No. 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.

Appeal 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 BRIEF OF PLAINTIFF-APPELLANTS ABBOTT LABORATORIES AND ABBOTT DIABETES CARE, INC.

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Therasense v. Becton

No. 2008-1511, -1512, -1513, -1514, -1595

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party) Abbott Diabetes Care Inc. and Abbott Laboratories certifies the following (use "None" if applicable; use extra sheets if necessary):

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

Therasense, Inc. (now known as Abbott Diabetes Care, Inc.) and Abbott Laboratories

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

None.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None.

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

See attachment

9/29/08
Date

Signature of counsel

Rohit Singla
Printed name of counsel

Please Note: All questions must be answered

cc: Bradford Badke, Esq. and Morton Amster, Esq.

CERTIFICATE OF INTEREST ATTACHMENT

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

MUNGER, TOLLES & OLSON LLP	Jason Rantanen Jeffrey I. Weinberger Rohit K. Singla John Peck (no longer at MTO) Ted G. Dane Bill Ward
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I. REPLY

A. '551 Obviousness

The question before this Court is whether the '551 patent is obvious based on the "optionally but preferably" sentence alone, (1) despite the fact that the rest of the '382 actually teaches away from a membraneless sensor for blood; (2) without proof that a PHOSITA would have had a reasonable expectation of success (which even the '382/'551 inventors did not have); and (3) without proof that the '382, together with the prior art, enabled the practice of the '551 invention.

1. Disclosure

a. *The phrase "optionally, but preferably" must be read in the context of the technical teachings.*

Despite their claim to "consider the entire disclosure of the '382 patent," all of the testimony defendants rely upon (like the district court) boils down to the "optionally, but preferably" language.[1] (Bayer Opp. 6-7.) But the "broad teaching" now being ascribed to that language (Trial Order 16) conflicts with the technical details of the '382. (*See* Opening Br. 30-31.) It is error to interpret such isolated phrases beyond a patent's specific technical teachings, because that is so

[1] Bayer cites, for example, to JA2531 at 239:13-22 (Turner on "optionally" sentence); JA2748-49 at 534:3-537:5 (Johnson on same); JA2618-19 at 333:18-338:3 (Turner testimony about "optionally" and "preferably"); JA3076 (Davis on "optionally" sentence); and JA3695-98 (same for Higgins).

easily subject to hindsight analysis, *i.e.*, reading the prior art with the invention at issue already in mind:[2]

> It is impermissible to first ascertain factually what appellants did and then view the prior art in such a manner as to select from the random facts of that art only those which may be modified and then utilized to reconstruct appellants' invention.

Application of Shuman, 361 F.2d 1008, 1012 (C.C.P.A. 1966). In *Shuman*, the Court rejected a similarly broad reading of a general suggestion in a prior art patent because that reading was "a departure from the more specific teachings" of the prior art and from the embodiments "discussed in detail." *Id.*

b. *The technical disclosures of the '382 teach away.*

Defendants do not dispute that despite thirteen working examples, descriptions of numerous additional sensor designs, and the undisputed advantages of membraneless sensors, *the '382 describes no membraneless sensor tested in blood.* This silence speaks volumes.

Indeed, the only membraneless sensors described in the '382 are expressly *not* used in blood. The first is described as "projecting *only* into the dermis," *i.e.*,

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[2] Even defense expert Dr. Turner admitted, when discussing the '164 patent, that words like "preferably" are "patent tease [sic]" and have to be "read . . . in context." (JA9738:3-19.) Bayer claims Abbott's witnesses testified that the words "optionally" and "preferably" had their "ordinary meaning" in the '382. (Bayer Opp. 7.) But Dr. Sanghera specifically said the opposite, that "[i]n the context of" of the '382, "optionally" and "preferably" "deems that it's required" for blood. (JA3009 at 748:6-12.) So did Mr. Scott. (JA3542.)

for interstitial fluid. (JA6508 col. 3:57-4:2. (emphasis added).) The second is in Example 8, which defendants try to explain by suggesting that buffer was used to "simulate testing in blood." (Bayer Opp. 8.) But the Example 8 sensor was in fact tested in blood — *after* it was "modified" by adding "a cellulose acetate membrane." Neither defendants nor the district court can reconcile this with their reading of the patent. The obvious implication is that a membrane was needed for blood.

Bayer claims that Abbott's expert Dr. Johnson testified that the Example 8 membraneless sensor was a "prototype" that could have been used in blood. (Bayer Opp. 9, 35-36.) But Johnson actually testified that the "prototype . . . wasn't a finished sensor" and that although it could be *tested* in blood, "making it work is a different story." (JA2756 at 565:19-21; JA2751 at 546:1.) Johnson merely stated the obvious: the membraneless sensor could have been tested in blood but was not. That would be telling to any reader of the patent.

Bayer cites *In re Inland Steel Co.*, 265 F.3d 1354, 1361 (Fed. Cir. 2001) for the proposition that "non-preferred embodiments" cannot be ignored. (Bayer Opp. 31.) However, none of the '382 embodiments — whether preferred or not — disclose membraneless sensors for blood.

BD/Nova repeatedly relies on the fact that the '382 claims cover sensors without membranes and that the ExacTech is marked with the '382 patent. (*See,*

e.g., BD/Nova Opp. 5.) BD/Nova is confusing claims and specifications. "[S]pecifications teach. Claims claim." *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 n.14 (Fed. Cir. 1985). The invention claimed in the '382 patent is a faster mediated chemistry. Just because the ExacTech uses that chemistry, and so falls within the '382 claims, cannot mean that the '382 specification teaches and renders obvious every feature of the ExacTech. *See In re Benno*, 768 F.2d 1340, 1346 (Fed. Cir. 1985) ("The scope of a patent's claims determines what infringes the patent; it is no measure of what it discloses.").

2. Reasonable Expectation of Success

a. *There was no evidence of reasonable expectation of success.*

The district court conceded that before the '382, PHOSITAs would have expected a blood sensor to require a membrane because of fouling.[3] (Trial Order 14.) Defendants are unable to cite any *evidence* that the '382 changed the conventional wisdom and gave a reasonable expectation of success for a membraneless blood sensor. *Tellingly, defense expert Turner did not testify on this issue.*

[3] Bayer's reference to the '166 Suzuki reference is another red herring. Turner offered no testimony about Suzuki, and the district court did not rely on it. (Trial Order 14.) Suzuki in fact refers to an electrode "free of a *semipermeable* membrane" — the kind of glucose limiting membrane used in the D1 reference discussed at the EPO — not the protective membrane at issue here. (*Id.*) And Suzuki acknowledges that a sensor without a semipermeable membrane does not work; it is subject to "noticeable variation[]." (*Id.*)

Bayer cites only seven pages of its own brief, in which no evidence of that supposed fact is cited. (Bayer Opp. 35, 4-11.) BD/Nova just echoes the district court's own "expert" opinion that a PHOSITA would have understood the '382 faster chemistry to eliminate the risk of fouling and render a membrane "no longer necessary." (BD/Nova Opp. 25). But again, there is *no* evidence to support that conclusion. Turner never so testified — and defendants pointedly never asked him that. Turner said only that fouling was somewhat *less* of a concern. Critically, however, he testified that, "[f]ouling is *still* a design feature in these devices because you're still dealing with blood." (JA2531 at 241:12-23 (emphasis added).) His testimony thus corroborates that a PHOSITA would have still thought fouling was a problem. Moreover, Johnson pointed out that Example 8's addition of a membrane before testing in blood indicated to a PHOSITA that the membraneless sensor would not work in blood. (JA2739 at 498:3-21.)

Indeed, Example 8 of the '382 reports a 5% oxygen discrepancy in *buffer* for the membraneless sensor, indicating that this sensor would *not* work in blood, which has a much greater oxygen concentration. (Opening Br. 15; JA6511 col. 9:19-21.) Dr. Sanghera testified to this based on his personal experience working with the Example 8 devices.[4] (JA3000-01 at 715:5-717:23.) Like the district

[4] BD/Nova's assertion that this issue is being raised for the first time is inexplicable. Dr. Sanghera testified to this at trial and it is discussed in Abbott's proposed findings. (JA14578.)

court, Bayer responds by noting the '551 reports a similar 4% oxygen sensitivity. (Bayer Opp. 10.) This is highly misleading. The 5% figure in the '382 relates to *buffer*. The 4% figure in the '551 is for "anaerobic and fully aerobic *samples*," *i.e.*, *blood samples*. (JA3861 col. 7:18-22.) Unlike the '382 sensors, the '551 sensors are directed entirely to blood samples. Turner's own research, while employed at MediSense, demonstrated that the older electrodes exhibited an oxygen sensitivity *in blood* of 23% not 5%. (JA6367.)

Thus, the evidence demonstrates that a PHOSITA would *not* have had a reasonable expectation of success in making a membraneless sensor for blood based on the '382 specification.

b. *Even the inventors did not know how to make a membraneless sensor for blood.*

Reasonable expectation of success is contradicted also by the testimony of the inventors — worldwide leaders in the field with no interest in the patent or the litigation — that they were themselves not confident they could make a membraneless sensor for blood in 1981. (*See* Opening Br. 12-13.)

Bayer grossly mischaracterizes this inventor testimony. It claims Dr. Hill testified that they had known "protective membranes were not necessary for *in vitro* devices tested with blood." (Bayer Opp. 13.) But Bayer critically omits the timing. Hill said they conceived of a membraneless sensor for blood during the research for the '551 invention, in 1982 or 1983 — after the '382 specification.

(JA3188-89; JA3210.) Hill testified, in fact, that even in "'82, '83, as far as I remember there were no electrodes that could be introduced into blood without a membrane." (JA3209.)

Bayer cites inventor Davis' testimony that the "'optionally, but preferably' sentence contemplated embodiments without a membrane." (Bayer Opp. 13.) But that is not in dispute. The question is whether a membraneless embodiment is taught *for blood.* Davis never said that. Indeed, Davis expressed surprise in his lab notebooks well after the '382 when they learned to test in blood. (JA6437.)

Finally, Bayer claims Dr. Higgins testified that "membranes were not necessary" for blood and a PHOSITA "would have understood" that from the '382. (Bayer Opp. 13.) In truth, Higgins (a witness paid by Bayer) said only that the inventors had *speculated* a membrane "*might* well not be necessary." (JA3105 (emphasis added).) They merely thought further research might produce a membraneless sensor for blood: that it was "quite *conceivable* that it would be *possible* to get that system to work in blood without a membrane." (JA3746 (emphasis added).) With respect to PHOSITAs, Higgins added speculation on top of speculation: that PHOSITAs "*might* well have concluded: *maybe* this will work without a membrane." (JA3117-18 (emphasis added).)

The inventor testimony is unambiguous: at the time of the '382 (and for perhaps a year or two afterwards), the '382/'551 inventors did *not* have a reasonable expectation of success, even with their superior skills in the art.

3. Enablement

a. *There was no evidence of enablement.*

Defendants cite no evidence that a membraneless sensor built with the '382 technology (or anything else in the prior art) would work in blood. Neither defendants' expert, nor any of the inventors, nor any other witness, testified that the '382 disclosures eliminated the central problem of fouling.

BD/Nova (but noticeably not Bayer) claims that Turner testified to that effect (BD/Nova Opp. 30, 32), but all he actually said was that *Example 8* does not expressly say the membraneless sensor would *not* work in blood. (JA2533 at 248:25-249:6.) That is hardly clear and convincing evidence of enablement. Moreover, Turner (and the district court) ignored the simple fact that the inventors *added* a membrane in Example 8 before testing in blood.

b. *The only evidence was that the prior art did not enable the '551 invention.*

Oxygen Effect. The '382 reports a 5% oxygen effect in buffer, indicating a severe problem if used in blood. (*See supra* 5-6.)

Dr. Sanghera's Testimony. Sanghera testified that when he worked at MediSense, he "replicated what was in the '382 patent" and experimented with

those devices. (JA3007 at 741:2-13.) Based on his personal knowledge, Sanghera testified that the membraneless sensor of Example 8 would *not* work in blood:

> There would be a very large reduction in the true value of the glucose signal because of the inhibition effect of the oxygen. . . .
> . . .
> The system would give a falsely low reading for a fixed glucose concentration.

(JA3001 at 717:14-23.) *That is the only testimony in the record regarding whether '382 technology worked in blood without a membrane.*

Oxidation. Defendants do not dispute that after the '382 invention, the inventors discovered that oxidized electrodes exhibit greater fouling, or "adsorption." (JA3212-14.) Nor do they dispute that the '551 teaches sensors that are not oxidized. Bayer's only response is that the '382 mentions non-oxidized electrodes. (Bayer Opp. 18.) But a non-oxidized sensor designed *for non-blood applications* and constructed *with a membrane* is beside the point, because fouling would not be a concern there. What Bayer ignores is that the membraneless sensor for blood supposedly taught in Example 8 is conspicuously oxidized: "heat [ ]in an oven for 40h at 200° C to give a[n] oxidi[z]ed surface." (JA6511 col. 9:1-3.) Bayer also complains that the '551 does not explain how it avoids the fouling problem. (Bayer Opp. 15, 18.) But that cannot render the patent invalid: "it is not a requirement of patentability that the inventor correctly set forth, or even know,

how or why the invention works." *Newman v. Quigg*, 877 F.2d 1575, 1581 (Fed. Cir. 1989).

Defendants' nitpicking at Abbott's evidence ignores that defendants bore the burden of proof.[5] Even without any of Abbott's evidence, the absence of clear and convincing evidence that the prior art enabled the '551 invention requires reversal.

4. The '551 is not a new use for an old product or the deletion of a function.

Bayer's "new use" argument is specious. (Bayer Opp. 40) There is no "old product" analogous to the '551 invention — which claims not just a membraneless sensor for blood, but other features such as an elongated, disposable test strip without the separate reference electrode taught in the '382. (JA128 at 13:29-14:17.) There is no dispute that the '382 sensors did not have these elements; the district court relied on other references for these elements. (Trial Order 39-48.)

The district court's alternative holding — that the '551 patent is invalid as "the mere deletion of the membrane with a corresponding loss of its functions" (Trial Order 21) — is just a variation of the same argument. As noted, the '551

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[5] In passing, Bayer cites *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 545 F.3d 1312, 1312 (Fed. Cir. 2008) suggesting that case switched the burden of proof. But *Impax* is an *anticipation* case and the issue here is obviousness. Obviousness requires the challenger to prove the prior art made the entire "subject matter" of the invention obvious (including how to practice it), not just that the invention is "*described* in a printed publication." 35 U.S.C. §§ 102 (emphasis added), 103. *Impax* followed *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355-1357 (Fed. Cir. 2003), which did not extend its holding to obviousness.

invention is *not* just the '382 sensor with the membrane removed. And in any case, the *Richards* case itself recognized that it *is* inventive to remove a functional element and reach the same result: "the omission of an element in a combination may constitute invention if the result of the new combination be the same as before." *Richards v. Chase Elevator Co.*, 159 U.S. 477, 486 (1895). The inventive "result" here is the ability to test in blood without a membrane. *See In re Deutsch*, 75 F.2d 994, 995-96 (C.C.P.A. 1935) (omission of element is a "patentable change" where omission in the prior art device would have rendered it inoperable).

B. '551 Inequitable Conduct

1. Defendants' claim of inconsistency is spurious.

a. *MediSense never argued that a membrane was optional for blood.*

Like the district court, defendants focus on MediSense's lawyers' statements to the EPO that a membrane was "optional" in the '636/'382 device. (*See, e.g.*, Bayer at 23, 44-45; BD/Nova at 39.) *But that is not in dispute*: everyone agrees that a membrane is optional in some embodiments of the '382. Pope and Sanghera never suggested to the PTO that the '382 required a membrane for *all* applications, just for blood.

As for whether the '382 required a membrane *for blood*, MediSense's lawyers told the EPO that:

> For use on human blood the sensor of Example 7 was provided with a protective membrane.

(JA6586; JA6531.) (Example 7 of the '636 is the same as Example 8 of the '382, discussed above.) In a silence that speaks volumes, neither the defendants nor the district court even address this statement to the EPO that a membrane was used for blood.

BD/Nova baldly asserts, without citation or support, that MediSense told the EPO a membrane was "optional" in "*all* cases." (BD/Nova Opp. 40 (emphasis in original).) But the EPO briefs say nothing of the sort. In a similar vein, Bayer argues that MediSense was *implicitly* telling the EPO that a membrane was optional for blood, because "Claim 1 of the '636 . . . specifically claimed measurements of glucose in 'blood' or interstitial fluid." (Bayer Opp. 45.) That accusation answers itself, as the '636 claim expressly calls out "interstitial fluid," for which all agree a membrane was not necessary. (JA2740 at 499:18-23; JA2745 at 521:12-522:2.). More importantly, basing inequitable conduct on supposed *implicit* assertions would be a radical and dangerous expansion of the law.

b. *MediSense's only argument to the EPO related to the difference between the D1 and '382 membranes.*

To distinguish the D1 reference, it would have been pointless for MediSense to argue that a membrane was always optional in the '636/'382 devices, because the '636 claims explicitly called out sensors with membranes. (JA6589, claim 9; JA2985 at 654:5-17; JA2985-86 at 655:20-656:9.) MediSense needed to distinguish the *type* of membranes used.

The reason MediSense's lawyers noted the membrane was "optional" in some situations was precisely to demonstrate the difference in the D1 and '636/'382 membranes. The semipermeable membrane used in the D1 reference controls the diffusion of glucose. (Opening Br. 8.) If that kind of membrane is needed, it is needed whenever glucose is measured, regardless of the liquid — buffer, blood, or interstitial fluid. (JA2745 at 520:16-25.) Thus, by showing that the '382/'636 did not use a membrane for at least some liquids, MediSense proved that it did not use the D1's glucose-controlling membrane. That is all MediSense needed to or did tell the EPO.

The district court and the defendants ultimately point to just two sentences — out of 25 pages of EPO briefs — in which the "optionally, but preferably" sentence is described as "unequivocally clear." (JA6585.) The inequitable conduct judgment boils down to the assumption that MediSense's lawyers said it was "unequivocally clear" that a membrane was optional for blood. But defendants and the district court ignore the surrounding context, which makes clear that what was described as "unequivocally clear" was that the '382/'636 membrane is "permeable to water and glucose," unlike the D1 membrane — not that the membrane was optional for blood. (Opening Br. 44-45; JA6585.) The surrounding text is all about the permeability of the membrane, not its optionality.

The EPO Board itself understood that MediSense cited the "optional, but preferably" sentence for its description of the *type* of membrane used. (Opening Br. 46-47 (citing JA6570-71).) The only statement about the membrane being "optional" is the quotation, and subsequent paraphrase, of the "optionally, but preferably" sentence itself. But the '382 specification and the "optionally, but preferably" sentence were already before the Examiner, and nothing in the EPO brief is inconsistent with what Pope and Sanghera told the PTO, *i.e.*, that while the membrane can be optional (*e.g.*, for interstitial fluid), the "optionally, but preferably" language cannot be read as a technical teaching that the membrane is optional for *whole blood.*

Bayer takes a critical liberty with the facts in arguing that Pope told the PTO the "'optionally, but preferably' sentence is . . . 'mere patent phraseology.'" (Bayer Opp. 28-29; 43-44.) Pope acknowledged, after all, that the *sentence* has content; it contains the clearest statement in the patent of the type of membrane used. (JA2990 at 672:13-23.) What Pope actually addressed, and what the Examiner cared about, was the "'optionally, but preferably' ***language***," the introductory phrase, not the whole sentence. (JA7645.) Given the teachings of

Example 8 and the rest of the '382, Pope concluded that phrase did not teach that a membrane was optional for blood.[6] (JA2986 at 658:19-659:20.)

c. *The only scientific testimony supported Abbott.*

Even though the district court and defendants insist that these few sentences of the EPO briefs were a material *technical* admission, the district court based its inequitable ruling solely on its own interpretation of those sentences, unaided by *any* supporting scientific testimony.

Defendants pointedly never had Turner testify on how a PHOSITA would have read the EPO briefs, whether they were material, or whether they were inconsistent with Abbott's PTO submissions. This is especially surprising as Turner reviewed the EPO submissions and testified about other aspects of them at length. (JA2603-05 at 275-81.) Defendants had several scientific experts (JA7; JA23), yet none came forward to opine about the EPO submissions. Turner did not rely on the EPO briefs even to support his obviousness opinion that the '382 patent disclosed a membraneless sensor for blood. If defendants were correct that

[6] The district court's view of whether patent phraseology is good public policy is irrelevant. The question is whether Pope's reading of the '382 was reasonable given that patent prosecutors in fact utilize such terms of art. *See* Robert Faber, *Landis on Mechanics of Patent Claim Drafting*, Section 3.7C (5th ed. 2008) ("the specification writer should avoid words like 'critical,' 'required,' 'necessary,'. . . as the claims will almost assuredly be construed to require a feature so characterized").

MediSense admitted that fact in the EPO briefs, defendants' expert would presumably have relied on that admission.

The *only* scientists to testify on the interpretation of the EPO briefs were Dr. Sanghera (JA3001-3004) and Dr. Johnson. Johnson, an eminent scientist in the field, testified at length and without impeachment that the EPO briefs should not be read as inconsistent with the PTO submissions. (JA2742-48 at 510-531.) The district court acknowledged that it was appropriate for Johnson to testify on the interpretation of the EPO briefs (JA2747 at 528:19-21), but then ignored his testimony. (*Id.* 529:7.)

d. *Inequitable conduct cannot be based on close interpretation of ambiguous language.*

The question is not whether Pope's reading of the "unequivocally clear" sentence and the rest of the EPO briefs was "correct." The question is only whether Pope's interpretation was *reasonable*. Close and conflicting interpretations of ambiguous legal arguments should not be the basis for rendering a patent unenforceable and jeopardizing a lawyer's career. (*See* Opening Br. 41, 46.)

Patentees subject to an inequitable conduct charge are entitled, after all, to all reasonable inferences from the evidence: "Whenever evidence proffered to show either materiality or intent is susceptible of multiple reasonable inferences, a district court clearly errs in overlooking one inference in favor of another equally

reasonable inference." *Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365, 1376 (Fed. Cir. 2008); *see also Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366-67 (Fed. Cir. 2008). BD/Nova (though not Bayer) argues to the contrary, but in both cases BD/Nova cites (*Cargill* and *Brasseler*) the evidence of materiality was in fact overwhelming.

2. Characterizations of prior art are not material.

As Bayer notes, "[d]efendants presented a single inequitable conduct argument":[7] that Pope failed to disclose the "prior *characterization* of the '382 disclosure" in *legal briefs* submitted to the *EPO* during the prosecution of *the foreign counterpart* to the '382, in an effort to distinguish yet another patent, the D1 reference. (Bayer Opp. 42, 47.) Defendants cite no precedent for such an attenuated claim. Nor do defendants respond to the concern that expanding materiality so broadly — to include any statement, from any proceeding in any forum, that someone might interpret as inconsistent with an argument to the PTO — creates an unbearable burden on inventors, patent counsel, and even patent examiners. (Opening Br. 47-50.)

[7] BD/Nova raises a new theory of inequitable conduct, that the PTO was not told the ExacTech was marked with the '382 patent. (BD/Nova Opp. 43.) Defendants raised this theory post-trial and never pled it with particularity, as required by Rule 9(b). (JA 541-47; JA1414-29.) In any event, as noted *supra* 3-4, that the ExacTech practices the '382 chemistry is irrelevant.

There is no dispute the prior art '382 patent was before the examiner, and this Court has consistently rejected inequitable conduct based on characterizations of prior art already before the examiner, even mischaracterizations in affidavits. *See, e.g., Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1482 (Fed. Cir. 1986). (*See also* Opening Br. 47-50.) Defendants have not cited any authority to the contrary.[8] Defendants try to distinguish *Akzo* and related cases by arguing this case involves characterizations of prior art in *foreign proceedings* rather than before the PTO. But a mischaracterization to the PTO is *more* likely to mislead the Examiner and should be more material than a supposedly inconsistent characterization in a foreign proceeding. Defendants argue that this case is different also because Dr. Sanghera submitted a declaration about the prior art. (Bayer Opp. 47.) But the issue here is the failure to disclose the EPO briefs, not Sanghera's declaration. Moreover, under *Akzo* and related cases, the characterizations of prior art in Sanghera's declaration cannot be inequitable conduct.

3. There was no basis to find an intent to deceive.

Although defendants insist that the district court did not merely infer intent from the supposed inconsistency between the EPO legal briefs and the PTO

[8] The cases BD/Nova cites involved a failure to disclose prior art (*McKesson* and *Pharmacia*) or factual misrepresentations about the identity of affiants (*Paragon*).

submissions, they are unable to identify anything else in the record to support an intent to deceive.

a. *Credibility determinations cannot substitute for evidence of intent.*

Defendants primarily rely on the district court's credibility determinations, but credibility determinations are no substitute for *evidence* of intent. Here the "credibility determinations" were simply another way of saying the district judge disagreed with Pope and Dr. Sanghera's reading of the EPO legal briefs. That is the only basis the district court gives for its credibility determinations. (Trial Order 33-34, 38.) Neither defendants nor the district court pointed to any significant inconsistencies in Pope or Sanghera's testimony. They were not contradicted by other witnesses or by extrinsic evidence. As BD/Nova concedes, Pope was never impeached. (BD/Nova Opp. 45.) Although BD/Nova claims Sanghera was impeached, the supposed "impeachment" was on entirely collateral issues that reflect, at most, an incomplete memory. (JA3012 at 763:25-JA3013 at 765:7; JA3013 at 766:13-767:9.)

In short, as the Supreme Court has explained, a trial judge may not "insulate his findings from review by denominating them credibility determinations." *Anderson v. Bessemer City*, 470 U.S. 564, 575 (1985).

b. *Intent to deceive could not be inferred.*

Intent to deceive can be inferred from the omission itself only when: (1) the withheld information is *highly* material; (2) the patentee *knew* of its materiality;[9] *and* (3) there was no credible explanation for withholding the information. *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 518 F.3d 1353, 1367 (Fed. Cir. 2008).

The few sentences in dispute from the EPO briefs were not "highly material" information — which means important prior art, critical technical data, and the like. There is no authority cited, and we know of none, suggesting that characterizations of prior art *already before the Examiner* can ever be "highly material." The cases defendants cite (*Monsato* and *Critikon*) involved critical prior art *unavailable* to the examiner. Defendants cite *Cargill*, but *Cargill* holds that "repeated rejections" on the same "point of novelty" can make information highly material. *Cargill, Inc. v. Cambra Foods, Ltd.*, 476 F.3d 1359, 1365-66 (Fed. Cir. 2007). Here, the Examiner had never previously rejected the '551 on the same point of novelty.

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[9] Although later cases mention a "should have known" standard, this Court's seminal *en banc* decision in *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988), explicitly rejected a "gross negligence" standard, which is precisely what the "should have known" standard produces. *See Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1442-43 (Fed. Cir. 1991) ("should have known of the materiality" was improper gross negligence standard for inequitable conduct).

Nor was there evidence that Pope or Sanghera knew of the materiality of the few sentences at issue now and gave them the weight and interpretation that the district court has now given them.[10] Pope, for example, testified that he had read the EPO submissions *over a year* before his interview with the examiner and the PTO submissions at issue. (JA2980 at 635:2-14; JA7636-39.) He explained that he remembered the briefs as discussing the types of membranes used, and not "whether or not the use of the membrane was optional when testing with blood." (JA2986 at 658:19-659:20).

Finally, "[i]ntent to deceive cannot be inferred simply from the decision to withhold the reference where the reasons given for the withholding are plausible." *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1367 (Fed. Cir. 2003). (*See also* Opening Br. 52-53.) As discussed above, Pope and Sanghera had a more than plausible interpretation of the EPO documents even if the district court read the briefs differently. (*See also* JA2982 at 643:19-25; JA3003 at 724:13-16, 725:6-15.) Neither defendants nor the district court point to anything that suggests otherwise. They do not identify, for example, any internal inconsistency in Pope

[10] BD/Nova alleges that *Abbott* had a motive for obtaining the '551 patent. (BD/Nova Opp. 46-47.) Even if true, that provides no basis to infer that Pope would have risked his entire career for one patent. Nor is there evidence that Sanghera, who was not even an inventor, stood to gain personally for the issuance of the patent. (JA3494-96.)

and Sanghera's interpretation or conflict with what MediSense was seeking to accomplish or contradiction in the briefs themselves.

4. There is no evidence that Dr. Sanghera's declaration was false.

Despite admitting that defendants had advanced only one theory of inequitable conduct (Bayer Opp. 42), Bayer argues at one point that Sanghera's declaration was knowingly false. (Bayer Opp. 52-53.) But there is no evidence of that. The declaration says that (1) in 1983, PHOSITAs "would have felt that an active electrode . . . would require a protective membrane" for use in blood; and (2) "[t]herefore," a PHOSITA would not have read the "optionally, but preferably" sentence to teach that a membrane was optional "or merely preferred" for blood. (JA7637.) The former opinion is entirely consistent with the district court's own understanding of the conventional wisdom at the time. (Trial Order 14.) The latter is just Sanghera's *opinion* about how a PHOSITA would read that sentence. There is no evidence Sanghera did not believe what he wrote. Bayer cites testimony from Higgins, but before it started paying him, Higgins had specifically reviewed Sanghera's declaration and the patents and concluded that Sanghera's conclusions "are perfectly reasonable."[11] (JA3760:9-20.)

[11] Defendants also suggest that Sanghera misled the Examiner into thinking that he was a PHOSITA in 1983. (Bayer Opp. 22; BD/Nova Opp. 9.) But the declaration clearly lays out Sanghera's educational history. (JA7636.)

5. Dr. Sanghera Was Entitled to Rely on Section 1.56(d).

BD/Nova does not dispute Sanghera's right to rely on Rule 1.56(d). But Bayer argues, without any support, that Rule 1.56(d) should be limited to people who have "no further involvement in the prosecution." (Bayer Opp. 54.) Rule 1.56(d) does not, however, read "attorney, agent, or inventor *or anyone else who participates in the prosecution*," which is how Bayer seeks to have the provision rewritten. Such a limitation would effectively eviscerate Rule 1.56(d) by requiring anyone who participates in the prosecution to second-guess their counsel's judgments — on pain of an inequitable conduct ruling. There is no justification for rewriting and narrowing Rule 1.56(d) in that way.

C. '164/'745 Infringement

1. "Non-flowing manner" cannot exclude convective motion.

It was error to find the BD/Nova strip did not infringe the '164/'745 patents because it had convective flow. Defendants do not dispute that ***convective flow is present in all liquids.*** (JA10553 ¶ 60.) Science has a word for a substance without convective flow: a solid. Defendants have *never* disputed this basic scientific principle. Instead, they confuse the issue by discussing Brownian motion and diffusion — but those were not the basis for the district court's summary judgment. The issue on appeal is whether there was any basis for the district court's

construction of "non-flowing manner" to mean "not moving," and more specifically to exclude even the convective motion present in all liquids.[12]

"Flow," in general and as used in the '164/'745, refers to a specific *type* of motion — the bulk movement of liquid as "in a stream." Merriam-Webster's Collegiate Dictionary (10th ed. 1999).[13] This interpretation conforms to both basic science and common sense: if a stream is dammed the liquid stops "flowing" downstream, but it will always have some internal motion, including the convective flow necessarily present in all liquids. The patents themselves use the metaphor of a "stream." (JA197.24 col. 11:37-40; JA197.30 col. 23:7-10.) The specifications speak only of stopping the "flow" of the "sample *stream*" or "fluid *stream*," not all motion. (*Id.* (emphasis added).) There is no method described in the patent specifications to stop all movement *within* the samples, much less to stop convective motion. In other words, the court's construction of non-flowing precludes even the embodiments described in the patents.

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[12] BD/Nova points to the court's denial of summary judgment to Roche on the "non-flowing" limitation. (BD/Nova Opp. 53.) But Roche and its expert had previously conceded the "non-flowing manner" limitation. (JA14548-49.) Abbott distinguished the Roche strips from the BD/Nova strips not based on convective motion, but because Roche was improperly relying on BD/Nova's expert's opinion regarding the BD/Nova strip to overcome that concession. (JA14547-48.)

[13] *See, e.g., B.V.D. Licensing Corp. v. Body Action Design, Inc.*, 846 F.2d 727, 728 (Fed. Cir. 1988) ("Courts may take judicial notice of facts of universal notoriety," and "[t]o that end, dictionaries . . . may be consulted.").

2. Defendants misrepresent the prosecution history.

As defendants implicitly concede (BD/Nova Opp. 13, 49), the Examiner's interview notes in the parent application provide the only indication of the rationale for the "non-flowing manner" limitation:

> Takata and Niwa were still applicable. [Applicants] will consider introducing a limitation regarding non-flow-through measuring.

(JA13791.) Non-flowing was intended to mean "not flowing through the chamber during measurement" because in "flow-through-cell" prior art, a blood sample is measured as it continuously flows through a small sample chamber.

Defendants now argue, for the first time on appeal, that the "non-flowing" limitation was added also to distinguish the "Nakajima" reference. This newly-hatched argument has no support in the record. Nakajima required a large sample size. Because a small sample size is a fundamental premise of the '164/'225 claims, the examiner proposed to combine Nakajima with the flow-cell of "Niwa," for its small *chamber* size. (JA13753.) In response, before the "non-flowing" manner limitation had even come up, Abbott distinguished Nakajima because it could not work using a small sample size and the Nakajima/Niwa combination because nothing taught how to combine the two. (JA13257-58.) At no point did Abbott distinguish Nakajima based on its having sample flow or other movement. (BD/Nova Opp. 13-14.)

Defendants make an even more tortured new argument that Abbott introduced the "non-flowing" limitation to distinguish a supposed "stop-flow-cell" operation of Niwa, *even though Niwa does not operate as a stop-flow-cell.* (BD/Nova Opp. 13, 49-50.) Rather than evidence, defendants present the following proposed chain of inferences: Abbott never disputed the Examiner's suggestion that it would be obvious to operate Niwa as a stop-flow-cell; therefore Abbott accepted that Niwa *disclosed* a stop-flow-cell; therefore, Abbott added the "non-flowing manner" limitation to distinguish Niwa not only as a flow-cell but also — *sub silentio* — as a stop-flow-cell. This chain breaks down at each link.

First, even if Abbott had not responded to the Examiner's suggestion that Niwa could be operated as a stop-flow-cell, that would not have constituted an acceptance of the Examiner's view. *Salazar v. Procter & Gamble*, 414 F.3d 1342, 1345 (Fed. Cir. 2005) (non-response to Examiner's statements is not disavowal of claim scope).

Second, Abbott *did* dispute the Examiner's suggestion *in the very next sentence* following the one quoted by BD/Nova:

> The Examiner suggests it would be obvious to operate the Niwa system in a stop-flow method so that coulometry could be performed. *Applicants assert nothing in the Niwa publication teaches or suggests that a meaningful coulometric method could be obtained from the system described nor at the volume claimed.*

(JA13254 (emphasis added).) The "volume claimed" refers to the sample size in a stop-flow method being the actual volume of the sample chamber, which would not produce sufficient signal for the Niwa device. Thus, there is no evidence that Abbott used "non-flowing manner" to distinguish Niwa as a stop-flow device.

Third, the Examiner did not conclude that Niwa disclosed a stop-flow-cell. He stated in the parent application's Notice of Allowability that Niwa "is distinguished from applicant's instant invention by disclosing *only flow-through* embodiments." (JA13805-06 (emphasis added).)

In sum, with respect to both Nakajima and Niwa, defendants ask this Court not only to review new arguments but also to imagine that the "non-flowing manner" limitation was added in response to hypothetical rejections found nowhere in the actual record. This is highly improper. *See Cordis Corp. v. Medtronic Ave, Inc.*, 511 F.3d 1157, 1177 (Fed. Cir. 2008) (requiring "clear and unmistakable surrenders of subject matter").

D. '745 Anticipation

1. The '225 does not disclose a diffusible mediator *with the invention*.

Defendants argue the '225 patent discloses the diffusible mediator limitation, for anticipation purposes, merely by mentioning diffusible mediators within its four corners. (BD/Nova Opp. 57-58; Bayer Opp. 56.) But to anticipate, the prior art "must *not only* disclose all elements of the claim within the four

corners of the document, but must also disclose those elements 'arranged as in the claim.'" *Net MoneyIN v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008 (emphasis added).) It is undisputed that the '225 reference discloses no device with a diffusible mediator arranged as in the '745 claims. To the contrary, in the very language relied upon by defendants, the patent describes only embodiments that do *not* use diffusible mediators. (JA8787:21-32.) Defendants argue for the absurd position that, by mentioning diffusible mediators to instruct PHOSITAs *not* to use them, the patent anticipates an embodiment using diffusible mediators. That turns anticipation on its head: a reference anticipates what it discloses, not the opposite of what it discloses.

2. Dr. Turner's testimony creates a triable issue of fact.

Defendants attempt to re-frame Turner's testimony as describing the '225 reference as "disclosing but teaching away" from diffusible mediators. But that is not what he said. When asked if the patent "teach[es] the use of diffusible mediators," he did not say yes. He testified instead that "[t]he '164 patent, according to my reading, tells you specifically not to use diffusible mediators." (JA9736:8-16.) Later he explained, "when you read this section of the patent in context, it's clearly telling me that the inventors want to talk and are talking about immobilized mediators *and not diffusible mediators*." (JA9741:20-24 (emphasis added).)

Like the district court, defendants try to bring the facts within *Upsher-Smith Laboratories, Inc. v. Pamlab, L.L.C.*, 412 F.3d 1319 (Fed. Cir. 2005). But in *Upsher*, the prior art described vitamin supplements with and without antioxidants and, thus, the disclosure expressly anticipated vitamin supplements "essentially free of antioxidants," even if such were disparaged. *See also Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1378 (Fed. Cir. 2001) (prior art "performed all the steps of the . ... claims at issue," thus disclosing the invention); *Celeritas Techs., Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354 (Fed. Cir. 1998) (although it disparaged the invention, prior art clearly described the invention in detail). By contrast, here there was no disclosure — no embodiment or example using diffusible mediators, as Bayer's own expert admitted.

3. Abbott's claim construction positions were consistent.

Defendants claim that Abbott argued during claim construction that the '164 patent disclosed diffusible mediators. Not true. At claim construction, defendants sought to limit the scope of the term "analyte sensor" to sensors employing *immobilized* mediators. (JA13829.) (Immobilized mediators are a subset of non-diffusible mediators.) What Abbott successfully argued was that defendants' proposed construction improperly limited the term to a preferred embodiment, and would have excluded other analyte sensors explicitly disclosed in the patent which do not use *immobilized* mediators. (JA197.30 col. 24:20-35.)

Defendants suggest also that the '164/'225 specification must disclose a diffusible mediator if the '164 is being asserted against strips using diffusible mediators. (Bayer Opp. 27; BD/Nova Opp. 22, 58.) But a device can infringe a patent without being disclosed therein, as often happens with improvement patents. "The scope of a patent's claims determines what infringes the patent; it is no measure of what it discloses." *Benno*, 768 F.2d at 1346.

4. There was a dispute of fact regarding whether the '745 "background signal" limitation is found in the '225.

There is no dispute that the '745 "background signal" limitation is not explicitly disclosed in the '225.[14] Bayer and BD/Nova rely on the report of another party's expert, Dr. Weber, who claimed this element is *inherently* disclosed in the '225. (JA1866-67.) But because Abbott's expert Dr. Bard credibly disputed Dr. Weber's methodology and conclusion, there was a triable issue of material fact. (JA10554 ¶ 63, JA10579-86.) Notably, the district court denied summary judgment of anticipation for the "Gotoh reference" on this exact basis: Bard raised sufficient questions regarding Weber's calculations of the background signals. (JA45-46.) There was no reason for a different outcome for the '225 reference.

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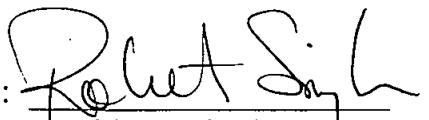
[14] Defendants contend that Abbott waived this issue below. But Abbott preserved the issue by raising it at the summary judgment hearing. (JA1572-73 at 142:24-145:15.) *See, e.g., U.S. v. Kitsap Physicians Serv.*, 314 F.3d 995, 999 (9th Cir. 2002) (argument waived if not presented in briefing ***or*** "at the summary judgment hearing").

II. CONCLUSION

For the foregoing reasons, the judgments on appeal should be reversed.

Date: February 9, 2009

By: 

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I am employed in the County of San Francisco, State of California. I am over the age of 18 and not a party to this action. My business address is 560 Mission Street, 27th Floor, San Francisco, California 94105.

On **February 9, 2009**, I served an original and 12 copies by Federal Express overnight delivery to the Court and two copies by Federal Express overnight delivery to opposing counsel of the following document, described as: **REPLY BRIEF OF PLAINTIFF-APPELLANTS ABBOTT LABORATORIES AND ABBOTT DIABETES CARE, INC.** to the address(es) listed below:

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This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) or FRAP 28.1(e). The brief contains 6994 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii). This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) or FRAP 28.1(e) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word, Version 2003 in 14-point Times New Roman font.

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