 2008); *Life Techs., Inc. v. Contech Labs., Inc.* 224 F. 3d 1320, 1326 (Fed. Cir. 2000); and *Young v. Lumenis*, 492 F. 3d 1336, 1348 (Fed. Cir. 2007). For example, in *Innogenetics* the patentee had “identified the Cha PCT application as the closest prior art” before the EPO and, when the EPO relied on the Cha PCT application, the patentee had amended its claims to disclaim the teachings of Cha PCT. The patentee then took another position before the USPTO, asserting to the USPTO that the Cha PCT application did “not relate to the invention.” 512 F.3d at 1379. Despite this conflict in the characterizations of the Cha PCT reference, the Court concluded that there had been no “material omission or misrepresentation” and no inequitable conduct, because the characterizations “amounted to mere attorney argument” and the Court’s “precedent has made clear that an applicant is free to advocate its interpretation of its claims and the teachings of prior art.” *Id.*

V. THE PANEL’S OPINION UNDERMINES THE INTENT DOCTRINE IN INEQUITABLE CONDUCT CASES

Amici share Judge Linn’s concern that the Panel’s majority has strayed from the intent doctrine as set forth in *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (*en banc*), which held “even gross negligence

insufficient to prove intent to deceive.” (Panel dissent at 16). The Panel majority infers intent solely from the fact that the district judge disagreed with the witnesses’ reading of the EPO briefs – without any other corroborating evidence that the witnesses actually had read the EPO briefs as he had, shared his view of their materiality, and acted with specific intent to deceive the USPTO.

As a result of the Panel’s opinion, patent practitioners will no longer rely with confidence on their own subjective conclusions regarding the non-materiality of a reference. If a district court later disagrees and concludes that his or her reading was implausible, the practitioner will be found guilty of inequitable conduct. Patent practitioners will have to worry that their reputations and careers will be ruined even if they have fully disclosed all the information they believe is material.

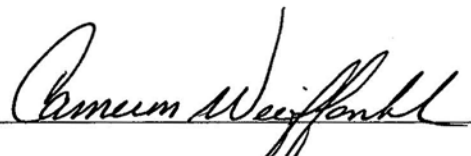
Allowing materiality to bleed into the intent analysis “makes it difficult for applicants and their attorneys, [sic] to be confident that they are free from liability if they actually believe something is not material or if they unintentionally overlook information in their possession. Even if these facts are true, and they did not intend to deceive the USPTO, inequitable conduct will likely be found because of bleed through.” Cotropia, *Modernizing Patent Law’s Inequitable Conduct Doctrine*, supra, at 776.

VI. CONCLUSION

The Panel opinion threatens the proper balance of disclosure of information essential to the efficient and thorough examination of patent applications by USPTO examiners. The submission of large amounts of extraneous or subjective information is counter-productive to the purpose of the doctrine because it burdens the patent examiner with having to review information not relevant to the application being examined, thereby slowing the process of patent application, decreasing the productivity of examiners, and increasing overall pendency. This, in turn, threatens the ability of the USPTO to carry out its constitutional purpose, essential to the competitiveness of the nation.

The Panel opinion in this case also undermines the bright line rule that characterizations of prior art are not material, thereby creating confusion about what constitutes prior art. Such confusion does not serve the interests of the overall patent system which is best served by clear standards easily understandable to patent applicants, their attorneys and agents. For these reasons Bruce Lehman, former Commissioner of Patents & Trademarks, and the International Intellectual Property Institute respectfully request this Court to grant plaintiffs-appellants' petition for rehearing *en banc*.

March 10, 2010



Cameron K. Weiffenbach

CERTIFICATE OF SERVICE

The undersigned, an attorney, certifies that on March 10, 2010, he caused the foregoing **Motion for Leave to File Brief of *Amici Curiae*** to be hand delivered to the Clerk of the Court for the United States Court of Appeals for the Federal Circuit, at the below address, and that a true and correct copy of the same was served on all counsel of record via Federal Express as set forth below.

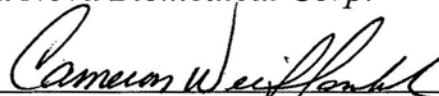
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