UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

IN RE RECOMBINANT DNA TECHNOLOGY PATENT AND CONTRACT LITIGATION	)	MDL Docket No. 912
THE REGENTS OF THE UNIVERSITY OF CALIFORNIA Plaintiff,	)	**CAUSE NO. IP 92-224-C D/G**
-vs-	)	Indianapolis, Indiana August 30, 1995
ELI LILLY AND COMPANY, Defendant.	)	

Before the

HONORABLE S. HUGH DILLIN

TRANSCRIPT OF PROCEEDINGS AT TRIAL

APPEARANCES:

For the Plaintiff:	Arthur I. Neustadt Jean-Paul Lavalleye Marc R. Labgold William J. Healey Amy Levinson Kevin Bell Susan B. Tabler
For the Defendant:	Donald R. Dunner Charles E. Lipsey Amy E. Hamilton John C. Jenkins Jeffrey Karceski Jan Carroll
Court Reporter:	Patricia A. Cline, CM Maria Wainwright, RPR

PROCEEDINGS TAKEN BY MACHINE SHORTHAND
COMPUTER-AIDED TRANSCRIPT

THE COURT: All right. We can do that. Speaking of corrections, it showed the ruling of the Court made a little while ago to show that each of the exhibits "is" received in evidence rather than "are".

And by the way, I can't see anything on my screen here. Am I supposed to be able to? Anybody know?

I have done without one for several years.

(Discussion off record.)

MR. LIPSEY: Your Honor, it has been pointed out to me there are two items I should clarify about the understanding on the paper record to be submitted by next Wednesday. We have agreed with Mr. Neustadt that we will not be designating any further deposition testimony from the U.C. inventors in that process. And also, when I referred to previously identified documentary evidence, I was referring to the documents that were on Lilly's exhibit list, Lilly's pretrial exhibit list, which we will call and offer a subset of subject to objections by U.C.

THE COURT: Amazing. Thank you. All right. You may proceed.

MR. NEUSTADT: Thank you, Your Honor.

CROSS-EXAMINATION (continuing)

BY MR. NEUSTADT:

Q. Good morning, Dr. Gilbert.

A. Good morning.

Q. You mentioned yesterday a procedure identified as the Maxam-Gilbert sequencing, and I think you also identified Mr. Maxam or Dr. Maxam as your technician. Does the fact that his name precedes your name in the identification of that sequencing indicate the nature of his contribution to that sequencing?

A. Not particularly -- not fully. The order of the names on the side of the paper is very often quite variable and determined by many principals. I generally put my name last on many papers I am involved. In the case of sequencing, Allen Maxam was my technician at the time. He made a unique contribution to the sequencing. He discovered the use of salt to distinguish the Cs and Ts, which was a very late but very critical step in developing the method. And I thought it was appropriate to honor him by that, in that way by putting his name first.

Q. And I think you mentioned yesterday that you shared your Nobel Prize with Dr. Sanger, and I think you also mentioned that Dr. Sanger also developed a procedure for sequencing. And my question to you is, has Dr. Sanger's procedure for sequencing largely supplanted the Maxam-Gilbert sequencing technique in this country?

A. That's quite correct as of today, as of the time we were discussing. In the earlier sequencing the two methods were used almost interchangeably -- not interchangeably but

about equally. At the moment the chemical method is used only if people wish to be unusually precise. Most of the sequencing today is done by automatic machines which have mostly been adjusted, mostly devised to use the particular patterns developed by the Sanger sequencing method.

Q. Do you know a Wes Brown?

A. I don't believe so.

Q. Would it be safe to assume that you haven't read his deposition in this case?

A. I don't remember having done so.

Q. Same question with respect to a Barbara Cordell?

A. I don't remember anything about that particularly.

Q. Same question with respect to a Pat Zambriksy?

A. That I am quite sure I have never seen.

Q. And just two more: A Fran DeNoto?

A. I remember seeing the name in some connection, but I certainly don't think I saw a deposition.

Q. And the last one is Ed Tischer, T-I-S-C-H-E-R.

A. I've read Ed Tischer's deposition and examined his notebooks.

Q. Now, you mentioned yesterday that the first biosynthetic human insulin was one made by Genentech, and I think that was the A and B chain; is that correct?

A. Insulin is always the A and B chain. The first biosynthetic human insulin was made by Genentech.

Q. And that didn't have anything to do with proinsulin, did it?

A. No.

Q. Let me show you what's previously been admitted into evidence as Defendant's Exhibit 3335, and I'll bring it up on the screen for you. This is a June 1, 1981 document from a Dr. Johnson of Lilly to the file of Dr. Herr and Dr. Pettinga. I would like to show you the matter that has been highlighted on the screen in front of you. "This memo is to document the rationale behind our proposal to have a discussion of the production of human proinsulin, as well as insulin via the proinsulin mode." I'll leave out the remainder of that sentence.

And then under the factors, number one, "Many of our competitors or potential competitors in this area are conducting propaganda campaigns, suggesting that they will produce insulin by the real method, i.e., via proinsulin, and not the sloppy A and B chain combination."

Are you aware of the distinction between the two methods, one being the proinsulin real method as referred to here and the other being the sloppy A and B chain combination as referred to here?

MR. LIPSEY: Objection, lack of foundation. No indication the witness ever saw this document or knows what the author intended or was referring to.

THE COURT: Well, wholly apart from the document, the question is are you aware of the difference between the two methods. So he may answer that question.

A. Yes, as a scientist I am aware of methods to construct insulin. One of the methods involved is the addition of the A and B chain separately, and is a long history of protein chemistry, detailed protein chemistry in that method. Another method involves an imitation of a natural method in which the insulin product is cut out of a proinsulin molecule by a set of enzymes in a test tube.

Q. Are you aware of any differences in the time it takes to make insulin under the A and B chain method as contrasted to via the proinsulin route?

A. Actually not particularly. There is no -- that's a production question, not a scientific question.

Q. Are you aware of the number of steps that are involved in each process?

A. That's a production question. The steps depend on the details of the production process, the number of steps of purification, things like that. And I have no -- I have general knowledge about production processes, but I have no knowledge about that level of detail about what would be required in the particular unique production process to be used by, for example, Lilly.

Q. Let me bring up on the monitor for you Plaintiff's

Exhibit 270. Were you aware that the chain process involves 79 steps and four months and that the pro process in contrast involved 29 steps and six weeks?

A. I have no knowledge that any statement on the time on that is true.

Q. I believe you mentioned yesterday that Genentech was the first to make the A and B chain process for biosynthetic human insulin. Are you aware of the fact that it was U.C. who first made proinsulin in collaboration with their research agreement with Lilly?

MR. LIPSEY: Objection, Your Honor. Assumes a fact not in evidence that I believe has not been established by the testimony of any witness.

THE COURT: I'll sustain the objection.

Q. Let my bring up on the monitor for you Defendant's Exhibit 3254, which has previously been admitted into evidence.

You will see this is the affidavit of J. Paul Burnett, who is the executive director of the Lilly Research Laboratories. And you also will see this affidavit was submitted in support of a memorandum that was filed in this Court in this case. I'd like to direct your attention to paragraph 11 which you have on the monitor before you.

It says, "Although Genentech succeeded in chemically synthesizing pieces of the insulin gene (known as the A and

B chains), other researchers, including those of Lilly, continue their efforts to isolate naturally occurring gene sequences coding for the human insulin gene. Scientists at the University of California, San Francisco (U.C.S.F.), in collaboration with Lilly, succeeded in 1978." Does that refresh your -- let me say did you have any knowledge of what is referred to here?

A. I have certain types of knowledge, but this doesn't particularly refresh my memory about it.

Q. Do you have any reason to dispute this statement?

A. This statement is in principal supposed to pertain to the period after Genentech announced the synthesis of human insulin?

Q. Pardon me? I'm sorry. I didn't understand.

A. I find this statement as it's presented confusing because it pertains to be about the period after the synthesis of human insulin, which would have been late 1978, except it seems to end with a date in 1978. So I am not quite sure what the -- what's being pointed to here.

Q. Are you aware that the first successful production of human proinsulin was made by U.C. in collaboration, in connection with its research agreement with Lilly?

MR. LIPSEY: Objection, lack of foundation, Your Honor. That fact has not been proven in the evidence presented in this Court.

THE COURT: Sustain the objection.

Q. Let me direct your attention to Defendant's Exhibit 3255, which has been admitted into evidence. This is the affidavit of Nancy G. Mayne, and she is an associate senior biochemist at Eli Lilly. I'd like to direct your attention to paragraph 9.

A. May I have the document?

Q. I think you may have to read this one from the monitor. Are you able to do that?

MR. LIPSEY: Your Honor, that precludes the witness from seeing the context of the paragraph. Surely somewhere in this courtroom there's a copy of the paper.

A. I think it's inappropriate without a copy of the paper.

Q. I can give him my copy.

A. What is the question?

Q. Let me direct your attention to paragraph 9, which reads, "Lilly's scientists, in collaboration with the University of California, San Francisco, constructed a microorganism capable of producing proinsulin before Genentech provided Lilly with such a microorganism." My question is, were you aware of that fact prior to giving your testimony?

A. I have no knowledge of that subject.

MR. NEUSTADT: I have no further questions at this time, Your Honor.

MR. LIPSEY: We have no further questions at this time, Your Honor.

THE COURT: That's all. Thank you.

THE WITNESS: Thank you.

MR. LIPSEY: Lilly would like to call as its next witness Dr. Donald F. Steiner.

DEFENDANT'S WITNESS, DONALD F. STEINER, SWORN

DIRECT EXAMINATION

BY MR. LIPSEY:

Q. Good morning. Would you state your full name and residence address for the record, please.

A. Donald F. Steiner, Apartment 2508, 2626 Lakeview Avenue, Chicago, Illinois.

Q. You should have a book of exhibits before you. Can you turn to Exhibit 3595, Defendant's Exhibit 3595, and tell us what that is?

A. That is a copy of my curriculum vita and bibliography.

MR. LIPSEY: Offer Exhibit 3595.

THE COURT: It will be received.

MR. NEUSTADT: No objection.

(Defendant's Exhibit(s) 3595 received in evidence.)

Q. Can you briefly describe your current position?

A. My current position is professor in the University of Chicago. I have the title of A.N. Pritzker distinguished service professor of biochemistry and molecular biology and