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

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 District 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.

REPLY OF PLAINTIFFS-APPELLANTS ABBOTT DIABETES CARE, INC. AND ABBOTT LABORATORIES IN SUPPORT OF PETITION FOR REHEARING *EN BANC*

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MARCH 25, 2010

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CERTIFICATE OF INTEREST

Counsel for petitioners Abbott Diabetes Care, Inc. and Abbott Laboratories certifies the following:

1. The full name of every party represented by me is: Abbott Laboratories and Abbott Diabetes Care, Inc. (formerly known as TheraSense Inc.), a division of Abbott Laboratories.

2. The name of the real party in interest represented by me is: Abbott Laboratories and Abbott Diabetes Care, Inc.

3. There are no parent corporations and publicly held companies that own 10% or more of the stock of Abbott Laboratories. Abbott Diabetes Care, Inc. is a division of Abbott Laboratories.

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

MUNGER, TOLLES & OLSON LLP	Jeffrey I. Weinberger Rohit K. Singla Ted G. Dane Jason A. Rantanen Andrew W. Song John Peck (no longer at Munger Tolles) Bill Ward (no longer at Munger Tolles)
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DATED: March 25, 2010

By: 

Rohit K. Singla

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

FEDERAL CASES

ARGUMENT

On three critical points, Bayer and BD/Nova ("Appellees") attempt to rewrite the panel majority's opinion or key precedent in order to save the panel's decision from en banc review.

I. The Majority's Decision Deepens The Intra-Circuit Split Over The Intent Standard

First, Appellees concede that inequitable conduct cannot be based on the mere finding that a patentee failed to disclose information it *should have known* would be material to the Examiner. (BD/Nova Response at 4.) Rather than defend that standard, which conflicts irreconcilably with precedent requiring specific intent to deceive, Appellees argue that the panel majority relied on evidence that Mr. Pope and Dr. Sanghera *actually knew* the nondisclosed EPO briefs were material. (Bayer Response at 10).

This simply is not true. Nothing cited by the majority, Bayer, or BD/Nova shows that Mr. Pope or Dr. Sanghera actually believed at the time that the EPO briefs were material. The majority based its decision on five specific factual findings made by the district court that at most show that Mr. Pope and Dr. Sanghera *should have known* the EPO briefs were material. (Panel Majority, slip op. at 28.) As Judge Linn explained, the district court did not specifically evaluate the witnesses' "subjective understanding of the facts," making it impossible to support a finding that they actually knew the briefs were material. (Panel Dissent,

slip op. at 22.) The first two district court findings cited by the majority were simply that the EPO briefs were ultimately judged to be material—not that Mr. Pope and Dr. Sanghera believed they were material at the time of the prosecution in 1997. (Panel Majority, slip op. at 28.) The third finding was that the witnesses were aware of the *existence* of the briefs—but that says nothing about whether they were actually aware of the supposed materiality of those briefs. (*Id.*) The final two findings were only that the district court did not believe the witnesses' explanation for nondisclosure. (*Id.*) But again, this does not establish that the witnesses appreciated at the time the basis for materiality found by the district court. This Court squarely held in *Star Scientific*, moreover, that a district court's disbelief of the patentee's explanation does not satisfy the *infringer's* burden to produce affirmative evidence of intent to deceive. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1368 (Fed. Cir. 2008).

Bayer repackages these same facts with misleading hyperbole into seven bullet points that it incorrectly claims show Mr. Pope and Dr. Sanghera actually knew the EPO briefs were material. (Bayer Response at 5–6.) For example, Bayer's first three points simply assert that Mr. Pope and Dr. Sanghera knew their statements *to the PTO* would be material. But that says nothing about their actual understanding of the content of the EPO briefs. The second and third points also argue that the EPO briefs are inconsistent—but not that Mr. Pope and Dr. Sanghera

recognized any such inconsistency in 1997. The fourth and fifth points simply point out that the witnesses considered the EPO briefs and concluded they did not need to be disclosed—not that they believed the briefs should have been disclosed. The sixth point is irrelevant and just a re-hash of Appellees' argument to the district court that the arguments made to the PTO contradict excerpts from the EPO briefs when taken out of context—but not when read appropriately in context. Finally, the seventh point simply notes that the district court did not accept Mr. Pope's and Dr. Sanghera's explanation. BD/Nova condenses the same evidence into three points that suffer from the same insufficiency as the seven points made by Bayer and five findings made by the district court.[1] (BD/Nova Response, at 7.) In none of these many arguments is there clear and convincing evidence that Mr. Pope and Dr. Sanghera believed the undisclosed information to be material.

Moreover, Appellees repeatedly mischaracterize the underlying record. For example, BD/Nova says that Mr. Pope and Dr. Sanghera told the EPO that the '382 patent does "not require" a membrane. (BD/Nova Response at 8.) In fact, they never said that. (*See* Panel Dissent at 5.) Bayer claims Mr. Pope "admitted at trial that the 'plain English reading of what Abbott told the EPO was contrary to what

[1] In addition, BD/Nova says that Mr. Pope and Dr. Sanghera sought the patent to sue a competitor (BD/Nova Response, at 5), but the majority correctly did not rely on that. *See Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988) (desire to "exclude a known competitor's product from the market" is "simply irrelevant" to intent inquiry).

Abbott told the PTO.'" (Bayer Response at 6.) However, Mr. Pope never said anything of the sort. What he actually said was that "as a matter of normal English construction," a particular sentence in the EPO brief could refer "to what comes immediately before and refers to all of it," but that he had, in fact, not interpreted the sentence that way because he had read it in the context of the *entire* brief, including the overall argument of the brief. (JA2990; *see also* Panel Dissent, at 24.) Accordingly, Mr. Pope testified consistently that he never believed the EPO briefs were inconsistent with or contrary to his argument to the PTO.

Similarly, Bayer's quotation of Dr. Sanghera's testimony is misleading. (Bayer Response at 6.) Bayer quotes the part of a question posed to Dr. Sanghera about how he would use the terms "optional" and "preferable" in "general English usage." (JA3009.) However, Dr. Sanghera was never asked how he understood those terms as they were used in the specific context of the EPO briefs—and when he was asked what those terms meant in the context of a paragraph in the prior art reference at issue, Dr. Sanghera testified that he understood those terms to mean "required." (*Id.*)

It is common for reasonable people to read the same language in a legal document in completely different ways. Even judges often read the same sentence in a statute entirely differently—but in good faith. *See, e.g.*, *Ariad Pharms., Inc. v. Eli Lilly and Co.*, 2010 WL 1007369 (Fed. Cir. Mar. 22, 2010) (en banc) (in which

the majority, at *5, interpreted first sentence of § 112 to require a written description separate from enablement, while Judge Rader, at *23, found the same language to be "unambiguous" in tying the written description to enablement). At best, the panel majority's reading of the EPO briefs shows that Mr. Pope and Dr. Sanghera should have known the briefs would be found material. This case is thus a good vehicle for this Court to resolve whether such evidence is sufficient to prove deceptive intent.

II. The Majority Violated The Rule Of *Scanner Tech*

Second, Appellees acknowledge that, under *Scanner Tech. Corp. v. ICOS Vision Sys. Corp.*, 528 F.3d 1365 (Fed. Cir. 2008), the majority was required to draw all reasonable inferences in favor of Abbott. (Bayer Response at 10.) They insist, however, that in this case "there were *no* reasonable inferences that could be drawn in Abbott's favor." (*Id.*) This brushes past the central issue in the case: that the EPO briefs can reasonably be read as consistent with the arguments Mr. Pope and Dr. Sanghera made to the PTO. Judge Linn himself read the EPO briefs in context as consistent. Dr. Johnson read the EPO briefs the same way (JA2746-47), and—contrary to Bayer's assertion—the district court did not find Dr. Johnson lacked credibility. (565 F. Supp. 2d 1088, at 1124, 1126; *contra* Bayer Response at 11.) Most importantly, there was *no* scientific testimony by any witness finding an inconsistency between the EPO briefs and Abbott's arguments to the PTO. The

district court therefore necessarily drew an inference unfavorable to Abbott to conclude that the EPO briefs were inconsistent. This case thus presents a clear conflict with *Scanner Tech*.

III. The Decision Conflicts With the *Innogenetics* Line Of Cases

Finally, Appellees mischaracterize the facts of both *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363 (Fed. Cir. 2008) and this case to make the decisions in the cases seem consistent. They ignore the fact that Innogentics had not only told the EPO that the Cha application was the "closest prior art" but had also amended its claims before the EPO "to disclaim the teaching of [the Cha PCT application]," thus acknowledging that the reference related to the invention. *Id.* at 1379 (alteration in original). These statements to the EPO were not provided to the PTO despite unambiguously contradicting the applicant's argument to the PTO that the reference "d[id] not relate to the invention." *Id.* Indeed, Innogenetics did not even try to defend the statements as consistent. Instead, it argued that it had "simply advocated a particular interpretation of the prior art, which the Examiner was free to accept or reject." Br. of Plaintiff-Cross Appellant Innogenetics N.V., Nos. 2007-1145, 1161, 2007 WL 1538568, at 24 (Fed. Cir. May 7, 2007) (internal quotations omitted) (citing *Life Techs., Inc. v. Clontech Labs., Inc.*, 224 F.3d 1320, 1326 (Fed. Cir. 2000)). This Court based its decision on that argument, stating that it had "made clear that an applicant is free to advocate its interpretation of its

claims and the teachings of prior art." *Innogenetics*, 512 F.3d at 1379.

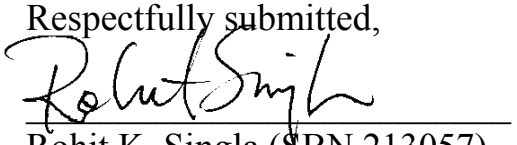
To reconcile *Innogenetics*, Appellees wrongly imply that Dr. Sanghera submitted false factual statements in his declaration. The only statements at issue in Dr. Sanghera's declaration were his *opinions* on how a person of ordinary skill in the art would interpret the prior art. (Panel Majority at 20). These are not like the *factual* statements in *Pharmacia Corp. v. Par Pharm., Inc.* (Fed. Cir. 2005), where the declarant stated that a compound does not reduce intraocular pressure. 417 F.3d 1369, 1371–72. Rather, Dr. Sanghera's declaration is like the affidavit in *Akzo N.V. v. U.S. Int'l Trade Comm'n* (Fed. Cir. 1986), which held that statements "advocating a particular interpretation of [the prior art]" are immaterial even when included in an affidavit. 808 F.2d 1471, 1482. As a result, Appellees cannot reconcile this case with the long line of precedent holding that interpretations of prior art are not material when the underlying art is before the PTO.

* * *

The specter of inequitable conduct affects every patent prosecution. As the standards for proving inequitable conduct have eroded, even with heightened pleading requirements, it has become a lottery for accused infringers. Inventors, patent practitioners, litigants, and lower courts all suffer when the standards are muddled. For these reasons, the Petition for Rehearing En Banc should be granted.

March 25, 2010

Respectfully submitted,



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DECLARATION OF AUTHORITY PURSUANT TO 28 U.S.C. § 1746 AND FEDERAL CIRCUIT RULE 47.3(d)

I, John C. Kruesi, Jr., being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by MUNGER, TOLLES & OLSON LLP, Attorneys for Appellants, to print this document. I am an employee of Counsel Press.

The attached Reply has been submitted to Counsel Press, by the above attorneys, electronically and/or has been reprinted to comply with the Court's rules. Because of time constraints and the distance between counsel of record and Counsel Press, counsel is unavailable to provide an original signature, in ink, to be bound in one of the documents. Pursuant to 28 U.S.C. §1746 and Federal Circuit Rule 47.3(d), I have signed the documents for Rohit K. Singla, with actual authority on his behalf as an attorney appearing for the party.

March 25, 2010

John C. Kruesi, Jr.

United States Court of Appeals
for the Federal Circuit

Therasense v Becton, 2008-1511, -1512, -1513, -1514, -1595

CERTIFICATE OF SERVICE

I, John C. Kruesi, Jr., being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by MUNGER, TOLLES & OLSON LLP, Attorneys for Appellants, to print this document. I am an employee of Counsel Press.

On the **25th Day of March, 2010**, I served the within **REPLY OF PLAINTIFFS-APPELLANTS ABBOTT DIABETES CARE, INC. AND ABBOTT LABORATORIES IN SUPPORT OF PETITION FOR REHEARING EN BANC** upon:

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via Federal Express, by causing 2 true copies of each to be deposited, enclosed in a properly addressed wrapper, in an official depository of Federal Express.

Unless otherwise noted, 19 copies have been hand-delivered to the Court on the same date as above.

March 25, 2010