

EXHIBIT 21

Not Reported in F.Supp.2d, 2008 WL 2323856 (N.D.Cal.)
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Only the Westlaw citation is currently available.

United States District Court,
N.D. California.
THERASENSE, INC., Plaintiff,
v.
BECTON, DICKINSON AND COMPANY, De-
fendant.
and Consolidated Cases.

Nos. C 04-02123 WHA, C 04-03327 WHA, C
04-03732 WHA, C 05-03117 WHA.
May 22, 2008.

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**SECOND OMNIBUS ORDER ON MOTIONS
FOR FINAL PRETRIAL CONFERENCE SUB-
MITTED WITH ORAL ARGUMENT**

WILLIAM ALSUP, District Judge.

INTRODUCTION

*1 This is the second omnibus order in a set of such orders that resolve various motions leading up to the trial of this case. The first addressed motions were decided on the briefings only. This order resolves all other motions after oral argument on May

21, 2008. The severance motions will be addressed separately.

**BAYER MOTION IN LIMINE NO. 1
(JOHNSON RELIANCE ON TEST)**

GRANTED. One of the worst abuses in civil litigation is the attempted spoon-feeding of client-prepared and lawyer-orchestrated “facts” to a hired expert who then “relies” on the information to express an opinion. Ordinarily, if a fact witness tries to recount to the jury some “fact” earlier communicated to the witness, a hearsay objection would be sustained, at least when offered to prove the truth of the alleged fact. For example, if a fact witness wishes to testify that a coating was made from zinc rather than copper based solely on what someone told the witness, a hearsay objection would ordinarily be well-taken.

To circumvent this and to manipulate the precise content of “facts,” some lawyers hire experts to promulgate favorable hearsay to the jury. The expert is induced to “rely” on some factoid told to the expert by the client or someone else outside the courtroom. For example, the expert may be induced to rely on a statement that a metal coating was zinc and not copper. Then the lawyer tries to use Rule 703 to place the hearsay information before the jury. Rule 703 provides (*italics added*):

The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. *If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence in order for the opinion or inference to be admitted.* Facts or data that are otherwise inadmissible shall not be disclosed to the jury by the proponent of the opinion or inference unless the court determines that their probative value in assisting the jury to evaluate the expert's opinion substantially outweighs their prejudicial effect.

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To continue with the example, the expert then testifies before the jury that the coating was zinc and not copper, claiming that he or she regularly relies on such hearsay. The plan is for the hearsay to sail into evidence when the truth might be materially different, such as the coating was actually an alloy containing more zinc than copper.

The source is almost always highly partisan, such as the client or another forensic witness on retainer. Everything is kept secret from the other side until the expert report, which almost always comes after the close of fact discovery. In this manner, the other side rarely learns of the supposed “fact” until *after* the close of fact discovery, thereby immunizing it from vetting via discovery. Secrecy is achieved by cloaking the factoid inside the work product or attorney-client privileges. What is more, the expert will only be told of the results of the client's work if it turns out favorably, the lawyer concealing all adverse or confidential test results and facts from the testifying expert.

*2 This order holds that no professional should reasonably rely on such a rigged and biased source of information for any materially important fact to his or her opinion, at least certainly not in the circumstances of the present case. There is no “particular field” in which experts go along with this charade other than in litigation. The field of testifying for a living is not what Rule 703 had in mind.

This order independently finds that under Rule 403, the “probative value” of such testimony is far outweighed by risk of “misleading the jury,” such that references and opinion dependent thereon should be excluded. The whole point of the maneuver is to pass off client-prepared litigation-driven “tests” as fact by having the “expert” bless them. In the context of complicated science, the jury can be easily misled into believing that the tests in question were tested and subjected to cross-examination.

Coming from the expert alone, this order fur-

ther finds that any opinion based on such untested and partisan foundation is not based on sufficient facts and data within the meaning of Rule 702. As the gatekeeper to scientific evidence under *Daubert*, the Court holds that the foundation tests should be testified to directly by the ones who actually did the tests, so that they can be quizzed under oath. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993).

The traditional and correct way to proceed is for a foundational witness to testify firsthand at trial to the foundational fact or test and to be cross-examined. Then the expert can offer his or her opinion on the assumption that the foundational fact is accepted by the jury. The expert can even testify before the foundation is laid so long as counsel represents in good faith that the foundational fact will be laid before counsel rests. When the foundational fact is tested during fact discovery, as by a deposition, for example, it is often true that opposing counsel forego any objection and allows the expert to summarize the foundation.

To be sure, there will be times when an expert can work directly with client representatives to run tests and to develop facts and reasonably rely on the results in expressing an opinion at trial. For example, if an expert chooses not to conduct a copper-zinc test himself, he might supervise qualified professionals employed by the client to do so. Even if an expert does not supervise the client-conducted test, the expert might scrutinize a client-conducted test, its protocol, and its participants so carefully that it would be reasonable to rely on it after the fact.

Given the obvious bias of clients, however, any litigation-driven test must be subjected to heightened scrutiny such that it would be reasonable for a truly independent professional in the field of endeavor to base an important decision on it. The more central the “fact” issue is in the overall opinion and overall trial and the more controverted the “fact” is in the context of the case, the more due di-

ligence an expert should exercise before merely taking a partisan's word. At some point, as here, the supposed fact is too important and too controverted and should be addressed by witnesses with firsthand knowledge.

*3 In the present case, Abbott proffers the opinion of Dr. Jay Johnson to support its claim that the accused products do not have a "whole blood filtering member," as required by claim 1 of the '551 patent. Dr. Johnson's opinion is based in part on three experiments that were conducted by Abbott employees: (1) the "paper towel" experiment; (2) the "hematocrit" experiment; and (3) the "washing" experiment. But Dr. Johnson did not participate in, observe, or supervise any of the experiments. Nor did Abbott permit defendants to question one Abbott-employee witness who did conduct and participate in the experiments, concealing all of the tests from discovery during all phases of discovery under a claim of privilege. The same instruction not to answer would plainly have been given as to all other fact deponents involved in the tests (even if their identities had been known). The entire foundational project was a secret clearly intended to thwart discovery into the foundation. It was sprung on all opponents only after the close of fact discovery. Without any foundation, Dr. Johnson's testimony would be improper. All testimony and opinions about the tests are hereby excluded.

Whether or not curative discovery could now, at this late hour, be undertaken was discussed at the hearing but it is unclear whether it would be fair and would be practical at this stage. Plaintiffs are invited to seasonably submit a cure proposal for depositions and documents and to be specific as to what relevant documents, including emails and correspondences with counsel and other forensic consultants, plaintiffs would produce versus try to withhold-and on what timetable. The burden is on plaintiffs to cure this foundational issue. Before any such proposal is made, all counsel concerned must meet and confer over the proposal and any objections thereto. Meanwhile, the testimony in question

is excluded.

**BAYER MOTION *IN LIMINE* NO. 3
 (REFERENCE LABEL)**

DENIED. A judge should not "fix up" unfortunate wording used by a litigant in its own documents. This wording will have to be explained under oath and fought out before the jury. An instruction will be given to the jury as to what Judge Jenkins ruled. At this stage and on this record, the Court cannot categorically find that the internal Bayer documents are excludable under Rule 403.

**BD/NOVA MOTION *IN LIMINE* NO. 1
 (JOHNSON AND THE BD TEST STRIPS)**

DENIED WITHOUT PREJUDICE to renew-al under Rule 50. Movant has not carried its burden to show a total failure of proof. All experts, however, including Johnson will be limited to the four corners of their expert reports on direct examination. As to the claim construction issue, it is not necessary that the blood drop reach both electrodes at exactly the same moment. But it must be designed to completely cover both electrodes at a moment in time.

**ROCHE MOTION *IN LIMINE* NO. 2
 (STANDING)**

GRANTED. Plaintiffs will be barred from presenting any evidence of lost profits for infringement of the '551 patent in relation to sales by Abbott Diabetes Care, Inc. ("ADC"). Plaintiffs have not shown that ADC is the exclusive licensee of the '551 patent. Nor can they. It is manifest that there is at least one other licensee, so ADC is *not* the only licensee. Here are the dispositive facts.

*4 Abbott Laboratories is the sole owner of the '551 patent, but it does not sell or make any products embodying the patented invention. ADC makes blood glucose monitoring products and sells them to its subsidiary Abbott Diabetes Care Sales Corporation, who in turn distributes the products publicly. Plaintiffs seek the lost profits of ADC as a measure for damages for the alleged infringement of the '551 patent. Under Federal Circuit law, a li-

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licensee may have standing to sue as a co-plaintiff with the owner of a patent only if that licensee is an exclusive licensee. See *Rite-Hite Corp. v. Kelly Co., Inc.*, 56 F.3d 1538, 1552 (Fed.Cir.1995). If the license is non-exclusive, the lost profits of the licensee are not recoverable. The distinction between exclusive and non-exclusive licenses is thus critical.

Here, the complaint does not allege that ADC is the exclusive licensee of the '551 patent. In fact, the record indicates that Abbott licensed the '551 patent to another entity prior to filing this suit. Significantly, plaintiffs responded to an interrogatory in August of 2005 by stating Abbott had "entered into a licensing agreement with Lifescan" in connection with a settlement agreement for a previous patent suit. Plaintiffs later amended this response on the last date for fact discovery to indicate that Abbott had never licensed the '551 patent to anyone other than ADC.

After the continued representations to Judge Jenkins and defendants that Abbott had never licensed the '551 patent, Judge Jenkins ordered plaintiffs to produce a redacted copy of the Lifescan agreement. Judge Jenkins noted in relevant part (Dkt. 605 at 5):

Abbott's repeated representations to Defendants, to the Magistrate, and to this Court that it has not provided any 'license' to LifeScan fail to convince this Court that the contents of the settlement agreement are irrelevant to lost profits issues.... It is evident to the Court, from its review of the settlement agreement [*in camera*], that the provisions of the settlement agreement alter the legal relationship between Abbott and LifeScan in a manner that, in patent parlance, might well be described as some form of a 'license.'

The Lifescan agreement provided (Hutchenson Exh. C):

Covenant Not to Sue: Abbott covenants not sue LifeScan or DDI in the United States and/or Canada for any past or *future* infringement of the

Abbott Patents with respect to the Covered Strips. The covenant-not-to-sue extends to United States and Canada, including agents, representatives, suppliers, distributors, resellers, purchasers, end-users, shareholders, officers, directors, attorneys, employees and Affiliates (emphasis added).

The "Abbott Patents" included the '551 patent and the "Covered Strips" were blood glucose testing strips made and sold by Lifescan.

Although plaintiffs argue this was not a license, this argument is most unconvincing. The fact is the agreement unequivocally prohibited Abbott from suing Lifescan "for any past or *future* infringement of the Abbott Patents with respect to the Covered Strips" (Hutchenson Exh. C). As the Federal Circuit put it in *Spindelfabrik Suessen-Schurr, Stahlecker & Grill GmbH v. Schubert & Salzer Mascinenfabrik Aktiengesellschaft*, 829 F.2d 1075, 1081 (Fed.Cir.1997):

*5 As a threshold matter, a patent license agreement is in essence nothing more than a promise by the licensor not to sue the licensee.... In any event, patent license agreements can be written to convey different scopes of promises not to sue, e.g., a promise not to sue under a specific patent or, more broadly, a promise not to sue under any patent the licensor now has or may acquire in the future.

The Lifescan agreement does exactly this-*i.e.*, obligates Abbott not to sue for infringement, including for *future* infringement. Regardless of how it was worded, Lifescan now has the right to practice the '551 patent. This license has extended not only to Lifescan, but to all distributors and other entities along its chain of distribution.

Plaintiffs' contradictory statements and stonewalling demonstrate that they eventually realized the implication of their Lifescan agreement. In an effort to circumvent the problem, they have repeatedly altered their story and offered conflicting explanations to fill in all the missing gaps. In dis-

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covery, plaintiffs conceded that they had granted Lifescan a license for the '551 patent. Then, in a brazen field reversal on the last day of discovery, plaintiffs substituted the opposite answer for the original answer.

Plaintiffs argue that even if the Lifescan agreement were construed to be a licensing agreement that it should not preclude ADC's ability to recover lost profits because such a result would preclude all exclusive licensees from recovering lost profits after any settlement including such a license. This policy argument is unpersuasive. To settle a case, there is no requirement to give a *future* license, *i.e.*, a patent holder can instead seek damages and a promise to stop infringement. Alternatively, a patent holder may manufacture on its own and need not setup the separate sales companies as Abbott has done here. These issues should have been clear to Abbott long before granting Lifescan a license in the first place. The ramifications of granting the license should have been one of the many considerations Abbott evaluated when deciding to settle the Lifescan litigation. Significantly, the Lifescan agreement was executed between *Abbott* and Lifescan. *Not* ADC. Abbott, as the owner of the patent, could have still sought any lost profits for infringement, *see Golden Blount, Inc. v. Robert H. Peterson Co.*, 438 F.3d 1354, 1371-72 (Fed.Cir.2006), although such a claim would be very weak given its peculiar arrangements with ADC.

This order finds and holds that ADC is not the exclusive licensee of the '551 patent. Plaintiffs are hereby prohibited from presenting any evidence of ADC's lost profits for infringement of the '551 patent. It is unnecessary to reach the issue of whether there was an implied license with ADC, for this order assumes that there was an implied agreement.

**PLAINTIFFS' UNNUMBERED MOTION IN
LIMINE TO PRECLUDE DISCUSSION OR
EVIDENCE REGARDING NEGOTIATIONS
AND AGREEMENTS**

***6 DENIED** as to Lifescan agreement. This agreement is highly relevant to the issue whether

ADC is an exclusive licensee (as well relevant to the marking and irreparable harm issues). The Court is disappointed that Abbott stonewalled and concealed the Lifescan agreement. Judge Jenkins all but found that Abbott had deliberately misled the Court in its representation that the agreement included no license. Judge Jenkins eventually read it *in camera* and ordered it to be produced, rebuking Abbott for its semantic hairsplitting over what constitutes a license. Elsewhere in this omnibus order explains why the agreement is a license despite being labeled as a "covenant not to sue" for past or future infringement. In turn, this seems to explain why Abbott stonewalled on this document, for it originally wished to hold ADC out as an exclusive licensee.

Rule 408, it must be added, only bars introducing offers to compromise to prove liability or disprove liability or to prove the value of a claim. The Lifescan Agreement would be used for an entirely different purpose-to show that ADC is not the only licensee. Thus, the Lifescan Agreement-which resolved a lawsuit-would not be used for any of the prohibited purposes. Note well that Abbott could have settled that litigation without giving a license going forward, *i.e.*, it could have accepted cash and released its claim for *past* damages and insisted no further infringement. Instead, it agreed that Abbott would not-*in the future*-sue Lifescan or its customers in the chain of distribution. That part of the agreement is a license-pure and simple. A license is a license is a license. That it was folded into a litigation settlement does not change that fact. At that moment, ADC ceased being an exclusive licensee, if it even was beforehand. Proving that fact in no way implicates any of the prohibited purposes in Rule 408.

As to the Abbott-BD communications, the evidence shows that BD/Nova, starting with counsel's letter dated August 4, 2003, agreed that the licensing discussions between BD/Nova and plaintiffs would be treated in confidence as settlement discussions. BD/Nova is estopped to argue

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otherwise now. For now, the motion is **GRANTED**. If, however, plaintiffs leave a false impression before the jury as to what happened, then the issue will be re-visited.

BD/NOVA MOTION FOR SUMMARY JUDGMENT ('890 PATENT INVALID DUE TO PRIOR PUBLIC USE)

DENIED. The issue of prior public use requires balancing of several factors. Defendant has a reasonable case that there was no confidentiality by mid-September 1994, especially given the shipment to the Netherlands on September 30, 1994. Plaintiff has evidentiary support, however, including verbal testimony, that can shore up confidentiality, if fully credited. On the present record, therefore, the summary-judgment motion must be **DENIED**. The Court, however, is concerned that Abbott has violated its obligations of disclosure and discovery, at least as to some documents. The recently produced confidentiality agreement, for example, clearly must be excluded as having been produced far too late without substantial justification. "Inadvertence" will not do. Neglect, even if excusable, does not translate into substantial justification. Conceivably, other materials and witnesses will be excluded on renewed objections at trial. For now, movants have not carried their burden to eliminate all possible material issues of fact.

BD/NOVA MOTION IN LIMINE NO. 2 (510(K) AND CLINICAL USE RE '890 PATENT)

***7 DENIED.** It has been the practice of the undersigned judge to enforce all local patent rules, including those relating to the disclosure requirements for documents evidencing conception or a reduction to practice. *See* Local Patent Rule 3-2(b). On the other hand, Judge Jenkins has previously allowed Abbott to present the 510(k) application and other clinical-use evidence to establish an actual reduction practice for the '890 patent. The undersigned's ability to fully enforce the local patent rules is therefore eclipsed by Judge Jenkins' allowance of at least some of such evidence.

Exactly what preclusion force the local patent

rules exert will need to be determined on a document-by-document basis. For sure, the confidentiality agreement produced by Abbott only last month will certainly *not* be allowed into evidence, at least at the behest of Abbott. Defendants suggest that Abbott has yet to produce hundreds, if not thousands, of documents relating to its clinical trials. These documents, if eventually produced, will also be excluded at trial if offered by Abbott. For its part, however, Abbott has shown that it produced many documents as early as December 2005 evidencing that the clinical trials took place before the filing date of the Ikeda patent. Once again though, these documents must be considered on an individual basis before offered into evidence.

Most of the 510(k) application is self-serving hearsay. But it is at least admissible to show that it was in existence at the time it was filed, if that is relevant. A categorical exclusion must be denied. Defendants request that Abbott be barred from using any testimony to supplement the 510(k) application and the other documentary evidence produced by Abbott relating to the clinical trials. The request is denied. This does not mean that Abbott can offer testimony without any limitation. Abbott's witnesses must testify based on personal knowledge. The motion is **DENIED**.

BD/NOVA MOTION IN LIMINE NO. 3 (TO EXCLUDE PRIOR INVENTION '890 PATENT)

DENIED. While BD/Nova casts its motion to exclude prior invention as a motion in limine, it is actually requesting the Court to reconsider an issue previously decided. In particular, BD/Nova argues that plaintiffs have not met their burden to show that the patented invention was reduced practice before the filing date of the Ikeda prior art reference. But this argument was already presented to and rejected by Judge Jenkins (Dkt. 534 at 37):

The declarations of Dr. Watkin and Dr. Scott also provide competent evidence that the '890 invention was reduced to practice, somewhere in the world, no later than when the 510(k) FDA application was submitted in November 2004.... Al-

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though Abbott's evidence that Dr. Watkin visited the United States to provide information about the invention to the United States research team does not satisfy this showing, the testimony that Abbott's witnesses have provided regarding the clinical trials that were performed on the test strip in New Mexico, Texas and Massachusetts between August and October 1994 is sufficient evidence to meet Abbott's burden of production that the '890 invention had been embodied in the tangible form in the United States no later than November 1994, particularly given the nearly identical drawings in the 510(k) application and the '890 patent.

*8 BD/Nova now maintains there is no issue of material fact as to whether the invention was reduced to practice prior to the relevant date. In light of the previous holding, however, this contention is untenable. It is also significant to note that the greater part of BD/Nova's current motion relies on extremely minor details regarding the corroboration requirements for proving an actual reduction to practice. But "an actual reduction to practice does not require corroboration for every factual issue contested by the parties." *Cooper v. Goldfarb*, 154 F.3d 1321, 1330 (Fed.Cir.1998). Rather, the corroboration requirement is evaluated under a "rule of reason" standard. Plaintiffs have presented significant evidence-through declarations and documentary support-to proceed to trial on this issue. Finally, the Court is not yet persuaded that the "mesh" statements are inconsistent with the claim limitation.

* * *

Finally, the Court is concerned that BD/Nova has been prejudiced by plaintiffs' eleventh-hour amendment of the '890 issues, specifically as to the issues of prior invention and prior public use. To mitigate this prejudice, the Court will extend BD/Nova the option to take three depositions and to propound requests for documents, either from Abbott or from third parties, all to be completed by July 31, 2008. Since plaintiffs are responsible for this eleventh-hour snafu, plaintiffs shall not be allowed

to take discovery (other than normal cross-examination of deponents after BD/Nova counsel's examination). If BD/Nova decides to take advantage of this opportunity, it must file an unqualified acceptance, by **MAY 27 AT NOON**, in which case the trial of the '890 issues will be postponed. If it does so, however, the late-produced agreement will *not* be excluded, as the discovery will cure the problem.

IT IS SO ORDERED.

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