

EXHIBIT 10

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

THE BOARD OF THE TRUSTEES OF
THE HELAND STANFORD JUNIOR
UNIVERSITY

Plaintiff

vs.

No. C-05-04158 MHP

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

Defendant

CERTIFIED
COPY

AND RELATED COUNTERCLAIM

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VIDEOTAPED DEPOSITION OF DAVID A. KATZENSTEIN M.D.

Palo Alto, California

Monday, August 28, 2006

Reported by
SUZANNE E. BOSCHETTI
CSR No. 5114
Job No. 3-52323

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
THE BOARD OF THE TRUSTEES OF
THE LELAND STANFORD JUNIOR
UNIVERSITY,
Plaintiff,
vs. No. C-05-04158 MHP
ROCHE MOLECULAR SYSTEMS, INC.;
ROCHE DIAGNOSTICS CORPORATION;
ROCHE DIAGNOSTICS OPERATIONS,
INC.; ROCHE DIAGNOSTIC SYSTEMS,
INC.,
Defendant.

AND RELATED COUNTERCLAIM.

Confidential videotaped deposition of DAVID
A. KATZENSTEIN, M.D., taken on behalf of Defendants
and Counterclaimants Roche Molecular Systems, Inc., et
al., at 5 Palo Alto Square, Palo Alto, California,
beginning at 9:05 a.m. and ending at 2:30 p.m. on
Monday, August 28, 2006, before SUZANNE F. BOSCHETTI,
Certified Shorthand Reporter No. 5111.

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1 **APPEARANCES:**

2
3 For Plaintiff and Counterclaim Defendants The Board of
4 the Trustees of the Leland Stanford Junior University,
et al.:

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15 **RAY TYLER**
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Q. Getting back to the idea and the discussion -- I'll call it a discussion or meeting that you had with Dr. Merigan and Dr. Holodniy. At that initial meeting where you -- you discussed the idea, did -- did you discuss or did you propose using this quantification technique to monitor the effectiveness of therapy?

A. Yes.

Q. And was it your idea at that time in mid-1989 to quantify viral RNA?

A. Yes.

Q. And that's from serum and plasma?

A. Well, whether it was going to be serum or plasma or a particular kind of plasma were the experiments that we needed to carry out, but the idea that you had an analyte that could be measured over time on a regular repeatable basis. The problem with cellular assays, as I saw it, was that a fluctuation in the number of infected cells could easily occur because of inter-occurring infection, progression of disease, you had loss of CD4 cells. What cells harbored cDNA -- HIV cDNA and provirus was at the time hotly debated, so it would not necessarily provide a very constant indication or -- of virus replication or production, but rather integration, and, in fact,

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proviral infection.

So the concept that we discussed, which we, I believe, subsequently tried to realize, was could you get a reproducible measure of -- of virus in the plasma or blood that was independent of the cellular infection.

Q. And in your answer previously you used a term analyte. And when you use the term analyte in this context, you're referring to the viral -- the virus, right?

A. No.

Q. What are you referring to?

A. The substance that you take out of people, which you then subsequently perform a test on is known as the analyte. So if you're doing stool cultures, the analyte becomes the stool. If you're doing blood cultures, the analyte becomes blood. And the specific properties of those for different tests subsequently became something that we did some research on.

Q. And then there were a subsequent series of experiments done, and I think you used the term realize, to realize this idea. And did the experiments that were done verify the idea that you had back in 1989?

MR. RODRIGUEZ: Objection. Vague.

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10:29:13 1

THE WITNESS: I think so.

10:29:13 2

BY MR. CANNON:

10:29:15 3

Q. They were successful, right?

10:29:16 4

A. They were.

10:29:16 5

Q. And you published --

10:29:18 6

MR. RODRIGUEZ: Objection. Vague.

10:29:19 7

BY MR. CANNON:

10:29:19 8

Q. And you published the results of those

10:29:21 9

experiments, right?

10:29:23 10

MR. RODRIGUEZ: The same objection.

10:29:24 11

THE WITNESS: That's -- well, the -- I

10:29:27 12

believe the JID article is the fulfillment of that

10:29:32 13

idea through a whole series of technical assay

10:29:36 14

development issues that went on over perhaps two

10:29:42 15

years.

10:29:42 16

BY MR. CANNON:

10:29:42 17

Q. Let's jump to that.

10:30:05 18

Previously marked Exhibit 72.

10:30:05 19

(Previously marked Exhibit 72 was

10:30:14 20

presented to the witness.)

10:30:14 21

BY MR. CANNON:

10:30:14 22

Q. If you could look at that for a moment,

10:30:16 23

please, Dr. Katzenstein, and confirm for me that

10:30:20 24

this is the JID article you just referred to.

10:30:33 25

A. Yes, it is.

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02:06:15 1 MR. RODRIGUEZ: Objection. Calls for a legal
02:06:17 2 conclusion.

02:06:21 3 THE WITNESS: I think again, the safest thing
02:06:22 4 to say and the closest to the truth is I don't know.
02:06:27 5 I will offer that in the times between the patent
02:06:33 6 being -- some patent being filed, communications going
02:06:36 7 on, which are well-established, I guess --

02:06:39 8 MR. RODRIGUEZ: Let me just caution you not
02:06:40 9 to reveal any attorney-client communications in what
02:06:43 10 you're about to say.

02:06:45 11 THE WITNESS: Oh, okay. No, this is simply
02:06:46 12 in my communications with Dr. Merigan, he explained
02:06:49 13 that these patents, should they go forward, would
02:06:53 14 belong primarily to Stanford University because our
02:06:56 15 work was done at Stanford, and that I -- neither I
02:06:59 16 nor -- I think that these were conversations that
02:07:01 17 involved Mark Holodniy as well -- should expect to use
02:07:05 18 the lay term we would get very much out of it
02:07:07 19 personally, that this was -- this was primarily a
02:07:11 20 Stanford effort.

02:07:12 21 BY MR. CANNON:

02:07:12 22 Q. Did you get paid anything for assigning
02:07:16 23 your rights to the patent to Stanford?

02:07:20 24 MR. RODRIGUEZ: Objection. Calls for a legal
02:07:22 25 conclusion.

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02:07:24 1 THE WITNESS: No, but I know I haven't been
02:07:26 2 paid anything around the assignment of patent rights
02:07:29 3 that I know of.

02:07:30 4 BY MR. CANNON:

02:07:30 5 Q. I'm not trying to trick you here, but
02:07:32 6 there is a line in this assignment that says on the
02:07:34 7 very first page that says:

02:07:36 8 "Now, therefore, in consideration of the
02:07:38 9 sum of One Dollar (\$1.00) to us in hand paid,
02:07:41 10 and other good and valuable consideration..."

02:07:44 11 And then it goes on. Do you see that
02:07:46 12 section?

02:07:46 13 A. On the first page.

02:07:47 14 Q. The first page of the assignment, so it's
02:07:49 15 the second to last page of the -- of the document.
02:07:58 16 Do you see that?

02:08:00 17 A. Mm-hmm.

02:08:02 18 Q. Were you in fact paid anything, \$1 or
02:08:06 19 anything in consideration for signing this?

02:08:08 20 A. I do not recall being paid anything for --
02:08:15 21 and this would have been about 20 cents apiece.

02:08:34 22 MR. CANNON: Let's mark the next.

02:08:34 23 (Deposition Exhibit 211 marked by the
02:09:01 24 court reporter.)

02:09:01 25 BY MR. CANNON:

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conclusion.

THE WITNESS: I haven't thought about it one way or the other.

MR. CANNON: Let's mark the next exhibit.

(Deposition Exhibit 212 marked by the court reporter.)

BY MR. CANNON:

Q. If you could look at Exhibit 212, please. It's a two-page document marked STAN 003837 to 003838. Appears to be a letter dated August the 6th, 2003, to Mark Holodniy, David Katzenstein and Thomas Merigan.

Do you recall receiving this letter?

A. I actually don't.

Q. You don't recognize the document?

A. No.

Q. Okay. Dr. Katzenstein, you understand that Cetus doesn't exist anymore, right?

A. I do.

Q. That some of its assets were sold to Roche and some of its assets were sold to Chiron, right?

A. Right.

Q. Do you remember Shirley Kwok?

A. Yes, very well.

Q. And she -- she was at Cetus back in the

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02:15:24 1 '89-'90 time frame, right?

02:15:26 2 A. Yes.

02:15:26 3 MR. RODRIGUEZ: Objection. Calls for
02:15:27 4 speculation.

02:15:28 5 BY MR. CANNON:

02:15:29 6 Q. And then she went to Roche, right?

02:15:31 7 MR. RODRIGUEZ: Objection. Calls for
02:15:32 8 speculation. Lacks foundation.

02:15:34 9 THE WITNESS: I recall that she went to Roche
02:15:37 10 and she was in the Alameda research office up there
02:15:41 11 and --

02:15:41 12 BY MR. CANNON:

02:15:41 13 Q. Did you have interactions with Shirley
02:15:45 14 Kwok after she went to Roche?

02:15:46 15 A. Well, I do have -- I do recall one visit that
02:15:48 16 I made to the Alameda facility where I remember both
02:15:52 17 Shirley and John Sninsky being welcoming, and we had a
02:15:55 18 number of discussions.

02:15:56 19 Q. What did -- when did this meeting take
02:15:59 20 place?

02:15:59 21 A. I can't recall.

02:16:00 22 Q. Was it in the mid-'90s?

02:16:03 23 A. Probably.

02:16:04 24 Q. Was it in connection with clinical trials
02:16:07 25 relating to Roche's Amplikor product?

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02:16:13 1

A. Yes.

02:16:13 2

02:16:15 3

02:16:18 4

Q. What was the nature of the discussions you had with Shirley Kwok and John Sninsky at that time?

02:16:18 5

A. I can't remember really.

02:16:19 6

02:16:21 7

Q. Why would you have visited them at the Roche facility in Alameda at that time?

02:16:24 8

02:16:25 9

MR. RODRIGUEZ: Objection. Calls for speculation.

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THE WITNESS: I don't know. I mean, I interacted with both of them professionally at both meetings, over the telephone, we exchanged some reagents, I supplied a number of plasma and virus isolates to Shirley. I was concerned about Africa, and she was interested in working on samples from some type C patients, and we had those.

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02:17:10 21

And I used to meet John Sninsky at a number of scientific meetings, and he was a good friend of a number of people at Stanford. Used to come down there. So we had normal social and scientific exchanges.

02:17:14 22

BY MR. CANNON:

02:17:14 23

02:17:17 24

02:17:21 25

Q. Did you ever coordinate a clinical trial that involved Roche's Amplicor HIV product?

MR. RODRIGUEZ: Objection. Vague.

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THE WITNESS: Yeah, the "involved" is a little hard to answer. I can give you the history of what I recall of the involvement of Roche with ACTG 175.

BY MR. CANNON:

Q. That's the protocol I had in mind.

A. I could perhaps give you that as a narrative as I remember it, and we can discuss it if that's easier rather than the one question at a time thing.

Q. Ah, right. Let me put a document in front of you and that might frame -- might frame some of the discussions.

Could we mark the next exhibit, please?

(Deposition Exhibit 213 marked by the court reporter.)

BY MR. CANNON:

Q. Marked as Exhibit 213, a document appears to be a letter or a draft letter from you to Shirley Kwok, and it has production labels STAN 9462 through 9463.

A. Okay.

Q. What was your involvement with ACTG 175 protocol?

A. Okay. Well, it was a -- a clinical protocol developed by initially Tom Merigan and Marty Hirsch,

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02:19:21 1 who were at the time the leadership of the what was
02:19:24 2 called the primary infection committee of the ACTG.
02:19:28 3 And with a number of other leaders of that at various
02:19:32 4 academic medical institutions, the question was what
02:19:35 5 was the next large clinical trial and what were the
02:19:37 6 principles to be evolved.

02:19:40 7 They essentially arranged for Scott Hammer
02:19:42 8 and I to be the co-chairs of that protocol, and that
02:19:47 9 went -- that took about a year's worth of development
02:19:50 10 from, I would say from mid-'91 to '92 or mid-'90 to
02:19:54 11 '91. The protocol -- actually I began enrolling
02:19:58 12 people, I believe, in '92. It was a three-year
02:20:01 13 follow-up of the longest time and we finished in '95,
02:20:05 14 so --

02:20:05 15 Q. What was the -- sorry. What was the
02:20:08 16 purpose of --

02:20:08 17 A. The primary objective was to compare two
02:20:12 18 drugs to one drug. That hadn't been done before in a
02:20:14 19 large efficacy trial in which the primary end point of
02:20:18 20 the study was maintaining CD4 cells at, you know, or
02:20:26 21 preventing a fall in CD4 cells to 50 percent of
02:20:30 22 baseline. And we spent a lot of time working with
02:20:33 23 statisticians, enrolled 2,000 patients at 50 sites
02:20:37 24 across the U.S., so it was a very large investment in
02:20:41 25 public funds in what was the first large -- it's still

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02:20:45 1 the largest ever AIDS therapy trial done in the United
02:20:49 2 States.

02:20:49 3 There was a very specific subset that was
02:20:53 4 called the virology subset. I was the protocol
02:20:56 5 virologist, and I was in charge of organizing real
02:21:00 6 time virology as well as the storage and maintenance
02:21:02 7 of samples. So we did a large number of things with
02:21:09 8 those 400 patients who are part of the virology
02:21:13 9 subset. And there are like 20 journal articles that
02:21:17 10 detail each one of those.

02:21:19 11 From your point of view, probably the most
02:21:21 12 important question was the use of RNA PCR to monitor
02:21:25 13 therapy in patients on this large trial. We, in fact,
02:21:30 14 at Stanford and the ACTG planned to do that using the
02:21:33 15 Stanford assay as the protocol that was initially
02:21:37 16 conceived in -- in the early '90s. And the first
02:21:41 17 patients enrolled in fact had samples stored in
02:21:45 18 solution D. As a result of discussions with people
02:21:49 19 from Roche that occurred as the protocol was -- was
02:21:53 20 well underway, we decided that, in fact, they were
02:21:58 21 willing to provide their prototype assay.

02:22:01 22 This particular letter represents, you know,
02:22:04 23 my first discussions, I guess, with Shirley Kwok about
02:22:08 24 this, and I keep blocking out the name of the guy from
02:22:12 25 Roche Diagnostics, who, in fact, ended up joining me

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02:22:16 1 in the 175 team calls. We had a series of discussions
02:22:21 2 and decided that the three laboratories named, ours,
02:22:23 3 Scott Hammer's and Brooks Jackson's, would run all of
02:22:25 4 these prototype RNA assays. The statistical analysis
02:22:31 5 was going to be done by the AIDS clinical trials
02:22:33 6 group, ESTEC, Harvard, Michael Hughes. And in fact,
02:22:36 7 that's the data that's contained in the New England
02:22:40 8 Journal paper eventually published in '96 that
02:22:43 9 established HIV RNA quantitation as in fact a
02:22:47 10 surrogate marker for the activity of any
02:22:51 11 antiretroviral drug, which I think was important for
02:22:53 12 the patients, important for regulatory purposes, and
02:22:56 13 subsequently proved to be a part of the package insert
02:22:59 14 for the Amplicor test.

02:23:01 15 Q. Amplicor being the Roche test?

02:23:04 16 A. Right.

02:23:04 17 Q. When did Roche propose to use their
02:23:08 18 prototype assay as part of this trial?

02:23:13 19 A. I think sometime in late '94 or '95.

02:23:16 20 Q. You mentioned something called the
02:23:17 21 Stanford assay.

02:23:18 22 A. Yes.

02:23:18 23 Q. What's that?

02:23:19 24 A. That's the one that's described in the JID
02:23:24 25 article essentially.

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02:24:53 1 Q. So you had a series of conversations with
02:24:55 2 Roche. They said they had the prototype assay and
02:24:58 3 then there was an agreement that the Roche assay
02:25:01 4 would be used as part of this trial?

02:25:03 5 A. Well, yes. But the trial had already
02:25:07 6 started, so there was an agreement that they would
02:25:10 7 provide the assay kits and training for the three
02:25:14 8 laboratories that were running. We, in turn, would
02:25:17 9 provide to them data which I believe would be useful
02:25:21 10 to them for the purpose of licensing their assay. In
02:25:28 11 other words, by -- by being a participant in the 175
02:25:33 12 virology study in which -- because we also had an
02:25:36 13 analysis using culture, using P24, using many real
02:25:42 14 time things that one has to do. And much of the
02:25:45 15 validation of the Roche assay was the correlation of,
02:25:49 16 in fact, the stored plasma with, in fact, the results
02:25:52 17 of P24 assays, virus culture assays, SI assays, a
02:25:57 18 number of other assays that could have only been
02:26:00 19 produced in real time at these 11 laboratories.

02:26:03 20 Q. So Roche got access to that data?

02:26:06 21 A. Roche was able to access the clinical data,
02:26:10 22 which is what they were primarily interested in in
02:26:13 23 terms of the analysis produced in the New England
02:26:16 24 Journal paper. And you will find the 175 trial
02:26:20 25 results in the package insert for Roche AmpliCor to

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this very day.

MR. CANNON: Let's take a short break.

THE WITNESS: Okay.

VIDEO OPERATOR: The time is 2:26. We are going off the record.

(Recess.)

VIDEO OPERATOR: The time is 2:29. We are back on the record.

MR. CANNON: I have no further questions at this time. Thanks very much for your cooperation.

MR. RODRIGUEZ: The witness would like the opportunity to review and correct the transcript.

I have no questions. Sure, we'll mark it attorneys' eyes only.

MR. CANNON: Thank you.

VIDEO OPERATOR: This concludes today's deposition of Dr. David Katzenstein. The number of media used was three. We're off the record at 2:30 p.m.

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