UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

04-1189, -1347, -1357

PURDUE PHARMA L.P.,
THE PURDUE FREDERICK COMPANY,
THE P.F. LABORATORIES, INC., and THE PURDUE PHARMA COMPANY,

Plaintiffs/Counterclaim Defendants-Appellants,

and

EUROCELTIQUE S.A.,

Counterclaim Defendant,

v.

ENDO PHARMACEUTICALS INC.,

Defendant/Counterclaimant-Cross Appellant,

and

ENDO PHARMACEUTICALS HOLDINGS INC.,

Defendant-Cross Appellant.

Appeals from the United States District Court for the Southern District of New York in Consolidation Case Nos. 00-CV-8029, 01-CV-2109, and 01-CV-8177, Judge Sidney H. Stein.

BRIEF OF *AMICUS CURIAE* BIOTECHNOLOGY INDUSTRY ORGANIZATION IN SUPPORT OF PLAINTIFF-APPELLANTS' POSITION SEEKING AN *EN BANC* REHEARING OF THE CASE BEFORE THE FEDERAL CIRCUIT

Counsel of Record

W. MURRAY SPRUILL, PH.D.
ALSTON & BIRD LLP
3201 BEECHLEAF COURT, SUITE 600
RALEIGH, NC 27604-1062
COUNSEL FOR AMICUS CURIAE
BIOTECHNOLOGY INDUSTRY ORGANIZATION

CERTIFICATE OF INTEREST

Counsel for Amicus, Biotechnology Industry Organization, certifies the following:

1. The full name of every party or amicus represented by me is Biotechnology Industry Organization.

2. The real name of the real party in interest represented by me is Biotechnology Industry Organization.

3. The parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus represented by me are: None.

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

W. Murray Spruill of Alston & Bird, LLP.

June 28, 2005

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W. Murray Spruill

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PETITION FOR REHEARING *EN BANC*

Based on my professional judgment, I believe the panel decision is contrary to the following precedent(s) of this court:

Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 9 USPQ2d 1384 (Fed. Cir. 1988).

Life Technologies, Inc. v. Clontech Laboratories, Inc. 224 F.3d 1320, 56 USPQ2d 1186 (Fed. Cir. 2000).

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Dayco Products, Inc. v. Total Containment, Inc., 329 F.3d 1358, 66 USPQ2d 1801 (Fed. Cir. 2003).

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W. Murray Spruill
ATTORNEY OF RECORD FOR
BIOTECHNOLOGY INDUSTRY ORGANIZATION

STATEMENT OF IDENTITY AND INTEREST OF *AMICUS CURIAE* (F.R.A.P. 29(C)(3))

The Biotechnology Industry Organization ("BIO") is a trade association consisting of more than one thousand member companies, academic institutions, and biotechnology centers. BIO represents and understands the needs as well as the demanding nature of the biotechnology industry. Segments of this industry provide biotechnology-based products that constitute an important and growing value to the public. To create this value, the biotechnology industry invests heavily in research and development.

Although intellectual property can be protected in a number of ways, patents form the intellectual property cornerstone for protecting research efforts in the biotechnology industry. The possibility of future protection through the patent system permits public disclosure and prompt public dissemination of information about new technology, thereby providing an immediate benefit to the public. This disclosure of information can enable others in the field to build on the technology and further advance the progress of science and the useful arts. Without the potential for meaningful protection through the patent system, some of these advances might remain trade secrets and unavailable to the bulk of the research community. Not only can other researchers build upon the information disclosed in a patent but also the patent system helps to avoid expensive duplication of research efforts by disclosing information that may otherwise be unavailable.

Academic researchers and public institutes also benefit from the broadened interest in and value of biotechnology patents. Many groups have initiated cooperative research and development efforts that assist in maintaining the vitality of American research. The prospect of patent protection is driving these efforts. Royalty revenue from patents also permits research backing at independent public institutes lacking government grants and aid. Once a product is marketed, the exclusive rights conferred by a patent allow the innovator to recoup the investment and continue researching new products.

Patents are vital to the members of BIO in a number of ways. By providing the prospect that any future invention could be protected, BIO members attract money for initial research. Clear evidence of patent protection then attracts further capital for the post-invention research that is needed for the costly development and marketing of an invention. BIO members encompass a heterogeneous group that invent, develop, and/or market valuable products for the world; therefore, BIO members have an interest in maintaining the patent system. Because of this, BIO would be concerned if this Court's position radically altered the enforceability of patents.

BIO has no interest in either of the parties or the outcome of this case.

CONSENT OF BOTH PARTIES (F.R.A.P. 29(a))

Both parties have consented to the filing of BIO's amicus brief.

ARGUMENT

I. ISSUES PRESENTED

In cases of inequitable conduct, this Court has consistently stated that a party must prove materiality and intent by clear and convincing evidence. *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1362 , 66 USPQ2d 1801, 1804 (Fed. Cir. 2003) (citing *Purdue Pharma L.P. v. Boehringer Ingelheim GMBH*, 237 F.3d 1359, 1366, 57 USPQ2d 1647, 1652 (Fed. Cir. 2001)); *Life Technologies, Inc. v. Clontech Laboratories, Inc.*, 224 F.3d 1320, 1324, 56 USPQ2d 1186, 1189 (Fed. Cir. 2000); *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 872, 9 USPQ2d 1384, 1389 (Fed. Cir. 1988). The Panel Opinion blurs the standards required to prove materiality and intent necessary to establish inequitable conduct.

BIO requests that the Court rehear the case to provide patentees clear guidance on the separate standards for materiality and intent required for a finding of inequitable conduct. A clear restatement of the objective standard for materiality and a confirmation of the requirement for clear and convincing evidence to prove materiality and intent are critical to protect investment in research. The decision if left unclarified creates additional risks for innovators who advance the well-being of society through scientific discovery by opening the door for challenge based on frivolous assertions of inequitable conduct.

A. Materiality Should Be Proven By Clear and Convincing Evidence Based on an Objective Standard

Applicants for patents have a duty to prosecute patents in the PTO with candor and good faith and to disclose information to the PTO known to applicants to be material to patentability. Information has historically been viewed as material to patentability when there is "a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue." *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1367, 66 USPQ2d 1385, 1394 (Fed. Cir. 2003) (citing *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1322, 56 USPQ2d 1001, 1006 (Fed. Cir. 2000)); *Baxter Int'l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1327, 47 USPQ2d 1225, 1229 (Fed. Cir. 1998). A "mere showing that art or information having some degree of materiality was not disclosed" is insufficient to maintain a charge of inequitable conduct. *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415, 5 USPQ2d 1112, 1115 (Fed. Cir. 1987).

Recent case law has applied the objective materiality standard set forth in PTO Rule 56, which was amended in 1992 to address criticism concerning a perceived lack of certainty in the materiality standard and to provide a "clearer and more *objective definition* of what information the [Patent] Office considers material." Manual of Patent Examining Procedure (MPEP) § 2001.04 (8th ed., 2001, rev. May 2004) (emphasis added); *see Bruno Independent Living Aids, Inc. v. Acorn Mobility Services Ltd.*, 394 F.3d 1348, 1352, 73 USPQ2d 1593, 1596 (Fed. Cir. 2005) (citing *Critikon, Inc. v. Becton*

Dickinson Vascular Access, Inc., 120 F.3d 1253, 1257, 43 USPQ2d 1666, 1669 (Fed. Cir. 1997)). This Court has stated that the PTO standard for materiality is the appropriate starting point "because it most closely aligns with how one ought to conduct business with the PTO." *J.P. Stevens & Co. v. Lex Tex Ltd., Inc.*, 747 F.2d 1553, 1559, 223 USPQ 1089, 1092 (Fed. Cir. 1984). Under current PTO Rule 56, information is material to patentability when

> [I]t is not cumulative to information already of record or being made of record in the application, and
>
> (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
>
> (2) It refutes, or is inconsistent with, a position the applicant takes in:
>
> (i) Opposing an argument of unpatentability relied on by the Office, or
>
> (ii) Asserting an argument of patentability.

Purdue Pharma L.P. v. Endo Pharmaceuticals Inc., 2005 WL 1330933, at *3 (Fed. Cir. June 7, 2005) (citing 37 C.F.R. § 1.56(b) (2004)).

In prior cases, significant affirmative actions or omissions, such as the submission of false data or the deliberate withholding of relevant prior art references, were traditionally required to satisfy the threshold prong of materiality. *See, e.g., Rohm & Haas Co. v. Crystal Chemical Co.*, 722 F.2d 1556, 1571, 220 USPQ 289, 300 (Fed. Cir. 1983) (holding patent unenforceable because the patentee submitted affidavits containing false data in order to overcome prior art rejections); *see also Hoffmann-La Roche*, 323 F.3d at 1367, 66 USPQ2d at 1394 (citing *Rohm & Haas*, 722 F.2d at 1571,

220 USPQ at 300). The Panel Opinion alters the standard by affirming the trial court's finding of materiality only on the basis of inferences from the language used by Purdue in both the patents and prosecution history. *Purdue* at *5. It was the trial court's subjective interpretation of patentees' arguments that led to a finding of materiality. No actual inconsistent arguments were identified, thus an objective standard for materiality was not applied.

The trial court in this case found materiality on the basis of patentee's failure to disclose how the invention was made. Applicants, however, are under no affirmative duty to expressly disclose how the invention was made and to expressly state that the discovery was based on insight and scientific knowledge rather than on clinical data. Examiners can ask for such information if they believe it would be helpful, and they often do require the submission of data to verify applicant's assertions of patentability. MPEP § 704.10. In fact, this Court has recognized that "[b]lind reliance on presumed candor would render examination unnecessary, and nothing in the statute or Manual of Patent Examining Procedure would justify reliance on counsel's candor as a substitute for an examiner's duty to examine the claims." *Kingsdown*, 863 F.2d at 874, 9 USPQ2d at 1390.

The subjective manner in which the Panel Opinion found materiality will essentially force applicants to exhaustively disclose not only what they have done, but also what they have not done, to protect themselves from allegations of inequitable conduct. The current decision expands PTO Rule 56 to expose patentees to the

"tactic of probing the hundreds if not thousands of experimental details, scrutinizing every experiment performed and not performed, criticizing everything done and undone, and then charging that the research process was somehow fraudulent." *Hoffmann-La Roche, Inc.* 323 F.3d at 1374, 66 USPQ2d at 1399 (Newman, J., dissenting). Should the present finding of materiality stand, patentees in subsequent litigations, in order to avoid a charge of inequitable conduct, will be forced to explain why they did not reveal every experimental detail.

Under the facts of this case, an objective standard would require that materiality be found by at least one affirmative and misleading statement, not solely by an inference drawn from the Court's interpretation of the patentee's language years after issuance of the patent, particularly when the language could be subject to multiple interpretations. A rehearing of this case will allow the Court to embrace and affirm the objective standard of materiality set forth in PTO Rule 56 and this Court's precedent.

B. Intent Must Be Shown By Clear and Convincing Evidence

Only once a threshold of materiality has been established does the inquiry focus upon whether the patentee intended to mislead. An accused infringer can prove intent by the applicant's acts and the presumption that the natural consequences of those acts were intended by the actor. *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180, 33 USPQ2d 1823, 1828-29 (Fed. Cir. 1995). Materiality does not presume intent, which is a separate and essential component of inequitable conduct. *See Allen Organ*

Co. v. Kimball Int'l, Inc., 839 F.2d 1556, 1567, 5 USPQ2d 1769, 1778 (Fed. Cir. 1988). This Court has made clear that a lesser quantum of evidence of intent is necessary when an omission or misrepresentation is highly material, and vice versa. *See, e.g.*, *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1358, 65 USPQ2d 1385, 1418-19 (Fed. Cir. 2003). In any event, there must be clear and convincing evidence of intent. A finding of inequitable conduct is improper where the record is completely devoid of evidence of intent to deceive the PTO. *Id.* (citing *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1352, 63 USPQ2d 1769, 1778 (Fed. Cir. 2002)).

Prior cases of this Court have required that to establish "intent to deceive" the alleged conduct must not amount merely to the improper performance or omission of an act one ought to have performed. *See Therma-Tru Corp. v. Peachtree Doors Inc.*, 44 F.3d 988, 995, 33 USPQ2d 1274, 1279 (Fed. Cir. 1995). Intent in the context of inequitable conduct "means that the inventor intended to deceive or mislead the examiner into granting the patent." *Id.* Clear and convincing evidence must prove that an applicant had the specific intent to accomplish an act that the applicant ought not to have performed, *viz.*, misleading or deceiving the PTO. *See Molins*, 48 F.3d at 1181, 33 USPQ2d at 1829.

A high level of proof of intent to mislead the PTO has been required in order to prove inequitable conduct. *See generally In re Harito*, 847 F.2d 801, 6 USPQ2d 1112 (Fed. Cir. 1988) and *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 5 USPQ2d 1112 (Fed. Cir. 1987). In contrast, the trial court held that Purdue acted with an intent to mislead

the PTO by not expressly stating that applicants' results were based on insight and scientific knowledge rather than on clinical data. Short of a request by the Examiner, the applicant is under no obligation to provide clinical data supporting patentability. Therefore, the Court had no basis under the clear and convincing standard to question the motivation behind statements that are open to more than one interpretation.

The Court is reminded that patent practitioners are required under the patent rules to "represent a client zealously within the bounds of the laws." 37 C.F.R. § 10.83 (2004). The American Bar Association Model Rules of Professional Conduct, which have been adopted by a majority of states, also provide that "[a]s advocate, a lawyer zealously asserts the client's position under the rules of the adversary system." *Model Rules of Prof'l Conduct, Preamble: A Lawyer's Responsibilities*, ¶2 (2004). While it is recognized that zealous representation cannot be a shield for misrepresentation of facts, intent should be based on clear and convincing evidence. A suggestion read into an applicant's specification and arguments years later is not enough.

Review of this decision with respect to the finding of intent is necessary to clarify questions regarding the proper standard of intent to support a finding of inequitable conduct.

II. CONCLUSION

BIO respectfully submits that the Panel Opinion be revisited by this Court in order to clarify the objective materiality standard that is set forth in this Court's precedent and PTO Rule 56 and to affirm the clear and convincing standard for proving materiality and intent. The case should be reheard to prevent a movement away from an objective standard to a subjective standard for materiality that will upset the balance between certainty in the validity of issued patents and the duty of disclosure required of applicants before the PTO. Already inequitable conduct is raised in a majority of the cases involving patent infringement, most allegations of which are never proven. Without clear guidance from the Court, many legitimate patentees will be forced to defend their patents against even more frivolous litigation based on inequitable conduct.

Respectfully submitted this 28th day of June, 2005.

W. MURRAY SPRUILL, PH.D.
ALSTON & BIRD LLP
3201 BEECHLEAF COURT
SUITE 600
RALEIGH, NC 27604-1062
COUNSEL FOR AMICUS CURIAE
BIOTECHNOLOGY INDUSTRY
ORGANIZATION

Counsel of Record

ADDENDUM

CERTIFICATE OF SERVICE

I hereby certify that I caused two copies of the foregoing document to be served on June 28, 2005 on counsel of record for Plaintiff-Appellant Purdue Pharma (Purdue Frederick Company) and on counsel of record for Defendant-Appellant Endo Pharmaceuticals at the following addresses via overnight courier:

HERBERT F. SCHWARTZ
ROPES & GRAY LLP
1251 AVENUE OF THE AMERICAS
NEW YORK, NY 10020
COUNSEL FOR PLAINTIFF-APPELLANT

EDWARD V. FILARDI
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
FOUR TIMES SQUARE
NEW YORK, NY 10036
COUNSEL FOR DEFENDANT-APPELLANT

This 28th day of June, 2005.

_____
W. Murray Spruill