EXHIBIT 22

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

Certified Copy

AMGEN, INC.,	)	
Plaintiff,	)	
vs.	)	No. 05-12237
F. HOFFMAN-LA ROCHE LTD., a	)	WGY
Swiss Company, ROCHE DIAGNOSTICS	)	
GmbH, a German Company, and	)	
HOFFMAN-LA ROCHE INC., a	)	
New Jersey Corporation,	)	
Defendants.	)	

The CONFIDENTIAL videotaped Deposition of EUGENE GOLDWASSER, called by the Defendants for examination, taken pursuant to notice, agreement and under the Rules of Civil Procedure for the United States District Courts pertaining to the taking of Depositions, taken before Richard H. Dagdigian, CSR No.084-000035, a notary public within and for the County of Cook, State of Illinois, and a Certified Shorthand reporter of said State, at the offices of Kaye Scholer LLP, Chicago, Illinois, on the 31st day May 2007,

decision. 15:17:39

A You said 58? 15:17:41

Q 58, yes. On the left-hand column, about three lines down, there is a sentence that says, "At the time of the filing", do you see that? 15:17:58 15:18:00 15:18:03

A Yes. 15:18:03

Q It says, "At the time of the filing of the 195 application, which was in 1985, those of ordinary skill in the art had not yet successfully developed a method of purifying EPO from recombinant sources". Do you see that? 15:18:05 15:18:10 15:18:12 15:18:15 15:18:18

A Yes. 15:18:18

Q Do you disagree with the Court's assessment here. 15:18:20 15:18:21

MR. MADRID: Objection. The question is a dirty trick, so I object on the grounds that it is unfair. 15:18:26 15:18:29 15:18:31

We are on page 58 of a 62-page document; to wit, there are many, many exhibits and information, and legal terms. 15:18:34 15:18:37 15:18:40

The witness is neither a lawyer nor has he seen all the underlying exhibits and, then, there is a legal issue of filing date. 15:18:43 15:18:45 15:18:48

So I object that it calls for speculation 5:18:49

as well, and calls for matters that are outside the expert report, so it's leading as well. 15:18:52 15:19:01

A Well, with all respect to the Judge, I think that was a mistake. 15:19:05 15:19:11

BY MR. SUH: 15:19:13

Q You can set that decision aside, Doctor. 15:19:50

A I'm sorry? 15:19:51

Q You can set that decision aside. I'm going to go back to your expert report. 15:19:53 15:19:56

A Okay. 15:20:01

Q Doctor, is it your opinion that one of skill in the art looking at the Lin patent specification in 1984, I believe, would have known what the standard was to use in performing the radioimmunoassay detection methods claimed in the 349 patent? 15:20:38 15:20:42 15:20:48 15:20:53 15:20:59 15:21:01

MR. MADRID: Objection, vague. 15:21:04

A Are you referring to a specific paragraph in this report? 15:21:06 15:21:08

BY MR. SUH: 15:21:08

Q No. 15:21:09

A Or is it just a general idea? 15:21:11

Q Yes. 15:21:12

A Would you please say the question again. 15:21:14

Q Sure. Is it your opinion, Doctor, that one of skill in the art reading the Lin patent specification in 1983 would have known what standard to use in performing the radioimmunoassay that is claimed in the 349 patent? 15:21:18 15:21:20 15:21:25 15:21:29 15:21:36

MR. MADRID: Objection, misstates the patent, and it's vague and ambiguous. 15:21:37 15:21:41

A It is. 15:21:43

BY MR. SUH: 15:21:43

Q And what would that standard be? 15:21:46

A There was an accepted standard in the field, and anyone who was interested could get a sample of it and use it as the reference either to make a secondary standard or a primary standard. 15:21:48 15:21:53 15:21:59 15:22:02

Q And what was that accepted standard at that time in 1983? 15:22:04 15:22:05

A I think that was the second IRP from the WHO lab. 15:22:09 15:22:10

Q And what is the WHO lab? 15:22:13

A The World Health Organization Laboratory in England. It's got a complicated acronym. 15:22:14 15:22:28

Their objective is to supply people with hormone standards deriving from their success at using insulin some years earlier. 15:22:31 15:22:35 15:22:43

Q If you look at paragraph 37 of your expert report, you have a reference to your second IRP. 15:22:47 15:22:59 15:23:01

Is that the same standard that you are talking about? 15:23:02 15:23:11

A You mean near the bottom the paragraph? 15:23:13

Q Yes. 15:23:13

A That's what I was talking about, yes. 15:23:17

Q Then you have -- second to the last paragraph -- the second to the last sentence of that paragraph says, "The second IRP was not available in unlimited quantities and people needed to prepare their own in-house secondary standards which they calibrated typically in an RIA, and/or a bioassay, against the second IRP". Do you see that? 15:23:21 15:23:24 15:23:26 15:23:29 15:23:32 15:23:36 15:23:41 15:23:41

A Yes. 15:23:42

Q Can you explain to me how someone would calibrate their standard with the second IRP? 15:23:44 15:23:54

A It's a known amount of what you are proposing as a secondary standard, and use the same assay with the IRP as the primary standard and compare them. It's a comparison assay. 15:23:55 15:24:01 15:24:06 15:24:09

Q So one would take a known amount of a 15:24:19

sample of erythropoietin, and would one run an RIA with that? 15:24:27 15:24:30

A It depends on how you wanted to do the assay. You could do it with an RIA. You could do it with animals, you could do it with cultures. 15:24:32 15:24:34 15:24:40

Q Now, in paragraph 50 of your report -- 15:25:02

A 50? 15:25:04

Q 50, 5-0, yes. You have a discussion there about calibration of a second standard to a primary standard, correct? 15:25:32 15:25:34 15:25:36

A Yes. 15:25:37

Q Okay. It says -- the second sentence says, "Calibration of secondary standards is performed by comparing the activity of the secondary standard with that of an accepted primary standard such as the second IRP or the subsequent reference preparations in the assays in which the secondary standard is going to be used". 15:26:05 15:26:07 15:26:09 15:26:12 15:26:18 15:26:21 15:26:24

Do you see that? 15:26:25

A I see that. 15:26:28

Q And then later on in the paragraph -- it's actually the last sentence of that paragraph on the next page, it says, "In many laboratories, secondary standards calibrated in one kind of assay 15:27:00 15:27:04 15:27:10 15:27:13

are used after calibration in other kinds of assays, but once again, as long as the secondary standard has been accurately calibrated as a dose response curve parallel to that of the primary standard, and has been shown to be stable, the results can be compared from one laboratory to another". 15:27:19 15:27:24 15:27:28 15:27:30 15:27:34 15:27:37 15:27:38

Do you see that? 15:27:39

A Yes. 15:27:54

Q In your experience, have you ever calibrated bile assays based upon a standard that you developed with an RIA? 15:27:56 15:28:02 15:28:13

A I think we never did that. 15:28:14

Q And why not? 15:28:21

A I think -- my impression right now is that I would want to make sure I was using as a standard something which had biological activity. 15:28:27 15:28:31 15:28:34

Q That's right, because an RIA does not necessarily detect biological activity, correct? 15:28:37 15:28:40

A Right. Could we have a break now, please. 15:28:43 15:28:44

MR. SUH: Yes. 15:28:45

THE VIDEOGRAPHER: Going off the record at 3:25 p.m. 15:28:47 15:28:49

(Whereupon, a short recess was taken.) 15:28:49 15:28:49

THE VIDEOGRAPHER: Going back on the record at 3:33 p.m. Please proceed. 15:36:38 15:36:42

BY MR. SUH: 15:36:43

Q Doctor Goldwasser, before the break, we were referring to this paragraph 50 of your expert report, the last sentence. 15:36:47 15:36:51 15:36:54

A All right. 15:36:54

Q And it says, "In many laboratories, secondary standards calibrated in one kind of assay are used after calibration in other kinds of assays, but once again, as long as the secondary standard has been accurately calibrated, has a dose response curve parallel to that of the primary standard, and has been shown to be stable, the results can be compared from one laboratory to another". 15:36:55 15:36:58 15:37:02 15:37:06 15:37:09 15:37:12 15:37:14 15:37:16 15:37:17

Do you see that? 15:37:18

A Yes. 15:37:18

Q That's not necessarily true with respect to using a standard for an RIA to calibrate a bioassay, correct? 15:37:19 15:37:26 15:37:31

MR. MADRID: To calibrate a what? 15:37:33

recombinant EPO, Amgen recombinant EPO in paragraph two? 15:47:58 15:48:01

A I have no recollection of what preparations P, L, C and K may be, but I'm telling Patrick Storring what our results were with that as a standard. 15:48:03 15:48:13 15:48:17 15:48:19

Q With recombinant EPO as a standard? 15:48:23

A Yes. 15:48:26

Q Is there currently -- does the NIBSASC currently have an international reference preparation standard for recombinant EPO? 15:48:40 15:48:43 15:48:47

A I don't know. I think so, but I can't be sure. 5:48:49 15:48:54

Q If one were to look at the claims of the 349 patent, if one were to try to understand that, would they understand the radioimmunoassay as claimed in the 349 patent to be using the recombinant standard or the urinary standard of the second IRP? 15:48:56 15:49:03 15:49:09 15:49:14 15:49:19 15:49:20

MR. MADRID: Objection, misstates the claim language. 15:49:23 15:49:24

A I would have to look at the document to see what they said they used as a standard. 15:49:27 15:49:33

BY MR. SUH: 15:49:33

Q Okay. Well, Doctor, can you please turn to Exhibit 5, which is the 349 patent, if you could take a look at the claims. 15:50:10 15:50:14 15:50:16

A I'm sorry, are you addressing me? 15:50:19

Q Yes, Exhibit 5, which is the 349 patent -- take a look at Exhibit 5. 15:50:22 15:50:24

A Something 5? 15:50:25

Q Exhibit 5. 15:50:26

A Exhibit 5. 15:50:27

Q Yes, that's the 349 Lin patent. 15:50:30

A Oh, okay. 15:50:38

Q And again we are looking at the claims, which is on the last page. 15:50:40 15:50:55

If one were to try to determine 100 units of erythropoietin for ten to six cells in 48 hours as determined by radioimmunoassay, would one use an RIA that was standardized to a recombinant EPO or an urinary EPO standard? 15:51:00 15:51:04 15:51:09 15:51:17 15:51:20

MR. MADRID: Objection, vague, incomplete hypothetical. 15:51:22 15:51:26

A If I were doing it, I would prefer to use an internationally accepted standard even though I have grave reservations about it. 15:51:28 15:51:32 15:51:35

BY MR. SUH: 15:51:35

Q And would that international reference standard be a standard for urinary EPO or recombinant EPO? 15:51:37 15:51:41 15:51:42

MR. MADRID: Objection, vague. 15:51:44

A A standard for EPO. 15:51:47

Q Is the standard -- is the IRP for recombinant EPO the same for a standard for urinary EPO? 15:51:49 15:51:53 15:51:54

MR. MADRID: Objection, vague. 15:51:58

A The standard using recombinant EPO was standardized against the international reference preparation. 15:52:03 15:52:09 15:52:10

BY MR. SUH: 15:52:10

Q I see. So the standard that is currently adopted by the WHO for recombinant EPO was calibrated against the second IRP? 5:52:12 15:52:18 15:52:20

A I think so. 15:52:31

Q Now, going back to Exhibit 14, which is your letter to Doctor Storring, paragraph four, it says, "Part of the problem could lie in the assumption (p5) of" -- there is a formula there, "A to the one percent, 280 equals 8.0 i.e". Do you see that? 15:52:34 15:52:39 15:52:42 15:52:50 15:52:58 15:52:58

A Yes. 15:52:58

Q What is that? 15:53:01
A A one percent to 80 is the absorption of 15:53:06
a solution at 280 nanometers in an ultraviolet 15:53:10
spectrophotometer when it has ten milligrams per 15:53:14
millimeter in there -- measured absorbent. 15:53:20
Q And why are you saying that part of the 15:53:21
problem lies in this assumption of this 15:53:24
calculation? 15:53:25
A Because it's an assumption. That would 15:53:28
depend on the protein, what the specific absorbents 15:53:31
was, whether the A one percent was 8.0 or 8.5 or 15:53:37
7.4 or 12. You just can't assume it. You have to 15:53:43
measure it. 15:53:44
Q But is this assumption an assumption 15:53:46
that's used for radioimmunoassays for 15:53:49
erythropoietin? 15:53:52
A No, not unless you want to express the 15:53:56
results as a specific activity. 15:54:11
Q I see. And it's because RIA does not 15:54:14
measure specific activity? 15:54:17
A It does not. 15:54:17
Q So this is really talking about 15:54:19
bioassays? 15:54:21
A Not necessarily -- 15:54:22

MR. MADRID: Objection, misstates the document. 15:54:24 15:54:26

BY MR. SUH: 15:54:26

Q What is it referring to? 15:54:27

A I don't know. I would have to look at page five of that document, which I don't have. 15:54:29 15:54:42

Q The next page, paragraph eight, it says, "The use of a uEPO preparation as a standard for 'naturally occurring' EPO I think is not warranted since we do not know that serum EPO is closer to eEPO than to rEPO". 15:54:45 15:54:49 15:54:54 15:54:57 15:55:01

Do you see that? 15:55:01

A Yes. 15:55:01

Q Why is it important to know whether serum EPO is closer to uEPO rather than to rEPO? 5:55:03 15:55:07

A I can't answer that. I'm responding to point eight in the original document. 15:55:10 15:55:17

My memory doesn't go that far back to let me know what I'm talking about, although I expect that Patrick Storring would know. 5:55:21 15:55:25 15:55:56

Q And in the last -- second to last paragraph it says, "Lastly: This immense effort on your part and by all the collaborating labs revealed that the second IRP is a rotten standard; 15:55:58 15:56:01 15:56:04 15:56:06

a point I tried to make back when it was first chosen". Do you see that? 15:56:10 15:56:11

A Yes. 15:56:12

Q That's what you referred to earlier when you said you had called the second IRP a rotten standard on the record? 15:56:14 15:56:17 15:56:19

A Yes. 15:56:25

Q So, Doctor, is it your testimony based upon your expert report that despite the fact that you believe that the second IRP is a rotten standard, nonetheless, it would provide guidance as to how you would actually determine units for radioimmunoassay for erythropoietin? 15:56:26 15:56:29 15:56:32 15:56:38 15:56:43 15:56:46

MR. MADRID: Objection, lacks foundation, and it's argumentative. You are putting two different things together. 15:56:48 15:56:50 15:56:55

A The only answer I can give to that question is, it was only one international reference preparation. If you didn't use that, people wouldn't know what you were talking about. 15:56:58 15:57:00 15:57:04 15:57:09

BY MR. SUH: 15:57:09

Q Couldn't they make their own standards? 15:57:13

A Not primary, no. Well, I suppose they could go back to cobalt chloride. 15:57:18 15:57:22

Q Sure. That was -- wasn't that the first standard that you developed? 15:57:24 15:57:26

A Yes. 15:57:28

Q Do you know whether people were referring to the first IRP standard in 1983? 15:57:31 15:57:37

A That was not cobalt. The first IRP, I think, was Standard A -- no, I think it was a urinary preparation. I don't remember. I would have to look that up. 15:57:41 15:57:46 15:57:48 15:57:53

Q But do you know whether anyone in 1983 was still referring to the first IRP standard? 15:57:55 15:58:02

A I don't know whether anyone was still using it. I rather doubt it because the reason for the second one was that there wasn't enough of the first one to go around. 15:58:05 15:58:07 15:58:09 15:58:12

But with proper standardization, it didn't make any difference what you referred to. Everyone knew what you were referring to, or what it meant when you gave a result in units or milli units. 15:58:15 15:58:16 15:58:20 15:58:25 15:58:42

Q Doctor, is the -- is the reference to a second IRP standard mentioned in the 349 patent? 15:58:47 15:58:52

A I don't know. Do you want me to look through the whole patent -- 15:58:54 15:58:56

Q Do you recall? 15:58:57
A I don't recall. 15:58:58
Q Does the 349 patent have a discussion 15:59:01
with respect to calibration from the a secondary 15:59:04
standard to a primary standard? 15:59:06
MR. MADRID: Objection, vague and ambiguous. :59:11
A Again, I'm not committed this to memory. 5:59:14
I would have to look for it in the document. 15:59:16
Q I'm sorry. Do you recall -- do you 15:59:18
recall? 15:59:19
A I don't recall. That's what I'm just saying. :59:22
I don't have any memory of it. 15:59:28
Q Doctor, can you turn to -- going to 15:59:35
Exhibit 5, which is the 349 patent -- 15:59:40
A I didn't hear what you said before 349. 15:59:43
Q I'm sorry. I want you to look at the 349 5:59:48
patent which was marked as Exhibit 5. 15:59:51
A Yes, I've got that. 15:59:52
Q Okay. Do you see on the second page, 16:00:02
there is -- on the very top middle, it says "page 16:00:05
two"? 16:00:06
A Yes. 16:00:06
Q And then there is page three, four, five, 6:00:09
and it goes on all the way up to page 11. Do you 16:00:14

see that? 16:00:15
A Yes. 16:00:15
Q And then the next page, there is a 16:00:16
figure 1? 16:00:17
A Yes. 16:00:18
Q Okay. 16:00:23
Q Can you tell me what figure 1 is? 16:00:29
A It's a dose response curve of an RIA or 16:00:37
four different runs with a standard curve and three 16:00:48
samples. 16:00:51
Q Do you know what this particular standard 6:00:53
was, this RIA standard human EPO that's being 16:00:57
reported here in figure 1? 16:00:58
A No, but it's probably in this document. 16:01:00
I would have to look for it. 16:01:08
Q Have you ever -- have you ever looked in 16:01:12
the patent to find the data which was used to 16:01:16
generate these dose response curves? 16:01:21
A I don't know that the data are in here. 16:01:24
As I keep saying, I've not committed this bulky 16:01:27
piece of paper to memory. 16:01:33
Q Can you spend some time to try to look 16:01:36
for me where that data is? 16:01:38
A You want to look for the data and the 16:01:40