

Exhibit 28

JEFFREY DAVID LIFSON, M.D.

September 5, 2007

Page 1

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

THE BOARD OF TRUSTEES OF THE :

LELAND STANFORD JUNIOR :

UNIVERSITY :

Plaintiff :

v. : Case No.

ROCHE MOLECULAR SYSTEMS, et al: C 05 04158 MHP

Defendants :

* * * * *

ROCHE MOLECULAR SYSTEMS, et al:

Counterclaimants :

v. :

THE BOARD OF TRUSTEES OF THE :

LELAND STANFORD JUNIOR :

UNIVERSITY; THOMAS MERIGAN; :

AND MARK HOLODNIY :

Counterclaim Defendants :

Deposition of JEFFREY DAVID LIFSON, M.D.

Baltimore, Maryland

Wednesday, September 5, 2007

9:05 a.m.

Job No.: 399424

Pages: 1 - 102

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JEFFREY DAVID LIFSON, M.D.

September 5, 2007

Page 38

1 A Yes.

2 Q Does the article show correlations between
3 quantitative HIV RNA measurements and therapeutic
4 efficacy?

5 A No.

6 MR. CANNON: Object to the form of the
7 question.

8 Q I'm sorry, could you repeat your answer?

9 A No.

10 Q Are you aware of any article in the PCR
11 Protocols book that does show any correlations between
12 quantitative HIV RNA copy numbers and therapeutic
13 efficacy?

14 MR. CANNON: Object to the form of the
15 question. Lacks foundation.

16 A Again, without having a clear understanding
17 of what's intended by the term therapeutic efficacy
18 it's hard to answer the question, but I don't believe
19 there's anything in there that even approaches the
20 question.

21 Q Are you aware of any articles prior to May
22 of 1992 that correlated quantitative HIV RNA copy
23 number analysis with therapeutic effectiveness?

24 MR. CANNON: Object to the form of the
25 question. Lacks foundation.

Page 39

1 A Can you repeat the question again? I just
2 want to make sure I understand exactly what you're
3 asking.

4 Q Sure, sure.

5 Are you aware of any articles prior to May
6 of 1992 that correlated quantitative HIV RNA copy
7 number analysis with therapeutic effectiveness?

8 MR. CANNON: Same objections.

9 A So the same point about the term therapeutic
10 effectiveness not really being defined is problematic
11 here as well, so from that perspective I'm not aware
12 of any article that, that did define that in that
13 time. In that time frame there were a number of
14 antecedent articles using a variety of other virologic
15 techniques suggesting that treatment might result in a
16 measurable decrease in a measurable parameter of the
17 amount of virus in blood samples.

18 Q Are you done?

19 A Yes.

20 Q Were you aware of the publications that were
21 being issued at that time?

22 MR. CANNON: Object to the form of the
23 question.

24 MR. DAMSTEDT: Let me strike that.

25 Q In this article -- there were a number of

Page 40

1 publications being published about quantitative PCR
2 analyses, correct?

3 A I'm sorry, say that again.

4 Q Yeah, let me strike that one, too.

5 At that time you kept up-to-date on the
6 publications that were being published about PCR,
7 correct?

8 A I certainly made a well-intentioned effort
9 to do so, yes.

10 Q And you did in fact do so, correct?

11 A To the best of my ability, yes.

12 Q What's the ordinary meaning of the word
13 measuring to a person of ordinary skill in May of
14 1992?

15 A In the specific context of quantitative PCR,
16 is that the person of ordinary skill we're referring
17 to?

18 Q Sure, we'll try that one.

19 Let me rephrase the question. We'll do that
20 one later.

21 What's the ordinary meaning of the word
22 measuring to a person of ordinary skill in May of
23 1992?

24 MR. CANNON: Object to the form of the
25 question. Same objections as before.

Page 41

1 A As applied to quantitative PCR?

2 Q In the field that was identified by you for
3 persons of ordinary skill in the art.

4 A I would say to perform a PCR manipulation
5 and then to perform an intervention to get some sort
6 of a quantitative parameter derived from the
7 manipulation.

8 Q Has the ordinary meaning of that term, the
9 word measure, to a person of ordinary skill in the art
10 changed since May of 1992?

11 A I think that the underlying concept of
12 performing a manipulation in order to derive a
13 measurement has not changed. What has changed
14 dramatically is the nature of the manipulations that
15 would be performed today to obtain that measurement.

16 Q Okay. So your testimony is that the
17 techniques that may be used to measure have changed,
18 but that the meaning of the word measuring itself has
19 not changed; is that correct?

20 MR. CANNON: Object to the form of the
21 question.

22 A I don't want to belabor a semantic point,
23 but I think the nature of the techniques used has
24 changed in a sufficiently dramatic way that the nature
25 of the measurements, to me as someone who works in

11 (Pages 38 to 41)

JEFFREY DAVID LIFSON, M.D.

September 5, 2007

Page 42

1 this field, is different. The basic idea of trying to
2 measure something is the same, but how we go about it
3 these days is very, very different.

4 Q And to, I guess push a semantic point just a
5 bit, the word measuring is used in applications today
6 just as it was used in applications in May of 1992;
7 correct?

8 MR. CANNON: Object to the form of the
9 question.

10 A Actually wherever possible I sort of prefer,
11 rather than use a vague term like measuring, to talk
12 about, you know, quantifying some specific thing
13 that's being analyzed and defining it operationally in
14 the context of a specific assay or measurement
15 technique.

16 Q You call the term measuring vague. Isn't it
17 true that it's in fact a broad term?

18 A If by that you mean that it can have many
19 meanings, yes.

20 Q And the term measuring can include a wide
21 range of different types of measurements, correct?

22 MR. CANNON: Object to the form of the
23 question. Are you saying as the term is used in the
24 patent claims or just independent of the patent
25 claims?

Page 43

1 A Could you clarify that point?

2 Q Let's talk first about the ordinary meaning
3 of that term to a person of ordinary skill in the art.
4 That can be used in a wide range of different types of
5 measurements, correct?

6 A I suppose so. I'm not sure I quite
7 understand your question.

8 Q Measuring is a broad term that encompasses a
9 wide variety of different types of measurements --

10 MR. CANNON: Object to the form of the
11 question.

12 Q -- isn't that correct?

13 MR. CANNON: Object to the form of the
14 question. I don't know if you're asking him about the
15 patent -- term used in the patent, or the term
16 separate from the patent.

17 MR. DAMSTEDT: Those are speaking
18 objections, Brian. I'll have to ask you to cut down
19 just a little bit.

20 Q Anyway, you can answer.

21 A I'm sorry, could you -- could you repeat the
22 question?

23 Q So measuring is a broad term that
24 encompasses a wide variety of different types of
25 measurements; isn't that correct?

Page 44

1 A As a general term used in common language,
2 measuring, you know, could apply to various different
3 measurements, I suppose.

4 Q And as applied in the field of art to a
5 person of ordinary skill that's also true; isn't that
6 correct?

7 MR. MARTER: Object to the form of the
8 question.

9 A So again, in the context that we've gone now
10 from general language to the context of in terms of
11 the patent and one of skill in the art measuring now,
12 I think for one of skill in the art, part of that art
13 is, you know, understanding, you know, what is the
14 particular approach to measurement that's under
15 consideration.

16 Q But there --

17 A Otherwise the term is sufficiently vague to
18 not be operationally useful.

19 Q In your view, did the patents and
20 prosecution history use the term measuring in a broad
21 sense to encompass a variety of different types of
22 measurements?

23 MR. CANNON: Object to the form of the
24 question.

25 A Based on my review of the patents and

Page 45

1 portions of the prosecution history, everything seems
2 to be referenced back to a particular measurement
3 technique that is spelled out in the specification of
4 the patents and in some of the published papers from
5 the group, which is basically an endpoint PCR with a
6 non-isotopic detection step and external standard for
7 the quantification step.

8 Q In your Declaration did you identify any
9 portion of the patent or any portion of the
10 prosecution history where the patentee redefined the
11 term measuring to mean only the measurement techniques
12 we described in the written description?

13 MR. CANNON: Objection to the form of the
14 question. Assumes facts not in evidence.

15 A No, I -- I believe that in the Declaration I
16 point out that the only one that seems to be
17 referenced, and referenced repeatedly, is the
18 particular technique I just described.

19 Q But is there anyplace where in the patent or
20 the prosecution history the patentee says, measuring
21 is normally a broad term that can be applied to a
22 variety of different measurements, but when we use the
23 term measure, we really mean it only to mean the
24 particular assay that we've discussed?

25 MR. CANNON: Object to the form of the

12 (Pages 42 to 45)

JEFFREY DAVID LIFSON, M.D.

September 5, 2007

Page 50

1 PCR-based methods for attempting to quantify a target,
2 but they differ from each other in fundamental ways.
3 And so if that's what you mean by are there different
4 kinds of PCR, then the answer would be yes.

5 Q Okay. What other kinds of PCR are there?

6 MR. CANNON: Object.

7 Q Let me rephrase it.

8 You talked about endpoint PCR with external
9 control, endpoint PCR with internal control, and
10 realtime PCR. Are there any other general types of
11 PCR of which you're aware?

12 A Quantitative competitive PCR would be
13 another category. For quantification -- quantitative
14 applications and for nonquantitative applications,
15 there are all different kinds of -- different
16 varieties for different specific applications.

17 So PCR is a very versatile technique that's
18 been adapted to a lot of different applications.

19 Q Is endpoint PCR a term that's used by
20 persons of skill in the art today?

21 A Yeah.

22 Q Is it a term that was used by persons of
23 skill in the early 1990s?

24 A Uh-huh.

25 Q I'm sorry?

Page 51

1 A Yes. Sorry.

2 Q So that was a term that people knew of and
3 were aware of in May of 1992?

4 A It was a term that I and my colleagues would
5 use with each other to describe the type of assay
6 we've been discussing, yes.

7 Q Was it generally known?

8 A I believe so, yes.

9 Q Do you agree that endpoint PCR is within the
10 scope of the claims of the patents-in-suit?

11 MR. CANNON: Object to the form of the
12 question. Calls for a legal conclusion.

13 A Certainly the assay that's described in the
14 patents is an endpoint PCR assay.

15 Q So as used in the patents-in-suit, PCR
16 includes at least endpoint PCR; is that correct? Is
17 that your testimony?

18 A That's what's described in the patents, yes.

19 Q I'm asking a slightly different question.

20 So as used in the patents-in-suit, PCR includes at
21 least endpoint PCR; is that correct?

22 MR. CANNON: Objection. Lacks foundation.

23 A Since that's the only thing that's described
24 or referenced, it seems that that's what is intended
25 by the use of PCR in the context of the patent.

Page 52

1 Q Do you agree that realtime PCR is within the
2 scope of the claims of the patents-in-suit?

3 MR. CANNON: Object to the form of the
4 question.

5 A I consider myself qualified to assess
6 technical questions, and from that perspective,
7 realtime PCR is conceptually different from endpoint
8 PCR in a very, very fundamental way. The technical
9 execution is fundamentally different. And there's
10 nothing in the published papers or the patents that,
11 to me, either states or implies anything having to do
12 with realtime PCR, which is based on a fundamentally
13 different principle than endpoint PCR, being a kinetic
14 assay rather than an endpoint assay.

15 Q Let's go to your Declaration for a second.

16 A Uh-huh.

17 Q The basis for your opinion in your
18 Declaration that realtime PCR is not covered by the
19 claims is that realtime PCR was not yet developed in
20 May of 1992 and that all the claims refer to 30 cycles
21 of PCR or about 30 cycles of PCR; is that correct?

22 A Just turning to the relevant text.

23 Q Please.

24 A Okay, I found it. I'm sorry, could you
25 repeat the question?

Page 53

1 Q Yeah. The basis for your opinion that

2 realtime PCR is not within the scope of the claims of
3 the patents-in-suit is that realtime PCR was not yet
4 developed in May of 1992 and that all the claims refer
5 to 30 cycles of PCR or about 30 cycles of PCR; is that
6 correct?

7 A So my understanding is that the use of
8 realtime PCR for quantitative applications was neither
9 developed or known within the field in 1992. The
10 patents and the published papers, again, all reference
11 an endpoint PCR assay based on 30 or around 30 cycles
12 of amplification with an endpoint measurement as the
13 basis for quantification. And realtime PCR is based
14 on a series of ongoing measurements through the course
15 of the PCR reaction using a non-invasive
16 quantification technique, and the basic principle of
17 measurement consists not in measuring the amount of
18 PCR product that's accumulated at the end of a fixed
19 number of amplification cycles, but rather determining
20 the amplification cycle at which you first achieve an
21 above-background measurable amount of product.

22 So it's a -- for me, a fundamentally
23 different approach to, to things, and there's nothing
24 in the patent that would lead me to that.

25 Q Okay. So I want to be clear about what

14 (Pages 50 to 53)

JEFFREY DAVID LIFSON, M.D.

September 5, 2007

Page 74

1 the specification of the patents and the supporting
2 publications, yes.

3 Q I'm going to read again from a bit of your
4 Declaration. It's the end of the first sentence where
5 you say specifically the HIV standards and methods
6 then available and/or described.

7 A I'm sorry, where are you?

8 Q Oh. I am in the first sentence of Paragraph
9 46.

10 A Still on 46. Okay.

11 Q Yeah. And the end of that sentence says,
12 specifically the HIV standards and methods then
13 available and/or described for quantification.

14 A Uh-huh.

15 Q So by HIV standards and methods then
16 available, what were your referring to?

17 A The methods that are referenced in the
18 patent specification and publications are endpoint PCR
19 as we've discussed.

20 Q So by publications, are you talking about
21 only things that were referenced in the patent itself,
22 or are you talking about publications more generally?

23 A I guess for me as one skilled in the art
24 reading the material, I understood the methods
25 referenced in the paper and publication and related

Page 75

1 methods. So if you had done an endpoint PCR and
2 instead of the horseradish peroxidase conjugated
3 detection probe you used an alkaline phosphatase
4 detection probe, it would still be an endpoint PCR
5 with non-isotopic detection in those methods, and that
6 was my understanding of what I intended there. That
7 was how I read the patent.

8 Q So in your Declaration, using the phrase
9 then available really means available and related in
10 some sense to the assay that's actually disclosed?

11 A Then available to do what they describe in
12 the patent.

13 Q How did you determine which assays were
14 sufficiently related to what was disclosed in the
15 patent to qualify as being within the scope of the
16 patent claims?

17 A I made that distinction based on my
18 accumulated expertise of working in the field for a
19 number of years on the conceptual principle of
20 measurement that was involved.

21 Q So how did you choose which techniques were
22 sufficiently close and which techniques weren't?

23 A Endpoint PCR with an external standard
24 quantification of the amplified product at the end of
25 the assay to me, even with variations on that, to me

Page 76

1 seemed within the scope of things. Something that
2 relied on an alternative principle of measurement
3 didn't seem to be stated or implied in the patent.

4 Q Well, what I'm trying to get at is how --
5 what principle did you use to distinguish between what
6 was described in the patent and what you say is
7 outside what was described in the patent?

8 MR. CANNON: Objection. Asked and answered.

9 A The principle of measurement.

10 Q What do you mean by principle of
11 measurement?

12 A The basis for quantification.

13 Q So how that assay specifically worked to
14 measure the HIV RNA; is that what you're saying?

15 A The underlying conceptual principle for the
16 quantitation, yes.

17 Q Continuing in Paragraph 46, the next
18 sentence reads, since that time numerous improvements
19 have been incorporated into quantitative PCR assays
20 for HIV. For example, including the use of internal
21 controls and armored RNA standards, and I'll end
22 there.

23 In using the phrase "for example" and
24 "including", are you intending to limit your opinion
25 as to only those two improvements, or are there other

Page 77

1 improvements?

2 A That was not intended to be a limiting
3 example.

4 Q And that's because you were -- you used the
5 word includes, or including, excuse me; is that
6 correct?

7 A It wasn't intended to be a limiting example.
8 Just an example.

9 Q And the way that you stated that it wasn't
10 intended to be a limiting example was by using the
11 words "for example" and "including", correct?

12 MR. CANNON: Objection. Asked and answered.

13 A I am just a scientist and I'm reluctant to
14 pars language with a lawyer. The -- it was written to
15 be an example, not a limiting example. And I don't
16 have an opinion on the exact grammatical construction,
17 I'm sorry.

18 Q Yeah. To your view as a scientist, using
19 the term including was not intended to be limiting; is
20 that correct?

21 MR. CANNON: Objection. Asked and answered.

22 A That's correct, it was not intended to be
23 limiting.

24 Q I want to talk a little bit about the
25 specific examples you used. The JID article describes

20 (Pages 74 to 77)

JEFFREY DAVID LIFSON, M.D.

September 5, 2007

Page 78

1 a CRNA gag gene construct as one of the standards
 2 that's used in quantification; is that correct?
 3 A Uh-huh. Yes.
 4 Q Could the CRNA construct have been used as
 5 an internal control?
 6 MR. CANNON: Objection. Incomplete
 7 hypothetical.
 8 A Could it technically have been used as an
 9 internal control? Is that your question?
 10 Q Yes.
 11 A I think there's -- there are -- to use it as
 12 an internal control would entail two elements, I
 13 think. One is the -- it being technically adequate to
 14 be employed as an internal control, and also sort of
 15 the understanding and notion that it was possible,
 16 useful and desirable to use as an internal control.
 17 Q Okay. Well, let's break those out. Was the
 18 CRNA construct technically adequate to have been used
 19 as an internal control?
 20 MR. MARTER: Objection. Incomplete
 21 hypothetical.
 22 A In principle that construct could be, could
 23 be used that way. We and others have used similar
 24 constructs as internal controls.
 25 Q Going to the second element, see if I've got

Page 79

1 this. Would it, or could it have been possible,
 2 useful and/or desirable to use the CRNA construct as
 3 an internal control?
 4 MR. CANNON: Objection. Incomplete
 5 hypothetical.
 6 A There is nothing in anything in the
 7 specifications in the patent or any of the supporting
 8 publications that indicated to me that the authors
 9 considered it to be potentially useful or helpful to
 10 do so.
 11 Q What's the benefit of using an internal
 12 control?
 13 MR. CANNON: Objection. Lacks foundation.
 14 A An internal -- an internal control provides
 15 you with some experimental feedback as to the adequacy
 16 of certain aspects of your procedure. As an example,
 17 if you were to simply run an assay without an internal
 18 control and to obtain a result that was below the
 19 threshold of your assay, that it scored less than your
 20 threshold, it is possible that that could be because
 21 the amount of a target template and your starting
 22 sample was actually below the threshold of your assay.
 23 It could also be possible that there was something in
 24 your sample that was inhibiting the reverse
 25 transcription reaction and/or the PCR amplification

Page 80

1 reaction.
 2 If you include an RNA standard internal
 3 control in the assay and that also fails to give you
 4 amplified product, then you know there was a problem
 5 with the assay. If you get the expected result from
 6 the spiked internal control but still have a
 7 below-threshold result for your test sample, it raises
 8 your level of confidence that that's a true negative
 9 result and not due to problems with the procedure.
 10 Q Was the distinction between internal and
 11 external controls known generally in the field prior
 12 to May of 1992?
 13 A There were certainly publications of
 14 procedures employing internal controls prior to May of
 15 1992.
 16 Q And did those publications relate to PCR --
 17 PCR quantitative assays for HIV?
 18 A I can't answer that question specifically as
 19 of May of '92 without reviewing the literature.
 20 Q Can you answer the question as to PCR assays
 21 generally? Were there publications as of May of 1992
 22 in which quantitative PCR assays included an internal
 23 control?
 24 A Yes.
 25 Q Let me go back a bit. I'm just trying to

Page 81

1 understand the logic behind your reasoning that a
 2 person of ordinary skill would not understand these
 3 improved techniques as you -- these improvements as
 4 you describe them for measuring to be within the scope
 5 of the term measuring.
 6 So is it your understanding that the scope
 7 of a patent's terms can never be construed to include
 8 later improvements?
 9 A We're getting into a question of law that's
 10 outside of my expertise.
 11 Q Is it your understanding that improvements
 12 cannot infringe an earlier patent?
 13 MR. CANNON: Objection. Lacks foundation.
 14 A Same answer.
 15 Q And is it your understanding that the scope
 16 of a claim term is limited to the specific examples
 17 that are described in the written description?
 18 A Again, that's a legal question, not a
 19 technical one, and I don't have an answer for you.
 20 Q So your opinion is that the assay that was
 21 specifically disclosed in the JID article and the
 22 additional assays that were disclosed in the patent
 23 specifications are different from some other assays;
 24 is that correct?
 25 MR. CANNON: Object to the form of the

21 (Pages 78 to 81)

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JEFFREY DAVID LIFSON, M.D.

September 5, 2007

Page 86

1 quantify HIV, yes.
 2 MR. CANNON: I'd like to take a short break.
 3 (Break taken.)
 4 BY MR. DAMSTEDT:
 5 Q In your Declaration, do you offer any
 6 opinion or explanation as to what the term qualitative
 7 result means?
 8 A Not as such. If you look at Paragraph 45,
 9 that is -- deals with testing for the presence or
 10 testing for the absence of a particular target
 11 sequence.
 12 Q Okay. Let's turn to that part. Paragraph
 13 45 states, to the extent that testing for the presence
 14 or testing for the absence are interpreted to refer to
 15 quantification of HIV RNA, it is also my opinion that
 16 those terms would have been understood to mean that
 17 HIV RNA was detectably present or absent based on an
 18 endpoint RT PCR assay of a fixed sensitivity.
 19 Did I read that correctly?
 20 A That's correct.
 21 Q What did you mean by the term detectably
 22 present or absent?
 23 A As laid out in the specification and the
 24 supporting publications, there is a threshold
 25 sensitivity that's repeatedly cited based on the

Page 87

1 optical density in the horseradish peroxidase readout
 2 reaction. I believe the value is 0.135, reflecting
 3 the average of HIV-negative samples plus, I believe
 4 three standard deviations. And if the signal in the
 5 assay is that level or less, the assay can distinguish
 6 between a positive or a negative result.
 7 Q Speaking more generally, what does the term
 8 detectably present or absent mean?
 9 A It means that the test target sequence can
 10 be reliably quantified in the sample, test sample
 11 using a particular assay. But those terms -- as I've
 12 alluded to before, those terms are problematic if
 13 they're not used in reference to a particular assay
 14 because let's say that we have a sample that has 5,000
 15 copies of a target sequence in it. If we test it in
 16 an assay that has a low sensitivity, it may be
 17 detectably present. If we test it in another assay
 18 that has a higher sensitivity above the copy number
 19 that's present in the sample, it won't be detectably
 20 present. It will be the same sample.
 21 Q So in your opinion, detectably present
 22 refers to whether or not the quantitative HIV RNA is
 23 above or below the specific threshold sensitivity for
 24 that -- for a particular assay; is that correct? Did
 25 I --

Page 88

1 A No. What I'm trying to say is that if the
 2 terms aren't used in reference to a particular assay,
 3 they're not meaningful.
 4 Q But when they are used in reference to a
 5 particular assay, the term simply refers to HIV copy
 6 numbers being above or below the threshold sensitivity
 7 of that particular assay; is that correct?
 8 A Yes.
 9 Q When did you come up with the opinions that
 10 you list in your Declaration?
 11 A Through the month of August of this year.
 12 In reference to providing an opinion here?
 13 Q Yes.
 14 A Through the month of August of this year.
 15 Q Did you participate in drafting a Disclosure
 16 of the expert testimony that you might provide with
 17 counsel?
 18 MR. CANNON: Object to the form of the
 19 question. To the extent we're getting into areas that
 20 are outside of our mutual agreement with respect to
 21 expert discovery, I object.
 22 Answer the question if you can.
 23 A I'm sorry, could you say the question again?
 24 Q Are you aware that there was a Disclosure of
 25 testimony that you might provide that was made to the

Page 89

1 Court and to Stanford?
 2 A Yes.
 3 Q Did you participate in drafting that
 4 Disclosure?
 5 MR. CANNON: Object to the form of the
 6 question.
 7 A I had a telephone conversation with
 8 Mr. Cannon that -- I think some of the ideas from that
 9 telephone conversation may have been incorporated into
 10 that Disclosure.
 11 Q Did you come up with any new opinions that
 12 are disclosed in your Declaration after the Expert
 13 Disclosure was filed?
 14 MR. CANNON: Object to the form of the
 15 question. Lacks foundation.
 16 You can answer it if you can.
 17 A I'm sorry, could you say that again?
 18 Q Yeah. Did you come up with any new opinions
 19 that are disclosed in your Declaration after the
 20 Disclosure was filed with the Court?
 21 MR. CANNON: Object to the form of the
 22 question.
 23 A I would have to review the exact timing of
 24 things to answer the question.
 25 Q Sure.

23 (Pages 86 to 89)

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Page 90

1 MR. DAMSTEDT: Handing to the Court Reporter
2 Roche's Patent Local Rule 4-3(d) Disclosure. It lists
3 at the top that it was filed July 6th, 2007.

4 (Exhibit No. 699 was marked for identification
5 and was attached to the transcript.)

6 BY MR. DAMSTEDT:

7 Q Have you had a chance to review that
8 document?

9 A I'm reviewing it now.

10 (Reviewing.)

11 Yes.

12 Q So does that refresh your recollection as to
13 about when the Disclosure was filed?

14 A It does.

15 Q And so my question is, did you come up with
16 any new opinions that are in your Declaration after
17 that Disclosure was filed?

18 MR. CANNON: Object to the form of the
19 question. Document speaks for itself. Both sets of
20 documents speak for themselves.

21 A I would reiterate that that -- and clarify
22 my recollection on the timing of working on the
23 Declaration through July and August, and I think
24 the -- I don't -- I don't believe that there is any
25 fundamentally new interpretation presented in the

Page 91

1 Declaration that isn't at least outlined in the
2 Disclosure.

3 Q Is there any statement in your Disclosure
4 about the terms presence, or testing for the presence
5 of HIV encoding nucleic acid or testing for the
6 absence of -- excuse me or absence of HIV encoding
7 nucleic acid being limited to endpoint PCR?

8 A I'm sorry, did you say Disclosure or
9 Declaration?

10 Q Disclosure.

11 A Because at least as I understand it, this
12 isn't my Disclosure in the sense that I didn't prepare
13 the document.

14 Q Yeah, let me rephrase the question. Is
15 there anything in that Disclosure that says you're
16 going to testify about testing for the presence of HIV
17 encoding nucleic acid or the term absence of HIV
18 encoding nucleic acid and that you will testify that
19 those terms are limited to endpoint PCR?

20 MR. CANNON: Object to the form of the
21 question. The document speaks for itself. Asked and
22 answered.

23 A There is nothing in here that explicitly
24 addresses that question. There's a general sentence
25 that says Doctor Lifson may also point out aspects of

Page 92

1 the patents that bear on each of the terms, which
2 seems it might generally cover the topic but there's
3 nothing specifically relating to the presence or
4 absence.

5 Q Anything specifically related to armored RNA
6 standards?

7 A No.

8 Q I want to have you look at the JID article.
9 That may take me a second to find it. I'm sorry.

10 A Uh-huh.

11 MR. DAMSTEDT: This one has already been
12 marked as Exhibit 1, so we'll just hand it over.

13 Q It's your opinion, if I understand it
14 correctly, that the JID article discloses a threshold
15 level of sensitivity of 40 copies per 200 microliters;
16 is that correct? Is that your opinion?

17 A What it actually discloses is a --
18 (reviewing) -- discloses a threshold sensitivity on
19 the second page, the first partial paragraph, of an
20 optical density absorbance cutoff of .135 optical
21 density units which -- so that's the sensitivity
22 that's --

23 Q Can you point any -- I'm sorry, were you
24 finished?

25 A So it's in the second page of the article

Page 93

1 below that graph --

2 Q Uh-huh.

3 A -- that first partial paragraph, and there
4 the optical density of .135 is what they define as
5 their cutoff that they're, in their reconstruction
6 experiments they say satisfy 30 cycles of
7 amplification, ten tissue culture infectious dose 50
8 units of HIV, 100 copies of CRNA, and 10 copies of HIV
9 plasma DNA gave an absorbance greater than a negative
10 absorbance cutoff 0.135 defined as the mean absorbance
11 obtained from 15 sera negative sera 0.084, plus or
12 minus 0.017, plus three standard deviations.

13 Q So what I'm looking for is, is there
14 anywhere in the JID article that says that that
15 absorbance level of 0.135 corresponds to 40 HIV RNA
16 copy per 200 microliters of sample?

17 A (Reviewing.)

18 I'm looking for it. I think that -- I think
19 there is.

20 (Reviewing.)

21 Q Please feel free to take as much time as you
22 need.

23 A (Reviewing.)

24 Can I have a copy of the JCI paper?

25 Q Sure.

24 (Pages 90 to 93)

JEFFREY DAVID LIFSON, M.D.

September 5, 2007

Page 94

Page 96

1 I don't seem to have it in the materials I
2 brought down --

3 A Okay.

4 Q -- but you do have the patents.

5 A Yeah.

6 Q I guess -- I mean the question really was is
7 there anything in the JID article that you can find?

8 A That specifically reference --

9 Q -- 40 copies per 200 microliters?

10 A It references the negative absorbance cutoff
11 in the optical density, which I believe in the JCI
12 paper and the patents -- and that's what I was looking
13 for -- the authors link a sensitivity of 40 copies per
14 200 microliters of plasma.

15 Q But there's nothing in the JID article that
16 says that?

17 A I don't see anything based on my review
18 right here.

19 Q Great. Thanks.

20 MR. DAMSTEDT: I'm done for now.

21 MR. CANNON: Okay, take a short break.
22 (Break taken.)

23 MR. CANNON: This is Brian Cannon on behalf
24 of Roche. I just wanted to reflect for the record
25 that this morning Doctor Lifson brought hard copies,

Page 95

Page 97

1 two copies of documents that had been previously
2 identified that reflect a response to Request for
3 Production No. 17, and I would just like to read into
4 the record the citations for these documents.

5 The first is a research report Quantitative
6 Competitive Polymerase Chain Reaction for Accurate
7 Quantification of HIV DNA or Other Species by Piatak,
8 et al. That's from Biotechniques, Volume 14, No. 1,
9 1993.

10 Next article is entitled High Levels of HIV
11 1 in Plasma During all Stages of Infection Determined
12 by Competitive PCR. That's by Piatak, et al. in
13 Science, Volume 259, March 19th, 1993.

14 Next article is from the Landset, Volume
15 341, April 24th, 1993, Page 1099, and is an article
16 by Piatak, et al.

17 Next article is Determination of Plasma
18 Viral Load HIV 1 Infection by Quantitative Competitive
19 Polymerase Chain Reaction by Piatak, et al. That's
20 from AIDS 1993, Volume 7, Pages S65 through S71.

21 The next article title is Viral Dynamics in
22 Human Immunodeficiency Virus Type 1 Infection, by Wei,
23 et al., and that is from Nature, Volume 373, January
24 the 12th, 1995.

25 The next article is entitled Non-cytolytic

1 Cd8 T-cell Anti-HIV Responses in Primary HIV 1
2 Infection. This is from the Landset, Volume 344,
3 December 17th, 1994, beginning Page 1671.

4 And finally, the last article is entitled
5 Clinical Evaluation of Branched DNA Signal
6 Amplification for Quantifying HIV Type 1 in Human
7 Plasma by Cao, et al. published in AIDS Research and
8 Human Retroviruses, Volume 11, No. 3, 1995, beginning
9 on Page 353.

10 MR. CANNON: Then I do have a follow-up
11 question. And I will note that those articles were on
12 Doctor Lifson's CV and were identified to counsel
13 before this deposition.

14 EXAMINATION BY COUNSEL FOR DEFENDANT/COUNTERCLAIMANTS
15 BY MR. CANNON:

16 Q Doctor Lifson, if you could turn to Exhibit
17 692, please.

18 A (Complying), uh-huh.

19 Q And within that, if you could turn to
20 Document Request No. 12. Is that the last page? You
21 see that?

22 A Yes.

23 Q Mr. Damstedt asked you some questions about
24 it earlier, and the Document Request is for, quote,
25 all communications with any of the following

1 individuals: Thomas Merigan, Mark Holodniy, David
2 Katzenstein, Michael Kozal, John Sninsky, Alice Wang,
3 Clayton Casipit, David Kellogg, Eric Groves and
4 Shirley Kwok. Do you see that?

5 A I do.

6 Q Are you in possession of any communications
7 with the individuals listed here?

8 A I don't believe I have any documents
9 involving communications with any of those
10 individuals.

11 MR. CANNON: No further questions.

12 FURTHER EXAMINATION BY COUNSEL FOR
13 THE PLAINTIFF/COUNTERCLAIM DEFENDANTS
14 BY MR. DAMSTEDT:

15 Q I have three questions to follow-up on that.

16 You stated that you don't believe you have
17 any documents. What's the basis for that belief?
18 Have you searched for any of these documents?

19 A I don't believe that I, you know, ever had
20 any documents. Some of these people I don't know.
21 Some of them I know and have spoken with verbally but
22 I don't believe I have any documents.

23 Q Okay. Two more questions. When did you
24 give the articles that counsel for Roche read into the
25 record just a moment ago to counsel?

25 (Pages 94 to 97)

JEFFREY DAVID LIFSON, M.D.

September 5, 2007

Page 98

1 A The hard copy?
 2 Q Correct.
 3 A Yesterday.
 4 Q When were you asked to collect documents for
 5 this case by counsel?
 6 A I don't recall exactly.
 7 Q What is the general time frame?
 8 A I believe in the last week or two.
 9 MR. DAMSTEDT: I'm done.
 10 MR. CANNON: No further questions. Thanks.
 11 Oh, before we go off the record, we reserve
 12 the right to have the witness review the transcript
 13 consistent with the parties' agreement and the Federal
 14 Rules.
 15 (Signature having not been waived, the
 16 examination of Jeffrey David Lifson, M.D., was
 17 concluded at 12:42 p.m.)
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Page 99

1 ACKNOWLEDGMENT OF DEPONENT
 2 I, Jeffrey David Lifson, M.D., do hereby
 3 acknowledge that I have read and examined the
 4 foregoing testimony, and the same is a true, correct
 5 and complete transcription of the testimony given by
 6 me, and any corrections appear on the attached Errata
 7 sheet signed by me.
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 9
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 11 (DATE) (SIGNATURE)
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Page 100

1 CERTIFICATE OF SHORTHAND REPORTER/NOTARY PUBLIC
 2 I, Dawn M. Hart, Registered Professional
 3 Reporter, the officer before whom the foregoing
 4 proceedings were taken, do hereby certify that the
 5 foregoing transcript is a true and correct record of
 6 the proceedings; that said proceedings were taken by
 7 me stenographically and thereafter reduced to
 8 typewriting under my supervision; and that I am
 9 neither counsel for, related to, nor employed by any
 10 of the parties to this case and have no interest,
 11 financial or otherwise, in its outcome.
 12 IN WITNESS WHEREOF, I have hereunto set my hand
 13 and affixed my notarial seal this 6th day of September
 14 2007.
 15 My Commission Expires:
 16 January 1, 2009
 17
 18
 19
 20 NOTARY PUBLIC IN AND FOR THE
 21 STATE OF MARYLAND
 22
 23
 24
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Page 101

1 ERRATA SHEET
 2 IN RE: Stanford v. Roche
 3 PAGE LINE CORRECTION AND REASON
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26 (Pages 98 to 101)

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