UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON
AT TACOMA
----------x

GRO-A and GRO-A, husband and wife and the marital community composed thereof, individually and as Co-Guardians Ad Litem for GRO-A GRO-A, a minor,

Plaintiffs,

-against-

SEATTLE PLASMA CENTER, et al.,

Defendants.

----------x

August 11, 1989
9:30 a.m.

Deposition of Non-Party Witness ALFRED M. PRINCE, taken by Plaintiffs, pursuant to notice, held at the offices of Sidley & Austin, Esqs., 875 Third Avenue, New York, New York, before Paul Kirschen, a Certified Shorthand Reporter and Notary Public within and for the State of New York.

Doyle Reporting, Inc.
CERTIFIED STENOTYPE REPORTERS
Total Litigation Support
WALTER SHAPIRO, CSR
CHARLES SHAPIRO, CSR
369 LEXINGTON AVENUE
NEW YORK, N.Y. 10017
(212) 867-8220

EXHIBIT 74

A p p e a r a n c e s:

BETTS PATTERSON & MINES, P.S.
Attorneys for Plaintiffs
800 Financial Center
1215 Fourth Avenue
Seattle, Washington 98161-1090

BY: JEFFREY C. GRANT, ESQ.,
-and-
MARGARET E. WETHERALD, ESQ.,

of Counsel

SIDLEY & AUSTIN, ESQS.
Attorneys for Defendant Armour
Pharmaceutical Co.
One First National Plaza
Chicago, Illinois 60603

BY: DOUGLAS F. FUSON, ESQ.,

of Counsel

Also Present:

MICHAEL E. HRINDA, Ph.D.

oOo

IT IS HEREBY STIPULATED AND AGREED by and between the attorneys for the respective parties hereto that the sealing and filing of the within deposition be, and the same hereby are, waived; and that the transcript may be signed before any Notary Public with the same force and effect as if signed before the Court.

IT IS FURTHER STIPULATED AND AGREED that all objections, except as to the form of the question, shall be reserved to the time of trial.

* * *

ALFRED M. PRINCE, having been first duly sworn by the Notary Public (Paul Kirschen), was examined and testified as follows:

EXAMINATION BY

MR. FUSON:

Q. My name is Doug Fuson. I am from Sidley & Austin in Chicago. We are here in our New York office for the purpose of taking your deposition. If at any time my questions are unclear or I misspeak or you don't understand me, please tell me so we can get it clarified and be sure that your answers are responsive to my questions.

A. Yes.

Q. If at any time you want to take a break or make a phone call or anything, just let us know and we will accommodate you.

Have you been deposed before?

A. Yes, I have.

Q. On how many occasions?

A. Once.

Q. What sort of litigation was that?

A. Pharmaceutical company against editor

activity. It is when heated in the liquid state that there are large losses of Factor XIII. And this is what made the procedure so attractive, that one could just take the final product and dry it, heat it, use very little Factor XIII, and supposedly get rid of a lot of virus.

Q. Was there a particular or a specific process of heat treatment that was employed by Armour when you were doing the studies?

A. Yes. The Armour procedure was to heat the product for 30 hours at 60 degrees centigrade.

Q. You indicated that, I take it, that Armour employed its heat treatment process to the dry product?

A. Yes.

Q. During this period of time, '85, when you were doing your studies, were there processes of heating the product in the wet state?

A. The Behring Company, in Germany, has used heating in the wet state, and indeed they asked me to evaluate the efficiency of that procedure. I don't know exactly when they started doing that.

Q. In terms of killing HIV, which heat treatment process is more effective? That is heating the product in the dry state or in the wet state?

A. No question that wet heating in aqueous solution is far more effective. Unfortunately, it has the disadvantage that one has much lower yields of active Factor XIII at the end of the heat treatment.

Q. The Behring company is located where?

A. Marburg, Western Germany.

Q. And the studies that you were doing for the Behring Company, evaluating its wet heat treatment process, was for a concentrate product that would be used to treat hemophilia?

A. Yes.

Q. For the Factor XIII efficiency?

A. That's right.

Q. Doctor, after receiving what we have had marked Exhibits 2 and 3, the agreement and the outline of the studies to be done by the New York Blood Center, did you and others at the blood center undertake to initiate and complete the study for Armour?

the Armour product?

THE WITNESS: Could you read the question.

(Record read)

A. I think that is reasonable.

Q. All right.

The question isn't so much whether that accurately characterizes the task that you have been presented with. The question really is, is that task or -- excuse me, is this the first time in your career you have been asked to address that question with respect to the Armour product Factorate.

A. No. Beginning in late '84, Armour approached me to ask for help in assessing the efficacy of their heat inactivation process.

Q. And I take it that was long before you ever heard of my law firm or the Wyatt farmly?

A. Yes.

MR. GRANT: Please mark these documents as Plaintiffs' Exhibit 2 and Plaintiffs' Exhibit 3 respectively.

(Documents marked Plaintiffs' Exhibits 2 and 3 for identification, as of

the question. This witness has been retained as an individual expert and he has his own individual expert opinion on some subjects. I think it is appropriate for you to ask him about that.

He is not here as a corporate witness on behalf of the New York Blood Center nor has he previously indicated that the New York Blood Center has any opinions about it.

MR. GRANT: I'm sorry. Let me rephrase the question to take care of the objection.

Q. What conclusions did you draw, as a result of the studies you did on behalf of Armour, in connection with the ability of the heat treatment process employed by Armour to kill HIV in its product?

A. My overall conclusion was that the efficacy of the 60-degree, 30-hour dry heat treatment step was disappointingly and even perhaps disturbingly low, and I stated these conclusions in a manuscript which I wished to submit for publication.

Q. Were these conclusions set forth in any of the studies that we have marked as an exhibit here so far?

A. The studies -- reports were limited really to summarizing the individual results of the individual experiments, giving the quantitative results but without commenting on its significance.

Q. The conclusion, however, you have just stated was based upon the data set forth in the five studies?

A. Correct.

Q. I think I would like to back up a second and talk a little bit more about the studies you did.

If I understand, just basically, what you were doing was attempting to determine the amount of HIV left in the product after it went through the freeze-drying process and the heat treatment process?

A. That's correct. In all of these studies, we assayed residual virus after freeze-drying and then again after the initial heat, and we distinguished between the amount of

kill achieved by these two different steps.

Q. At the time the studies were done in '85, was it assumed that the freeze-drying process was sufficient or adequate to kill HIV?

A. It was clearly not adequate. I think we had become well aware of the fact that unheated Factor XIII preparations, from all manufacturers, transmitted HIV to a disturbing degree. And these preparations had all been manufactured with a variety of steps that could be supposed to remove the virus, including freeze-drying, which we knew did inactivate virus. Nevertheless, without heating, these preparations were all capable of transmitting HIV.

Q. What was the specific procedure that you employed in attempting to measure the amount of the kill performed by the heat process?

A. If a given spiked product is frozen and then freeze-dried, or lyophilized, and then rehydrated, and the amount of virus determined, that provides the baseline quantity of virus present at the beginning of the heating step. And if one does the same with the product after heating, the difference between those two is an

product -- did you find that the Armour heat treatment process of 60 degrees centigrade for 30 hours resulted in a 5 log kill of HIV?

A. Unfortunately, we did not. We found in two experiments 1.5 logs. One experiment between point 5 and 1.5. And two other experiments, 1. -- less than 1.7, less than 1.9. So considerably less than 5 logs. Indeed less than 2.

Q. For the moment, let's talk specifically about study 2 and study 5.

What were the results of the heat inactivation studies and testing that you did?

A. In study 2, we looked at HIV in two different products, generation two AHF and Factor IX. And we looked at various times, 10-hour exposure to 60 degrees, 30-hour, 48 and 72.

Q. Those numbers being hours?

A. These are hours of exposure.

Q. All right.

A. And in the case of Gen-2, it is of some interest, in 10 hours we had a drop of 1 log; in 30 hours 1.5 logs; 48 hours, greater than 1.5 but less than 3.5; and at 72 hours, greater than

4.

So in that experiment, 72-hour heating was very much more effective than 30 hours heating.

In the case of the Factor IX, 10 hours gave us no loss of virus; 30 hours, between 0.5 log and 1.5 log; same for 48 hours; and 72 hours, greater than 2 but less than 4.

Experiment 2-B, results were essentially similar but this was with Gen-1. There was no kill detectable at 10 hours, 1.5 log at 30 hours, between 2 and 4 logs at 48 hours, and 2 logs at 72. Here the 72 was not that much stronger than the 30.

Q. And the results that you have just testified about were in the April 5, '85 study?

A. Yes.

Q. And what you have labeled as study 2 and study 2-B?

A. Yes.

Q. Doctor, what was the difference between the generation one product and the generation two product?

A. Purity. Generation two was a higher

talking with. But Hrinda was the one who talked to me.

Q. And was it your understanding that Dr. McDougal had earlier worked with LAV?

A. Yes.

MR. GRANT: Please mark this document as Plaintiffs' Exhibit 9 for identification.

(Manuscript marked Plaintiffs' Exhibit 9 for identification, as of this date.)

Q. Doctor, we have had marked for purposes of identification Exhibit No. 9. Would you be kind enough to identify what that document is, please.

A. Yes. Exhibit 9 is a manuscript which I wrote, summarizing my experiences with the dry heat inactivation process for HIV, and which I sent to Armour for their comment.

Q. The date of the manuscript is what?

A. I sent it to Dr. Hrinda October 1st, '85.

Q. Relative to the five studies, Exhibits 4 through 8, when was Exhibit 9 prepared?

Before or after?

A. I believe after.

Q. And what is the relationship between the five studies, that is Exhibits 4 through 8, and the manuscript, Exhibit 9?

A. Well, Exhibit 9 is based on those studies.

Q. And Exhibit 9 was prepared by you in the course of your employment at the New York Blood Center?

A. Yes.

Q. And does Exhibit 9 accurately reflect the comments you made and the conclusions that you drew based upon the five studies you did for Armour?

A. Yes.

MR. GRANT: How about a lunch break now?

MR. FUSON: O.K.

(Luncheon recess: 12:00 noon)

for publication. It is prudent, on all of our projects.

This was being submitted to Armour with a view to getting their scientific and technical input into the publication. Specifically, my letter of transmittal asks for information on possible presence of stabilizers in the product. That is information that should go into a scientific paper.

Armour, however, reminded me that in our original agreement, we had agreed that we would give them the right not to permit publication of anything that we did, without their support. Something that we do not normally do, but somehow it happened. And so when they said that they did not feel it was desirable to have it published, we had no choice but not to publish it.

Q. What was the objection that Armour raised in connection with publication of Exhibit 9?

A. Well, on the one hand, they felt that this information would be disturbing to patients who had received or were receiving their product.

On the other hand, Dr. Terry

expressed a desire to see the confirmation or lack of confirmation of the parallel studies that Dr. McDougal and I were doing.

And actually, we sort of left it that -- you remember we studied at the same time, and we sort of left it that he would, when he obtained the results from McDougal, would see whether McDougal was observing the same as we were and would be back in touch with me, which he was not.

MR. GRANT: Please mark this as Plaintiffs' Exhibit 15 for identification.

(Document marked Plaintiffs' Exhibit 15 for identification, as of this date.)

Q. Doctor, I have had marked as Exhibit 15 to your deposition a memorandum. Would you take a look at that and see if you can identify what that is.

A. This is a memorandum from Dr. Rodell of Armour --

MR. FUSON: Are you asking him to identify the document for the record? Or are you asking him whether he has seen it before? What are you asking about.