

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,

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US COURT OF APPEALS
FEDERAL CIRCUIT

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

Bayer's Response to Abbott's Petition for Rehearing *En Banc*

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I. INTRODUCTION

This is not an appropriate case for *en banc* review. This case applies established law to a “rare set of facts” and is limited to those facts. The majority and the District Court properly based their finding of intent on Abbott’s conduct as a whole, as required under *Kingsdown*. Consistent with *Star Scientific*, the inference of deceptive intent was “the single most reasonable inference able to be drawn from the evidence.” And in contrast to *Innogenetics*, this case involved the deliberate withholding of the applicant’s own prior inconsistent statements, as well as the submission of an affidavit inconsistent with those prior statements. Finally, contrary to the suggestions by Abbott and *amici*, the decision imposes no new burdens on prosecutors.¹

II. FACTUAL BACKGROUND

This case involved a clear instance of inequitable conduct: making factual statements to the PTO on the key issue of patentability while deliberately withholding directly contradictory statements made to the EPO. Abbott’s representatives, Lawrence Pope and Gordon Sanghera, became involved with the prosecution of the ’551 patent after it had been rejected over Abbott’s prior art ’382 disclosure *eleven times*. Abbott sought a claim for membraneless sensors, but the ’382 patent plainly disclosed sensors that *did not require* a membrane:

¹ Bayer is not separately addressing arguments raised by *amici* to the extent they are either duplicative of Abbott’s arguments or beyond the scope of this appeal.

Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules.

To overcome the rejection, Mr. Pope made an agreement with the Examiner to submit a declaration from Dr. Sanghera. The declaration stated that to those of skill in the art, this sentence meant that membranes were *required* for use with blood.² Citing the declaration as support, Mr. Pope stated in his accompanying remarks that one of skill in the art (1) would *not* have understood this sentence to mean that membranes were “optional” when used with whole blood, and (2) would *not* have read the sentence as a technical teaching, but as “mere patent phraseology.” (Maj. Op. at 22-23.) However, in Europe, referring to *exactly the same sentence*, Abbott’s predecessor (with full participation from Dr. Sanghera) had stated that the ’382 membrane was *optional* in order to overcome prior art. *Id.*

In other words, to save its European counterpart to the ’382 patent, Abbott told the EPO that “optional” meant optional, and that it was a technical teaching sufficient to overcome a rejection. But to obtain the ’551 patent, Abbott told the PTO that the same “optional” language did not mean optional, but meant required, and that it was not a technical teaching. Mr. Pope and Dr. Sanghera were fully

² *Amici*’s statement that “Appellants do not stand accused of inequitable conduct based on [] factual assertions” (Washington Legal Found. Br. at 7) is simply wrong. (Maj. Op. at 27 (“[T]he representations to the PTO were not merely lawyer argument; they were factual assertions as to the views of those skilled in the art, provided in affidavit form.”).)

aware of the prior contradictory statements in Europe, and deliberately chose not to disclose them to the PTO. In defense of their actions, they testified that they did not believe the EPO statements were material. But the District Court found them not credible and rejected their explanations as implausible.

III. ARGUMENT

A. This Case Is Not Appropriate for *En Banc* Review.

“An *en banc* hearing or rehearing is not favored and ordinarily will not be ordered unless: (1) *en banc* consideration is necessary to secure or maintain uniformity of the court’s decisions; or (2) the proceeding involves a question of exceptional importance.” FRAP 35(a). Neither of these requirements is met here.

En banc consideration is not necessary to secure or maintain uniformity of the court’s decisions, because the majority decision did not depart from Federal Circuit precedent. The crux of the disagreement between the majority and dissent was differing interpretations of the *facts*, not differing interpretations, much less an expansion, of the law. The majority viewed the facts the same way the District Court viewed them, properly gave deference to the District Court’s factual and credibility findings, and held that those findings were “manifestly correct.” (Maj. Op. at 23.) The dissent had a different interpretation of the facts, one that conflicted with that of the District Court, but the case did not turn on *legal* issues.

Moreover, this is not a case of “exceptional importance.” It is a clear instance of inequitable conduct, limited to making statements to the PTO on the key issue of patentability while deliberately withholding contradictory statements made in another forum. The District Court invalidated the patent in view of the very same reference involved in the inequitable conduct, the Federal Circuit affirmed, and Abbott no longer challenges that finding. Thus, the facts of the case were unique, leading the majority to find this case to be “one of those rare cases in which a finding of inequitable conduct is appropriate.” (Maj. Op. at 18.) A decision applying established law to “rare” facts is not suitable for *en banc* review.

B. Neither the District Court Nor the Majority Inferred Intent Solely From Materiality.

Abbott argues that this decision creates intra-circuit conflict by “permitting intent to be inferred *entirely* from the alleged implausibility of the applicant’s arguments regarding materiality.” (Abbott Br. at 9 (emphasis in original).)

Neither the facts nor the law supports Abbott’s argument.

1. There Was Ample Evidence of Intent Beyond Materiality.

This is not a case in which the evidence of intent was limited to a mere failure to disclose a reference later found to be material. The record was replete with evidence of Mr. Pope and Dr. Sanghera’s intent to deceive, from which the District Court properly found intent. The majority rightly concluded that that

finding was “clearly correct.” (Maj. Op. at 19.) Several facts establish Mr. Pope and Dr. Sanghera’s actual knowledge of materiality of the contrary statements made to the EPO, and their intent to withhold the statements to deceive the PTO:

- Mr. Pope knew that the meaning of the “optionally, but preferably” sentence was absolutely critical to the issuance of the ’551 patent. He argued to the examiner that this sentence meant a membrane was “required,” and the examiner told him that if he submitted an affidavit stating that a membrane was required, it would overcome the pending rejection. (Maj. Op. at 20, 28.)

- The argument and declaration that a membrane was “required,” which flatly contradicted statements previously made to the EPO, resulted from brainstorming sessions between Mr. Pope and Dr. Sanghera. (Maj. Op. at 19; *Therasense, Inc. v. Becton, Dickinson & Co.*, 565 F. Supp. 2d 1088, 1105 (N.D. Cal. 2008).)

- To satisfy the examiner and overcome the pending rejection, Mr. Pope submitted an affidavit from Dr. Sanghera, which included factual statements about the understanding of those of skill in the art that contradicted the statements previously made to the EPO. (Maj. Op. at 20-21.)

- Dr. Sanghera had attended the EPO hearings and had been active in crafting the submissions made in that proceeding, including the very submissions

that contradicted his own affidavit and Mr. Pope's argument to the PTO.

Therasense, 565 F. Supp. 2d at 1093-94.

- Not only were Mr. Pope and Dr. Sanghera well aware of the contradictory EPO statements, they “together evaluated the documents from the EPO proceedings during the prosecution of the '551 patent and made a conscious decision to withhold them from the PTO.” (Maj. Op. at 28.)

- Mr. Pope admitted at trial that the “plain English reading of what Abbott told the EPO was contrary to what Abbott told the PTO.” (*Id.* at 25-26.)

Dr. Sanghera also admitted at trial that he believed “‘general English usage’ contradicted the representations that he had made to the PTO.” (*Id.* at 30.)

- The District Court found that Mr. Pope and Dr. Sanghera's explanations for withholding the EPO documents were implausible and that neither witness was credible. (*Id.* at 28-29.) The explanations were “so incredible that they suggested intent to deceive.” (*Id.* at 28.)

The majority highlighted one particularly incredible example of the “explanations” provided by Mr. Pope. (*Id.* at 29-30.) The relevant language in the EPO submission was as follows:

“Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules.”

It is submitted that this disclosure is unequivocally clear. The protective membrane is optional, however, it is preferred when used on live blood in order to prevent the larger constituents of the blood, in particular erythrocytes from interfering with the electrode sensor. Furthermore it is said, that said protective membrane should not prevent the glucose molecules from penetration, the membrane is "permeable" to glucose molecules.

(*Id.* at 22.) Mr. Pope agreed that as a matter of normal English construction, the phrase "it is submitted" refers to the entire immediately preceding phrase, *i.e.*, the "optionally but preferably" language. (*Id.* at 29-30.) However, he testified that as a patent attorney, he "didn't believe that they were trying to convey anything about the optional[ly] but preferably language." (*Id.*)

The majority found that the District Court did not err in finding that Mr. Pope's explanation was not plausible, particularly in view of his admission that the EPO statement's "normal English construction" directly contradicted his representations to the PTO on a critical issue. (*Id.* at 30.) The majority also found that Dr. Sanghera's admission that "general English usage" contradicted his affidavit to the PTO supported the District Court's finding of bad faith. (*Id.*) Thus, there was ample evidence from which the District Court properly concluded that Mr. Pope and Dr. Sanghera knew of the materiality of the contrary statements, and that they therefore intended to deceive the PTO by consciously withholding them. The majority's holding that the District Court's *factual* findings were not

clearly erroneous, and were in fact plainly correct, is not grounds for *en banc* review.

The evidence in this case is sufficient to support an inference of intent even under the case law Abbott cites in an attempt to contrast “proper” inequitable conduct findings with this case. (See Abbott Br. at 10 n. 18.) Abbott cites to *Molins* and *Bruno* to support its argument that requiring independent evidence of intent, even if circumstantial, is not too high a bar, and that “such evidence is found in many cases [such as *Molins* and *Bruno*],” but not here. (Abbott Br. at 10.) The evidence in this case is at least as, if not more, compelling than the evidence relied upon in *Molins* and *Bruno* to support a finding of intent.³

In *Molins*, the independent evidence of intent consisted of reminders to the prosecuting attorney of the reference’s materiality “through its prominence in the prosecution of several foreign counterpart applications” with which the attorney was “intimately involved.” (Abbott Br. at 10, n.18.) Similarly here, the materiality of the contradictory statements was obvious to Mr. Pope, given the focus of the

³ The *Nilssen* case cited by *amicus* Ole Nilssen did not involve deliberately withholding contrary statements on the key issue of patentability. (Nilssen Br. at 8-9.) In *Nilssen*, the asserted patents were found unenforceable based on multiple grounds of inequitable conduct, one of which was the failure to disclose related litigation involving the same patents. *Nilssen v. Osram Sylvania, Inc.*, 440 F. Supp. 2d 884, 901-911 (N.D. Ill. 2006). The district court followed Federal Circuit precedent that related litigation is “*per se* material information,” and found, in view of the totality of circumstances, that Mr. Nilssen intended to mislead the PTO by failing to disclose it. *Id.* at 909-10.

examiner on the “optionally, but preferably” sentence, the prominence of that sentence during prosecution, and his admitted familiarity with the EPO proceedings through his “brainstorming sessions” with Dr. Sanghera.

In *Bruno*, the independent evidence of intent was “[t]he fact that an official of Bruno, who was involved in both the FDA and PTO submissions, chose to disclose the [reference] to the FDA, but not to the PTO.” (Abbott Br. at 10, n.18.) Similarly here, an official of Abbott (Dr. Sanghera) who was involved in both the EPO and PTO submissions, chose to inform the EPO that the “optionally, but preferably” sentence meant that a membrane was “optional,” but then later submitted a declaration to the PTO stating that it was not optional, but “required.” And Mr. Pope and Dr. Sanghera “together evaluated the documents from the EPO proceedings during the prosecution of the ’551 patent and made a conscious decision to withhold them from the PTO.” (Maj. Op. at 28.) Thus, the evidence here supports an inference of intent even under cases cited with approval by Abbott.

2. No Reasonable Inferences Could Be Drawn in Abbott’s Favor.

Abbott next argues that the majority inferred intent, despite testimony to the contrary, and thus failed to follow the rules of *Star Scientific* and *Scanner*. (Abbott Br. at 9, 11.) Abbott is wrong. In *Star Scientific*, the defendant provided *no evidence* for its theory that the plaintiff changed law firms in order to prevent

disclosure of a prior art reference known by the prior firm. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1537, 1386 (Fed. Cir. 2008). In fact, the evidence showed that the company's executives, who decided to change law firms, had never even seen the prior art reference. *Id.* Thus, unlike the present case, there were no facts from which the court could reasonably infer intent.

Nor is this case one like *Scanner*, in which "multiple reasonable inferences" could be drawn from the evidence and there existed an "equally reasonable inference" favorable to Abbott. (Maj. Op. at 25.) Based on the implausibility of the explanations given by Abbott's witnesses and their lack of credibility, the court found that it was reasonable to infer that they understood they were withholding material information. Because there were *no* reasonable inferences that could be drawn in Abbott's favor, the inference of deceptive intent was indeed the "the single most reasonable inference able to be drawn from the evidence." *Star Scientific*, 537 F.3d at 1366. Again, the dissent's contrary view was not based on a differing view of the law, but on a factual disagreement: whether any other plausible inferences could be drawn from the facts. But the fact that a different inference can be articulated does not make it a *reasonable* inference supported by the facts found by the District Court, nor does it merit *en banc* review.

Finally, contrary to Abbott's argument, the District Court's findings were not based on "its conclusion that it could better interpret the scientific relevance of

the EPO briefs than the scientists who testified to the issue at trial.” (Abbott Br. at 11.) Abbott’s attempt to dismiss the efforts of district court judges because they have “no training or experience in the specialized field” is unwarranted. (Abbott Br. at 3.) As the majority found, the District Court’s findings as to materiality and intent were “careful and thorough.” (Maj. Op. at 18.) The District Court made a specific and independent finding that Abbott’s witnesses were not credible. For example, the District Court stated that, “As a trial witness, it must be said that Dr. Sanghera was impeached on substantive points with his prior inconsistent statements and exhibited an unconvincing demeanor.” (Maj. Op. at 29 (citing District Court Op.)) The District Court also properly discredited the testimony of Abbott’s expert, Dr. Johnson, who testified that a membrane was “required” for testing with blood. (Maj. Op. at 10.) The court should not rehear this case *en banc* to re-review the trial court’s assessment of witness credibility. (Maj. Op. at 28.)

C. Neither the District Court Nor the Majority Applied a “Should Have Known” Standard to Find Intent.

Abbott and *amici* also argue that the majority “deepens persistent confusion” about inferring intent by applying a “should have known” standard, which Abbott says amounts to “gross negligence” and is contrary to the holdings of *Kingsdown* and *Halliburton*. (Abbott Br. at 5-6, 9.) Neither the majority nor the District Court, however, applied a “gross negligence” standard to find intent.

Abbott's entire argument rests on a single sentence in the District Court's opinion reciting the "knew or should have known" standard. But the District Court went beyond finding that Mr. Pope and Dr. Sanghera "should have known" of the materiality. It found that Mr. Pope and Dr. Sanghera *actually knew* of the materiality and intended to deceive the PTO: "Both knew that the EPO materials made affirmative statements inconsistent with the declaration and the attorney remarks concerning the '382 sentence in question." *Therasense*, 565 F. Supp. 2d at 1110. "Inconsistency is called out by Rule 56 as a specific indicum of materiality." *Id.* at 1112. "[I]ntent to deceive, not just to withhold, was clearly in the mind of Attorney Pope." *Id.* at 1114. Thus, this case does not depend on any split regarding the "should have known" standard.

Furthermore, Abbott's supposed concern about the increased prevalence of inequitable conduct charges, which is based on the "percentage of answers and counterclaims" alleging inequitable conduct (Abbott Br. at 4 n.2.), is fully addressed by the recent *Exergen* decision. See *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1325-31 (Fed. Cir. 2009). *Exergen* created a higher threshold for pleading inequitable conduct, making it much more difficult for accused infringers to assert the defense. *Id.* To the extent that there are problems with the

allegedly high prevalence of inequitable conduct, the most effective reform will be at the pleadings stage (addressed by *Exergen*), not at the judgment stage.⁴

D. The Majority Decision Is Distinguishable from the “Attorney Argument” Cases Cited by Abbott and *Amici*.

Finally, Abbott argues that this decision “subverts” case law holding that “arguments, especially lawyer arguments, about what the prior art teaches are not material if the prior art itself is before the PTO.” (Abbott Br. at 12-13.) *Amici* echo Abbott’s argument. The majority, however, properly distinguished these cases because they did not “speak to the applicant’s obligation to advise the PTO of *contrary representations* made in another forum.” (Maj. Op. at 26-27 (emphasis added).) None of these cases involves what happened here: the deliberate and knowing withholding of the applicant’s own prior inconsistent statement as specifically prohibited by Rule 56(b)(2).⁵ Further, none of these cases involves a situation where, as here, the applicant submitted both a sworn declaration and attorney argument, each of which directly contradicted its own prior statements.

⁴ Recent decisions have also tightened the standards for proving intent to deceive. *McMahon & Boyle*, 10 Sedona Conf. J. 197, 201 (2009) (cited by Abbott) (concluding based on *Star Scientific* and *Scanner* that “the standard for proving the factual elements of materiality and intent is high and may be getting higher.”) As discussed above at pages 9-10, Bayer met this higher standard.

⁵ See 37 C.F.R. § 1.56(b)(2) (a prior statement must be submitted if “[i]t refutes, or is inconsistent with, a position the applicant takes in . . . [a]sserting an argument of patentability”); *Pharmacia Corp. v. Par Pharm., Inc.*, 417 F.3d 1369, 1373 (Fed. Cir. 2005) (upholding inequitable conduct based on declarant’s failure to disclose prior inconsistent statement in article that declarant had co-authored).

Abbott argues that *Innogenetics* involved similar facts because the attorney told the EPO that a reference was the “closest prior art,” but later told the PTO that the reference “did not relate to the invention.” (Abbott Br. at 13.) As the *Innogenetics* court recognized, however, the reference was identified as the “closest prior art” to adhere to European practice, where a reference is identified as such “whether relevant or not.” *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1379 (Fed. Cir. 2008). The attorney did not make contradictory statements about the reference: he told the EPO that “none of the submitted references” (which included the reference at issue) “taught or disclosed the method claimed,” and later told the PTO that “the references do not relate to the invention.” *Innogenetics*, 512 F.3d 1363 at 1379. Thus, *Innogenetics* did not involve the deliberate withholding of contradictory statements from the PTO. Moreover, *Innogenetics* recognized that “[c]ases involving affidavits or declarations” — as is the case here, given the submission of Dr. Sanghera’s declaration — “are held to a higher standard.” *Id.*

The *Life Techs.* case cited by Abbott is even further removed from the facts of this case. (Abbott Br. at 13.) In *Life Techs.*, the inventors had failed to disclose that a particular article had served as their motivation to develop the claimed invention. *Life Techs., Inc. v. Cloneteck Labs., Inc.*, 224 F.3d 1320, 1322-23 (Fed. Cir. 2000). While the inventors disclosed the article itself, they argued during prosecution that the article did not render the claimed invention obvious. *Id.* at

1325-26. The district court found, *inter alia*, that the inventors' statements regarding patentability in view of the article amounted to inequitable conduct. *Id.* The Federal Circuit reversed, holding that the inventors' statements were not material misrepresentations, because they "did not contain any factual assertions" about the article. *Id.* at 1326. Nothing in *Life Techs.* addresses the facts at issue here: concealing from the PTO factually contradictory assertions about the prior art. The remaining cases cited in Abbott's footnote 20 are similarly distinguishable: none of them involves the deliberate withholding of a prior inconsistent statement. (Abbott Br. at 12 n20.)

Finally, Abbott and *amici* exaggerate the effect of this decision. Nothing about the decision expands the scope of required disclosure. The majority followed Rule 1.56(b)(2), which requires disclosure of known prior inconsistent statements, and it is undisputed that Pope and Sanghera knew of the statements. Neither Rule 56 nor this decision requires anyone to search for all "legal arguments and briefs . . . submitted in foreign prosecutions of other patents." (Abbott Br. at 14.) If those with a duty to disclose do not know of prior inconsistent statements, there can be no inequitable conduct under Rule 56(b)(2) or *Therasense*.

IV. CONCLUSION

For the above reasons, the Court should deny Abbott's petition for *en banc* review.

Dated: March 19, 2010

Respectfully submitted,

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**DECLARATION OF AUTHORITY PURSUANT TO
FEDERAL CIRCUIT RULE 47.3(d)**

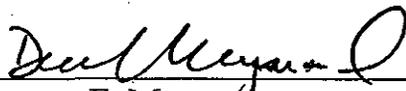
I, Deanne E. Maynard, hereby declare as follows:

1. I am a partner at the law firm of Morrison & Foerster LLP. I make this declaration pursuant to Federal Circuit Rule 47.3(d). I have personal knowledge of the matters contained in this declaration.

2. Rachel Krevans is a Partner at Morrison & Foerster LLP. She has authorized me to sign the Response to Abbott's Petition for Rehearing En Banc on her behalf because she is unavailable to do so herself.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on March 19, 2010, in Washington D.C.



Deanne E. Maynard

CERTIFICATE OF SERVICE

I, Judith A. Jackson, hereby certify that on the 19th day of March, 2010, I caused one original and eighteen copies of the foregoing document:

Bayer's Response to Abbott's Petition for Rehearing *En Banc*

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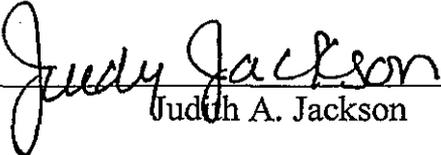
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I declare I am employed in the office of a member of the bar of this court at whose direction the service was made. Executed on March 19, 2010, at Washington, DC.



Judy A. Jackson