

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

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BRISTOL-MYERS SQUIBB COMPANY
Plaintiff and Counter-Defendant,
-against- Case No.
2:13-cv-05400-MRP-JEM

GENENTECH, INC., and CITY OF HOPE,
Defendant and Counter-Plaintiffs.

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GENENTECH, INC., and CITY OF HOPE,
Third-Party Plaintiffs,
-against-
MEDAREX, L.L.C.,
Third-Party Defendant.

-----x
CONFIDENTIAL

December 23, 2014
9:30 a.m.

Videotaped Deposition of
SAUL J. SILVERSTEIN, PH.D., taken by Defendant,
pursuant to Notice, at the offices of MAYER BROWN
LLP, 1675 Broadway, New York, New York, before
TAMMEY M. PASTOR, a Registered Professional
Reporter, Certified LiveNote Reporter and Notary
Public within and for the State of New York.

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2
3 THE VIDEOGRAPHER: This is the
4 video operator speaking, David Pelozo
5 for Merrill Legal Solutions.

6 Today's date is December 23, 2014.
7 The time is 9:29. We are at 1675
8 Broadway, New York City for the
9 deposition of Dr. Saul J. Silverstein in
10 the matter of Bristol-Myers Squibb
11 Company versus Genentech, Inc.

12 I would like the attorneys to
13 introduce themselves starting with Mr.
14 Brausa.

15 MR. BRAUSA: Sure. Adam Brausa
16 here for Genentech.

17 MR. McCORMICK: Richard
18 McCormick, Mayer Brown for Brisol-Myers
19 and Medarex.

20 MR. DAHIYA: Neal Dahiya for
21 Brisol-Myers and Medarex.

22 MR. SCHWARTZ: Robert Schwartz
23 from the Fitzpatrick firm for Lilly.

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1 A P P E A R A N C E S:

2 MAYER BROWN LLP
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4 Medarex, L.L.C
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19
20 ALSO PRESENT:
21 NEAL DAHIYA, Bristol-Myers Squibb
22 DAVID PELOZA, Videographer
23 Merrill Legal Solutions

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1 SAUL J. SILVERSTEIN, PH.D.-CONFIDENTIAL

2 SAUL J. SILVERSTEIN, PH.D.,
3 having been first duly sworn by the
4 Notary Public (Tammey M. Pastor), was
5 examined and testified as follows:

6 EXAMINATION CONDUCTED BY
7 MR. BRAUSA:

8 Q. Good morning, Dr. Silverstein.
9 Can you state your full name for the record.

10 A. Saul J. Silverstein.

11 Q. And you have been deposed
12 before; correct?

13 A. I have.

14 Q. So you are familiar with the
15 rules, but if I ask questions and you don't
16 understand them, you can ask me to clarify,
17 I'll try and do that.

18 A. Very good.

19 Q. If you need to take a break at
20 any time we can do that. The only thing I
21 ask if there is a question pending we finish
22 the question on the record, okay.

23 You have submitted two Expert
24 Reports in this litigation; correct?

25 A. I have submitted an Expert

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2 Report and rebuttal.

3 Q. And the rebuttal was in
4 response to a report submitted by
5 Dr. Matthew Scott?

6 A. Yes. Yes.

7 MR. BRAUSA: I am going to go
8 ahead and mark Silverstein 1.

9 (Silverstein Exhibit 1
10 for identification, Expert Report of
11 Saul J. Silverstein, no production
12 numbers.)

13 BY MR. BRAUSA:

14 Q. After you have taken a look at
15 that can you confirm for me that is the
16 opening report you submitted in this
17 litigation?

18 A. Yes, this is the opening
19 report.

20 MR. BRAUSA: We will mark
21 Silverstein 2 as well right now.

22 (Silverstein Exhibit 2
23 for identification, Silverstein Rebuttal
24 Expert Report, no production numbers.)

25 BY MR. BRAUSA:

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2 am referring to U.S. patent 6,331,415. Okay.

3 A. Okay.

4 Q. And when I say Cabilly III
5 patent I'm going to be referring to
6 7,923,221. Okay?

7 A. Very good.

8 Q. I think those are the same
9 terms you use in your Expert Reports to
10 describe the Cabilly patents; correct?

11 A. Yes.

12 Q. Okay. If there is ever any
13 question about which specific Cabilly patent
14 I'm referring to, just let me know.

15 Now, I think your report, my
16 impression was you have some specific
17 factual disagreements with Dr. Scott about
18 whether certain sections of the Cabilly
19 specification would provide guidance to one
20 of skill in the art in April 1983 about in
21 vivo assembly of heavy and light
22 immunoglobulin chains in eukaryotic cells;
23 right?

24 A. That's correct.

25 Q. There are several sections of

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2 Q. Can you confirm for me that is
3 the rebuttal report you submitted in this
4 litigation?

5 A. Yes, this is the rebuttal.

6 Q. Now I've read your opening
7 report, Dr. Scott's response to your report
8 and your Rebuttal Report and the impression
9 I came away with was you and Dr. Scott
10 disagree on several issues; is that fair?

11 A. I would say that's fair, yes.

12 Q. Before we get into some
13 detailed questions about your opinions and
14 disagreements you have with Dr. Scott, I'd
15 like to make sure I understand all the
16 disagreements that you have with Dr. Scott.
17 Is that okay?

18 A. Fair enough.

19 Q. Okay. We are going to be
20 referring to the Cabilly patents during this
21 questioning. And as I think you know there
22 is a Cabilly II and a Cabilly III patent;
23 correct?

24 A. Yes.

25 Q. When I say Cabilly II patent I

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2 the Cabilly specifications that you disagree
3 with Dr. Scott as to whether one of skill in
4 the art would understand those two be
5 referring to in vivo assembly of heavy and
6 light chains in eukaryotic cells; correct?

7 A. That's also true.

8 Q. So first there is a section at
9 column 12, actually we can just refer to the
10 paragraph in your report, if you can turn to
11 paragraph 35 of Silverstein 1.

12 A. I'm just going to get another
13 pair of glasses. Okay.

14 Q. In paragraph 35 of Silverstein
15 1 you quote a section from the Cabilly II
16 patent at column 12, lines 47 through 49. Do
17 you see where I'm referring?

18 A. Yes.

19 Q. That is a statement that says,
20 "Tissue culture cells as hosts also appear
21 in general to permit reasonably facile
22 recovery of heterologous protein." Correct?

23 A. Yes.

24 Q. And my understanding you and
25 Dr. Scott disagree about whether that clause

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 2 would tell one of skill in the art that the
 3 Cabilly inventors intended their invention
 4 to cover in vivo assembly of heavy and light
 5 chains in eukaryotes; correct?
 6 A. That's correct.
 7 Q. Dr. Scott is of the opinion
 8 you'd agree that section of the Cabilly
 9 patent does in fact refer to in vivo
 10 assembly of heavy and light chains in
 11 eukaryotic host cells; right?
 12 A. He believes that to be true.
 13 Q. And do you disagree with
 14 Dr. Scott on that point?
 15 A. I disagree with him.
 16 Q. You don't think that that is
 17 section of the Cabilly II patent refers to
 18 in vivo assembly of heavy and light chains
 19 in a eukaryotic host cell?
 20 A. I do not believe that it does.
 21 Q. That is not exactly what you
 22 say in paragraph 35; is it?
 23 A. I think that's open to
 24 interpretation.
 25 Q. That is sort of what you're

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 2 saying in paragraph 35 about the section of
 3 the Cabilly patents we've been discussing
 4 you say it is not an unambiguous disclosure
 5 that that includes recovery of in vivo
 6 assembled immunoglobulins?
 7 MR. McCORMICK: Objection.
 8 A. It is not directed to
 9 immunoglobulins.
 10 Q. What do you mean when you say
 11 it is not unambiguous in paragraph 35 of
 12 your report?
 13 A. Well, I think that it's
 14 difficult to interpret the meaning of that
 15 phrase in terms of reasonably facile
 16 recovery because nothing is -- there is no
 17 description for what that is.
 18 Q. Your opinion in paragraph 35
 19 doesn't say Dr. Scott is wrong, correct, it
 20 just says his interpretation of that section
 21 of the Cabilly II patent isn't clear?
 22 MR. McCORMICK: Objection to
 23 form.
 24 A. Well, actually, actually this
 25 paragraph relates to the patent per se and

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 2 not so much to Dr. Scott's opinion at this
 3 point.
 4 Q. Okay. And your opinion about
 5 the patent is that that section of the
 6 patent referring to reasonably facile
 7 recovery is that's that is an unambiguous --
 8 that is an ambiguous statement rather?
 9 A. Absolutely.
 10 Q. It is just not clear whether
 11 that is referring to in vivo assembly in
 12 eukaryotic host cells or something else;
 13 right?
 14 A. It is not clear as to what it
 15 is that is being recovered or how it is
 16 being recovered or for that matter what it
 17 is that -- what it is they are trying to do.
 18 Q. Okay. When you say it is not
 19 clear from that clause what is being
 20 recovered, what else would that be referring
 21 to aside from heavy and light chains based
 22 on the rest of the specification of the
 23 Cabilly II patent?
 24 A. Well, regardless of the rest of
 25 the specifications what it is referring to

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 2 here is heterologous proteins, at that time
 3 there were just a few proteins that had been
 4 made. As I said, they don't describe
 5 immunoglobulins as one of the proteins at
 6 this point.
 7 Q. Is your opinion one of skill in
 8 the art would read this phrase, referring to
 9 reasonably facile recovery of heterologous
 10 proteins and conclude that the reference to
 11 heterologous proteins did not include
 12 immunoglobulins?
 13 A. I'm not sure what it includes.
 14 Q. In your opinion as the expert
 15 in this case do you think it includes
 16 immunoglobulins when they refer to facile
 17 recovery of heterologous proteins?
 18 A. I would assume that that is
 19 what they meant. But it is not what they
 20 said.
 21 Q. Why would you assume that's
 22 what they meant when they said, "reasonably
 23 facile recovery of heterologous proteins?"
 24 A. Well the subject matter is the
 25 production of immunoglobulins by recombinant

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2 technology.

3 Q. So based on the fact?

4 MR. McCORMICK: Let him finish.

5 A. Continue.

6 MR. McCORMICK: Did you want to
7 finish your answer?

8 A. No. I want to hear the next
9 question.

10 Q. Based on the fact the Cabilly
11 II patent is about the recovery of
12 heterologous immunoglobulins, it is fair to
13 conclude that when they refer to
14 heterologous proteins and recovering those,
15 that includes immunoglobulins as well;
16 right?

17 MR. McCORMICK: Objection.

18 A. I would say that you've got to
19 say what it is that you're referring to to
20 be specific.

21 And, of course I think more to
22 the point is that this entire patent is
23 dedicated to its work in bacterial cells.
24 There is no demonstration of using tissue
25 culture cells for anything.

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2 A. I'm saying that in the context
3 of having written this patent, whoever wrote
4 it would like to be all inclusive.

5 Q. Okay. I guess my question for
6 you as the technical expert in this case,
7 looking at this sentence as one of ordinary
8 skill in the art as of April 1983, do you
9 think the reasonably facile recovery of
10 heterologous proteins would refer to the
11 recovery of immunoglobulins, given the
12 specification of the Cabilly patents?

13 MR. McCORMICK: Objection, asked
14 and answered.

15 A. I would say somebody of
16 ordinary skill in the art would not be able
17 to make that conclusion.

18 Q. So they just wouldn't be able
19 to make a conclusion at all about what
20 heterologous proteins refers to or includes?

21 A. Well, I think that specifically
22 we are talking about immunoglobulins. At
23 this point in time, to my knowledge the only
24 proteins that had been made were single
25 chain proteins.

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2 Q. I understand that's one of your
3 opinions. We'll get to that point. But I
4 guess I'm still focused on your opinion
5 about whether the reference to reasonably
6 facile recovery of heterologous proteins
7 includes the recovery of immunoglobulins
8 based on the specification of the Cabilly II
9 and Cabilly III patents?

10 A. I think we've actually answered
11 that question and addressed it. I think that
12 there is reasonable doubt about what this
13 includes. I think they would like it to have
14 been, but I don't think they state that's
15 the case. I think that's a big difference.

16 Q. When you refer to "they," and
17 "we would like to be," who are you referring
18 to?

19 A. The authors of the patent.

20 Q. So the PTO would like it to
21 include immunoglobulins; is that your
22 testimony?

23 MR. McCORMICK: Objection,
24 mischaracterizes his testimony. Go
25 ahead.

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2 Q. So the fact that the entirety
3 of the Cabilly patent or large part of the
4 Cabilly patent specification is about the
5 recovery of heterologous heavy and light
6 immunoglobulin chains, would not give one of
7 skill in the art any guidance as to what
8 they were referring to when they said the
9 reasonably facile recovery of heterologous
10 proteins in the patent?

11 A. I think you can read into that,
12 but I don't think the specifications say
13 that. I'll leave it at that.

14 Q. I understand the specification
15 does not say the word immunoglobulin in this
16 sentence. It says heterologous proteins. But
17 throughout the specification the word
18 immunoglobulin is used; correct?

19 A. That's true.

20 Q. That's what the specification
21 is about; right? Recovery of heavy and
22 light immunoglobulin chains?

23 A. Yes.

24 Q. So your opinion is that after
25 reading that specification when one of skill

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 2 in the art arrived at this sentence that
 3 states "Tissue culture cells as host cells
 4 also appear in general to permit reasonably
 5 facile recovery of heterologous proteins"
 6 they wouldn't be sure whether that was a
 7 reference to immunoglobulins?

8 MR. McCORMICK: Objection, asked
 9 and answered.

10 A. I would state that this is an
 11 extension of the ideas in the patent. But it
 12 not stated. And you can say it can be
 13 recovery of anything you like.

14 Q. At a minimum, you'd agree with
 15 me, though, I think, and correct me if I'm
 16 wrong, but you'd agree with me that sentence
 17 is open to interpretation? That's your
 18 opinion; correct?

19 A. I would think so, otherwise we
 20 wouldn't be having this discussion.

21 Q. That is just a factual dispute
 22 between yourself and Scott; right? About how
 23 one of skill in the art would understand
 24 this sentence?

25 A. Well, yes.

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 2 Q. Now, there is another section
 3 at, that is referred to actually in the next
 4 paragraph of your report, that refers to
 5 column 12, lines 36 through 49 of the
 6 Cabilly patents; right?

7 A. Uh-huh. Yes.

8 Q. And this is another section of
 9 the patent that Dr. Scott is of the opinion
 10 refers to in vivo assembly of heavy and
 11 light chains in eukaryotic host cell; right?

12 A. Yes.

13 Q. And you disagree with that
 14 opinion of Dr. Scott as well?

15 A. I do.

16 Q. Again, there is a sentence that
 17 starts "More over at the bottom of page 13
 18 in paragraph 36 of your report. Where you
 19 say, "Moreover, recovery of antibody would
 20 not necessarily be understood by a person of
 21 ordinary skill in the art to refer to only
 22 to recovery of already assembled antibody."

23 Do you see that?

24 A. Yes.

25 Q. So I want to focus on when you

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 2 say it would not necessarily be understood
 3 by a person of ordinary skill in the art.
 4 When you say that, the way I read that
 5 sentence, is that you're saying they could
 6 understand it, in the way that Dr. Scott
 7 interprets it; is that correct?

8 A. I think you have to include the
 9 rest of this sentence before we can continue
 10 this discussion.

11 Q. What portion of the sentence
 12 would you like to include?

13 A. The part that refers to when
 14 Dr. Scott says that additional steps and
 15 processes must be undertaken before the
 16 thing that is recovered is actually
 17 recovered.

18 Q. Why is that important to take
 19 into consideration?

20 A. Because there is no evidence
 21 that complete assembled antibody is made in
 22 the bacteria. What we know is that they
 23 extracted material from bacteria and
 24 reconstituted antibody in the fashion of
 25 Adelman, et al.

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 2 Q. The description of recovery of
 3 antibody from spun bound whole cells or from
 4 cell culture containing both the medium and
 5 suspended cells that's referred to in
 6 paragraph 36 of your report, is a reference
 7 to bacterial host cells, in your mind?

8 A. Yes. It's a reference to in the
 9 patent, I believe.

10 Q. We were discussing earlier,
 11 with respect to paragraph 35, that's not
 12 what the patent says. I don't see the word
 13 bacterial or E. coli or anything synonymous
 14 with bacteria in this section of the Cabilly
 15 patent.

16 A. May I have a copy of the
 17 patent, please?

18 Q. Sure.

19 MR. BRAUSA: I will mark as
 20 Silverstein Exhibit 3 the Cabilly II
 21 patent, U.S. patent --

22 A. Give me II or III, the specs
 23 are the same.

24 Q. -- 6,331,415.

25 (Silverstein Exhibit 3

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