UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,

Plaintiff

vs. CASE NUMBER: C-05-04158 MHP

ROCHE MOLECULAR SYSTEMS, INC.,
ROCHE DIAGNOSTICS CORPORATION;
ROCHE DIAGNOSTICS OPERATIONS, INC.

Defendants

ROCHE MOLECULAR SYSTEMS, INC.
ROCHE DIAGNOSTICS CORPORATION;
ROCHE DIAGNOSTICS OPERATIONS, INC.,

Counter-Claimants

vs.

THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY; AND THOMAS MERIGAN.

Counter-claim Defendants

CONFIDENTIAL - ATTORNEYS'EYES ONLY

The video deposition of DAVID H. SCHWARTZ, M.D. was held on Monday, October 16th, 2006, commencing at 9:15 a.m. at the Law Offices of Bowie & Jensen, LLC, 29 West Susquehanna Avenue, Suite 600, Towson, Maryland, 21204, Baltimore, Maryland, before R. Dwayne Harrison, Notary Public.
JOB NO. 54638

APPEARANCES:

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On behalf of Board of Trustees of the Leland Stanford Junior University; and Thomas Merigan

ALSO PRESENT:
SUJATHA IYENGAR, Ph.D.
JANET THOMAS, VIDEOGRAPHER

STIPULATION

It is stipulated and agreed by and between counsel for the respective parties that the filing of this deposition with the Clerk of Court be and the same are hereby waived.

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follows:

VIDEOGRAPHER: Here begins media number one of the deposition of Dr. David Schwartz in the matter of the Board of Trustees of Leland Stanford Junior University vs. Roche Molecular Systems, et al. and Roche Molecular Systems, et al. vs. the Board of Trustees of Leland Stanford Junior University. This case is in the court of the United States District Court Northern District of California and the case number is C-05-04158 MHP. Today's date is October 16th, 2006 and the time is 9:18. The deposition is taking place at 29 West Susquehanna Avenue, Suite 600, Towson, Maryland 21204 and it's being taken on behalf of the -- is it the Plaintiffs?

MR. BOOZELL: Both.

VIDEOGRAPHER: Plaintiffs and defendants. The videographer is Janet Thomas appearing on behalf of Sarnoff Court Reporters & Legal Technologies located in Irvine, Los Angeles, San Francisco, California.

Would counsel please identify yourselves and state who you represent?

MR. BOOZELL: Jeff Boozell from Quinn, Emanuel, Urquhart, Oliver & Hedges representing the Roche defendants.

MS. RHYU: Michelle Rhyu from Cooley, Godward, Kronish representing Stanford University and the counter-defendants.

MR. GLIKIN: Joshua Glikin from Bowie & Jensen in Towson, Maryland representing Dr. Schwartz.

Whereupon,

DAVID H. SCHWARTZ, M.D.,

called as a witness, having been first duly sworn to tell the truth, the whole truth, and nothing but the truth, was examined and testified as follows:

EXAMINATION BY MR. BOOZELL:

Q Good morning, Dr. Schwartz. Thank you for being here. As we said, I am Jeff Boozell. I represent Roche in this patent litigation where Stanford has sued Roche. We appreciate you taking time out of your busy schedule. I know that time is short and we will get right into it.

Can you please state your name for the record?

Q Is there anything in this letter of November 7th, 1988 that suggests that you were collaborating to develop a quantitative assay at all?
MR. BOOZELL: Misleading, vague and ambiguous, leading.
A If I understand your question correctly, you are asking me is there anything in this letter that refers to quantitation of HIV DNA.
Q I'm asking you, based on this November 7th, 1988 letter, you are simply requesting a copy of the protocol that Cetus is using, correct?
MR. BOOZELL: Vague and ambiguous, misstates the document, it's misleading, it's leading.
A That's what it appears to say, yes.
Q So at least in this letter of November 1988, you are not working together to come up with new methods of quantifying DNA?
MR. BOOZELL: It's vague and ambiguous, misstates the document, it's misleading, misstates his prior testimony, it's leading.
A This letter refers to existing methods and then it just says that we're going to look at individuals longitudinally.
Q It was your understanding that the existing methods were being used on samples from a clinical

trial of HIV patients who were being given AZT and IL-2, correct?
MR. BOOZELL: Vague and ambiguous, misstates his testimony. It's misleading and it's leading.
A Yes, that's my understanding.
Q And what did you know about the Cetus protocol that was being used on those samples?
MR. BOOZELL: Vague and ambiguous.
A Can you clarify or elaborate?
Q Did you know anything about the details of the protocol that was being used by Cetus on the samples that you were sending to Cetus?
MR. BOOZELL: Vague and ambiguous.
A I knew that they were using polymerase chain reaction to amplify certain regions and I believe at that time I knew that they were developing it with radioactive probes.
Q And this was an assay that quantified HIV DNA, correct?
MR. BOOZELL: Vague and ambiguous, leading.
A My feeling at that time was that it probably wasn't quantifying the DNA very well but that that was the goal.
Q You are saying that the Cetus protocol that

was being used at the time on the samples that you were sending to Cetus was not quantifying DNA very well. Is that what you just said?
MR. BOOZELL: Vague and ambiguous, misstates his testimony.
A I'm saying from my understanding of the state of the science at that time, I had difficulty seeing how the assay was going to be sufficiently quantitative and it was necessary to look at what was being done and improve it in order to have sufficient quantitative resolution to be useful.
Q But by this time, November 7th, 1988, you hadn't yet looked at the assay, the protocol that was being used by Cetus?
MR. BOOZELL: Vague and ambiguous, misstates his testimony, it's leading.
A It would appear that I hadn't obtained a hard copy of it. I don't recall whether I ever looked at it in full detail. I would have been aware of the general principles of it.
Q So let's turn to the next page that shows the PCR results, still on Exhibit 28. What does probe number one indicate, the column under probe number one?
MR. BOOZELL: Vague and ambiguous.
A That would have been one of the probes they

used to hibernize with the amplified compound.
Q Do you know what probe they were using?
A I wouldn't know which one was probe number one.
Q Do you how probe number one was distinct from probe number two?
MR. BOOZELL: Vague and ambiguous.
A My understanding at the time was that it saw a somewhat different nucleotide sequence.
Q Did you know at that time what the two probes were?
A I may have known at that time. I don't recall now.
Q And can you explain what the columns, the first three columns indicate?
MR. BOOZELL: It's vague and ambiguous. It's compound.
A The first column didn't -- well, I can see it's weak. So these -- the first come column is weeks of trial. The second column gives the patient's name and I believe the start -- I believe the start and stop dates of when IL-2 would have been administered, although I'm not sure if that's the case. And I actually don't know what this third column refers to.
Q Do you know what the numbers under the

columns for probe number one and probe number two indicate?
A I believe looking at these, to the best of my recollection, these are relative intensity scores of the hybridization after being developed radiographically. So a quantitation of the band intensity, I believe, of each probe with the amplified template.
Q And are these the results that you alluded to earlier which were inadequate quantitations?
MR. BOOZELL: Vague and ambiguous. Misstates his testimony. Misleading.
A These results would be among those that I would have found inadequate for quantitation in this trial.
Q Upon reviewing these results, did you do anything to improve the quantitative method?
MR. BOOZELL: Vague and ambiguous.
A One thing I discussed with Dr. Merigan at one point, I believe with one of the Cetus scientists, would have been that using a radioactive probe was fraught with problems.
Q So these were results from using a radioactive probe?
MR. BOOZELL: Vague and ambiguous. Calls

for speculation. Let him finish his answer.
A I cannot be absolutely sure. I know at one time early on that's what was being used. These kinds of scores would be consistent with that but I can't be absolutely sure that that's what was used here. Other things I would have discussed is that this kind of a scoring system of basically one to four as well as the obvious inconsistencies between the two probes would have made it extremely difficult to quantitate drug effects that were less than a log.
Q And you appreciated that in November of 1988?
MR. BOOZELL: Vague and ambiguous and leading.
A That was my impression at that time.
Q Was Cetus conducting blind tests meaning that they didn't know what the samples were that they were testing?
MR. BOOZELL: Asked and answered.
A My recollection is that they did not have the codes indicating what the therapy was that each of these individual was on or not on. That's my recollection and obviously that would have been the correct design for the study.
Q Do you know if anyone from Cetus designed

the study or assisted in designing the study?
MR. BOOZELL: Calls for speculation, lacks foundation, leading.
A My recollection is that we discussed with John Sninsky and his staff when they were going to receive these, what they would receive and how they would send them back to us.
Q Were there any statistical analyses done to evaluate whether one could monitor the efficacy of the treatment using -- by following the levels of DNA obtained in these assays?
MR. BOOZELL: Vague and ambiguous and leading.
A These data don't really warrant statistical analysis. Any experienced scientist can look at these and say this is not going to give statistically significant data and certainly that there's no statistically significant effect indicated by these data. These kinds of considerations were taken by me to a very senior biostatistician, Lincoln Moses, at some point in the development, with the idea that -- of getting an idea how many repetitions would be needed or how many parallel amplifications would have to be done to get statistically meaningful data if the interassay variability was what we had been seeing which was

roughly four-fold between samples, as I recall. And he did some calculations and told us that it would be more than 20 replications that would be required to get data that would detect half log variations.
So in answer to your question, what was done to analyze this, these data were not -- did not require analysis but I asked a very sophisticated senior statistician to project what would be needed if you had lots of data of this type in order to get an idea of how many replications would have to be performed and it was a high number.
Q Do you mean to suggest that obtaining high quantities of data like the data reflected in Exhibit 28 would ultimately have proven that this assay works for monitoring efficacy of treatment?
MR. BOOZELL: Vague and ambiguous, calls for speculation, misstates his testimony, leading.
A From these data, I cannot say nor do I believe anyone can say anything about the quantitative nature of this assay. What I'm saying is that if you were to posit or assume that you had an assay that was variable such that repeat samples varied by four-fold most of the time so they had a certain coefficient of variation, certain standard deviation, if you can do them enough times, there is some number of times at

which you would be able to detect true changes of a certain magnitude.

At the time this work was being done, the magnitude of changes induced by AZT or AZT and IL-2 was generally less than a log. So that is a very tight window to try to hit with an assay. And my understanding, after consulting with Lincoln Moses and looking at things myself, was that it would require many, many, many runs of this particular technology to be able to pick up a four to ten-fold difference. So, I presented that to Merigan and Dr. Holodniy, who was actually with me in these things, as a problem with that particular line of pursuit.

Q So you recognized that a different type of assay was necessary in this November 1988 time frame?

MR. BOOZELL: Vague and ambiguous and leading.

A We recognized one of two things or both was necessary. One, either looking for more dramatic viral changes, so drugs -- either drugs would have to have a bigger impact than a one-log reduction in load or you would have to have another strategy.

Q IL-2 was never shown to have an effective treatment for HIV, correct?

MR. BOOZELL: Leading, vague and ambiguous,

calls for speculation, lacks foundation.

A In my opinion, the field would consider the jury to be out on that bearing in mind that there are two aspects, essentially, of treatment. One is improvement of the immune response, the other being reduction in viral load. So, to the best of my knowledge, IL-2 has never been shown to be helpful in reducing viral load. But there are -- there's a large body of work on both sides of whether or not IL-2 is helpful for immune system.

Q So the jury is still out on that question?

MR. BOOZELL: Vague and ambiguous, misstates his testimony, leading.

A The last time I checked with people conducting a trial, the jury was still out on the long-term benefit of IL-2 therapy in HIV.

Q I want to go back to Exhibit 29 and ask you, do you recall ever specifically receiving materials or information that were identified to be exchanged pursuant to this agreement?

MR. BOOZELL: Vague and ambiguous, calls for speculation, lacks foundation, calls for a legal conclusion, misleading.

A To the best of my knowledge, such materials did end up in our lab. I personally cannot recall

opening the package that contained them or being handed the package.

Q You don't recall any reference to this material transfer agreement?

MR. BOOZELL: Same objections.

A Can you clarify the question?

Q Do you recall whether any materials that appeared in the Stanford laboratory had any notation that they were received pursuant to Exhibit 29, the material transfer?

A I don't recall.

MR. BOOZELL: Same objections.

Q Do you see the asterisk? There's an asterisk in the middle of paragraph three of following the sentence: "As used in this agreement, confidential information shall mean all data, protocols, technical and economic information, commercialization, clinical and research strategies, trade secrets and know-how disclosed or provided by Cetus to scientists." And then there's an asterisk. At the bottom of the page it says, "and designated in writing as confidential at the time of disclosure."

Do you see that?

A Yes.

Q Do you recall ever being given any

information that was designated in writing as confidential at the time that it was transferred from Cetus?

MR. BOOZELL: Vague and ambiguous, calls for speculation, lacks foundation, it's leading.

A The only other confidentiality or materials transfer type of agreement I can recall, I believe related to interleukin-2 standards and perhaps some information on interleukin-2 assay. I cannot recall any other specific material transfer agreements other than this visitor's consent relating to PCR.

MR. BOOZELL: Let me just add an objection. Calls for a legal conclusion.

Q If you'd focus your attention to paragraph three, the first sentence: "The material shall be used in research studies on the detection of human HIV in samples accumulated by ATCG. Do you know what ATCG is referring to there?

A Well, let's define elsewhere as the AIDS therapy cooperative group.

Q Do you mean the AIDS treatment cooperative group's --

A Treatment cooperative group. I have to be honest with you, that in recent usage I've remembered it as being ACTG standing for aids clinical trials

you mean by proprietary technology? What is the proprietary technology?

MR. BOOZELL: Vague and ambiguous, calls for speculation, lacks foundation and it is a legal question.

A My assumption was that this exciting PCR technology that had been so much in the news and was so promising, that was the technology I was thinking about. I believed or I was under the impression that the company owned that technology and, again, perhaps naively, I don't know, but that things accomplished with that technology in our lab would be part of that.

Q So you're referring to the CPR technology invented by Kary Mullis?

A Yes.

Q Do you have any opinion of Dr. Mark Holodniy?

MR. BOOZELL: Vague, ambiguous, calls for speculation.

A In what respect?

Q You interacted with him regularly?

A Yes, I liked him. I liked him very much.

Q Was he a competent scientist?

MR. BOOZELL: Vague, ambiguous.

A I thought he was a very competent

scientist. I have the highest regard for Dr. Holodniy, his competence and professionalism. I thought he was excellent.

Q Is it fair to say that he took the lead in the project relating to developing an assay for quantitating HIV RNA using PCR?

MR. BOOZELL: It's vague, ambiguous and calls for speculation.

A It's fair to say he took the lead from me in the development of the quantitative assay. I have no knowledge, for example, on whether David Katzenstein was more influential in pushing the switch over to RNA, nor do I have any knowledge about the specific role or the magnitude of the role played by Cetus employees. But certainly I passed the baton to Dr. Holodniy at the stage when we were still looking at DNA.

MS. RHYU: I have no further questions.

MR. BOOZELL: And it's 3:00. So given the testimony that we've elicited and the documents reviewed, I'd like to designate the transcript as confidential "attorneys eyes only."

VIDEOGRAPHER: This concludes the third media used. We are off the record at 3:01.

(Deposition was concluded at 3:01 p.m.)

I, DAVID H. SCHWARTZ, M.D., do hereby declare under penalty of perjury that I have read the foregoing transcript; that I have made any corrections as appear noted, in ink, initialed by me, or attached hereto; that my testimony as contained herein, as corrected, is true and correct.

EXECUTED this _____ day of _____, 20_____, at _____, _____.
(City) (State)

_____
DAVID H. SCHWARTZ, M.D.

State of Maryland
County of Baltimore, to wit:

I, R. DWAYNE HARRISON, a Notary Public of the State of Maryland, City of Baltimore, do hereby certify that the within-named witness personally appeared before me at the time and place herein set out, and after having been duly sworn by me, according to law, was examined by counsel.

I further certify that the examination was recorded stenographically by me and this transcript is a true record of the proceedings.

I further certify that I am not of counsel to any of the parties, nor in any way interested in the outcome of this action.

As witness my hand and notarial seal this 19th day of October 2006.

_____
R. DWAYNE HARRISON
Notary Public

My Commission Expires:
September 15th, 2009