UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GmbH, and HOFFMANN-LA ROCHE INC. Defendants.	CIVIL ACTION No.: 05-CV-12237WGY **[REDACTED VERSION]**

APPENDIX B, EXHIBIT 1 TO DEFENDANTS' MEMORANDUM IN SUPPORT OF ITS MOTION TO COMPEL PRODUCTION OF DOCUMENTS IMPROPERLY WITHHELD ON GROUNDS OF PRIVILEGE

The filing of this confidential exhibit has been deferred pursuant to the provisions of the Court's Order entered on 2/7/07 [274].

Dated: March 27, 2007
Boston, Massachusetts

Respectfully submitted,
F. HOFFMANN-LA ROCHE LTD,
ROCHE DIAGNOSTICS GMBH, and
HOFFMANN-LA ROCHE INC.

By their attorneys,
/s/ Robert L. Kann

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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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APPENDIX B, EXHIBIT 2 TO DEFENDANTS' MEMORANDUM IN SUPPORT OF ITS MOTION TO COMPEL PRODUCTION OF DOCUMENTS IMPROPERLY WITHHELD ON GROUNDS OF PRIVILEGE

Dated: March 27, 2007
Boston, Massachusetts

Respectfully submitted,
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EXHIBIT
2

In the Matter of:

Amgen, Inc. v.
Hoechst Marion Roussel, Inc., et al.

Trial Volume 21
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in —
Q: And the work you were doing at that time, "Gene's standard," is Dr. Goldwasser's pooled EPO; isn't that right?
A: It's my understanding that Gene's standard referred to — it's my understanding now that Gene's standard refers to material that Dr. Goldwater — Goldwasser obtained as a pool of urine from aplastic anemia patients.
Q: And going back to Column 28 of the patent, line 40, when you wrote, "The pooled source human urinary extract," that's a reference that — to Gene's standard; isn't that right?
A: Well, I wouldn't connect it to Gene's standard, because — but I was referring to pooled source urinary erythropoietin.
Q: And the only — isn't it correct that the only one you had been told about at that time was the one that came from Dr. Goldwasser?
A: The time being November of 1984?
Q: That's correct.
A: I believe that — well, it's my recollection that the information I got from Dr. Lin and his coworkers about carbohydrate analysis or characteristics was — involved a reference to material from Dr. Goldwasser.
Q: Thank you.

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A: I didn't use the word "standard," but —
Q: I appreciate that, but the pooled source human urinary extract was the material received from Dr. Goldwasser; is that correct?
A: I don't recall being aware that Amgen had any other pooled source urinary EPO product.
Q: Other than this? Other than what it told you it had gotten from Dr. Goldwasser?
A: I'm pretty sure I understood that it was Dr. Goldwasser's material.
Q: Thank you.
Now, it then goes on to say in the next line of page 22, "Size of CHO cell materials is larger than COS or Gene's standard."
Do you find that? That's the very next line.
A: Okay.
Q: And then it says, "CHO is —" looks like "— approximately equal to Lot 82 EPO."
A: It looks to me like "CH" stands for "carbohydrate," then SDS, then there's a wavy line. It doesn't say approximately, it's a wavy line, which isn't approximate, to Lot 82 EPO.
Q: It says as seen in Section 3?
A: That's what it says, yes.
Q: If we turn to Section 3, that's on page 6.

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A: I have hand-numbered at the top right, page 6, and there's a Roman Numeral III right at the top there.
Q: And that says, "Heterogeneity of native human urinary EPO." Do you find that?
A: Yes.
Q: And that says, "Comparison of EPO from two different patient sources"; correct?
A: Yes, it does.
Q: And the first source is identified as Gene Goldwasser's EPO. Do you find that?
A: Yes.
Q: And that's the pooled EPO we've been talking about; isn't that right?
A: Well, I only understood there to be —
Q: One pooled EPO?
A: One source of EPO, and that was the pooled EPO.
Q: And then right under, it says, "Lot 82 urine was provided by Kirin Brewery — from Kirin Brewery from Japan."
Do you find that? It says the material was purified to homogeneity at Amgen, by Amgen and Kirin scientists jointly?
A: Urine was provided by Kirin Brewery, it looks like, "and is from one patient."
Q: "One patient," I'm sorry. That's right.

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A: "The material was purified to homogeneity at Amgen by Amgen and Kirin scientists jointly." That's what it looks like to me.
Q: And isn't it correct that that's the Lot 82 EPO which is referred to on page 22 that we talked about a few minutes ago?
A: I have no reason to doubt that that's — that these are references — I mean, the same Lot 82 and Lot 82.
Q: Now, you say, going back to Column 28 of the patent, that these studies indicated that the CHO-produced EPO material had a somewhat higher molecular weight than the COS 1 expression product. Do you find that?
A: Yes.
Q: And the CHO-produced EPO is the EPO that's the recombinant EPO that was the subject of Example 12 of the patent; right?
A: Example 10. I believe the CHO-produced EPO material that was referring here is this — is the material obtained from Chinese hamster ovary cells as described in the immediately before preceding text of Example 10.
Q: That's right. And the COS-1 expression product, that was the — that was the material of both human and monkey made in COS cells that was described in the patent; is that right?
A: Now, this, the COS-1 material here is using human — it

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says in the third line —
Q: Yes.
A: — line 35, third line of the paragraph, it says, "Conditioned medium," so it's the stuff outside the cells growing in the medium, "of COS-1," and these are monkey cells, "and CHO," those are Chinese hamster ovary cells, "expression of the human EPO gene."
Q: So that was human and COS cells; correct?
A: That's correct, that was human and COS cells.
Q: And you're reporting here that EPO and CHO had a somewhat higher weight than EPO and COS; right?
A: That's right.
Q: And then you say the COS was, in turn, slightly larger than the pooled source human urinary extract?
A: That's correct.
Q: And going back to Note 1, it said, "Size of Gene's standard is approximately equal to the size of COS-produced EPO."
Do you find that?
A: You're going back to page 22 of 2400?
Q: That's correct.
A: Middle of the page where it says "note," and it says "approximate EPO," yes.
Q: That's correct. And it refers back to Paragraph 4 of this document; correct?

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A: That would be consistent.
Q: And —
A: Paragraph 4 doesn't — I'm sorry. I'm sorry.
Q: Paragraph 4 is on page 17. Are you looking at page 17?
A: Have we looked at that before?
Q: I don't believe we have. And what it says in Paragraph 4 is: Recombinant monkey and human EPO produced by COS cells have the same molecular weight as native urinary EPO, Goldwasser's EPO. This result indicates that the recombinant EPO is glycosylated to the same extent as the native protein.
Do you find that?
A: I'm finding it, yeah.
Q: And so that's saying that at least the human EPO produced in COS has the same molecular weight as Goldwasser's EPO; correct?
A: That appears to be what this document says.
Q: That's right. And as I said, on page 22, it — I read from earlier, the reference would be approximately equal to that paragraph; correct? We just looked at that.
A: Those are inconsistent.
Q: Why are they inconsistent?
A: They can't be the same and approximately equal.
Q: One says approximately equal to and one says the same.
A: Yes.

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Q: Okay. Now, going to the patent, you say in the Paragraph 33 — I'm sorry, Column 28, line 39, "The COS expression product which in turn was slightly larger than the pooled source of human urinary extract."
My question is, sir: What information did you have to rely on to write that, in addition to the two references I referred you to in document 2400?
A: Well, I'm — that was information that I got from Dr. Lin or his coworkers. I discussed the experiments with them, and that was the sum of the information that I had.
Q: That's based on some information that you got in some verbal form; is that right?
A: I don't recall getting it in written form.
Q: And did you ever compare that information to what we've been looking at in document 2400?
A: Yes, I have. In the context of this litigation.
Q: I meant at the time you prepared the application.
A: I have no recollection of having 2400 at the time I prepared that text of the application.
Q: You have no recollection of having it?
A: No, I do not.
Q: So you can't tell one way or another whether you made any use at all of 2400 in preparing that portion of the application; correct?
A: Ah, no, I can't.

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Q: And can you point me to any other writing that you were aware of at the time, other than 2400, that discusses the specific issue to which I'm now talking about, which is why the COS-1 product was, quote, slightly larger than the pooled source human urinary extract here?
Do you have any writing in mind that you relied on at that time?
A: No, not a writing. No.
Q: Nothing. Okay.
A: Not that I have nothing, I have no writing.
Q: You have no writing, that's right.
Now, it's correct, is it not, that in the discussion of urinary EPO, in the paragraph we're talking about, you make no reference to the Lot 82 EPO — isn't that right? — or a single-source EPO? What I'm talking about is Column 28, line 33 to line 50.
A: No, I was referring to EPO obtained from, you know, pooled urine from aplastic anemia patients.
Q: And that's all you referred to in this paragraph; isn't that right?
A: That's all I knew about, yeah.
Q: That's all you knew about. So it's your testimony that you never heard of Lot 82 EPO at the time you prepared the application?
A: I have no recollection of knowing about Lot 82 EPO at

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the time I prepared the application, the November 1984 application. That's the text of which is in the '933 patent.
Q: Nobody ever told you anything about that at the time?
A: Not at that time. I don't have any recollection or knowledge of a Lot 82 or single-patient source EPO.
Q: So you have no recollection of having ever gotten any of the information which Joan Egrie says she sent you in Exhibit 2400; isn't that right?
A: I — I don't — as I said in my deposition, Dr. Egrie seems to recall giving it to me in person. I have no recollection of that. It appears, from the front of 200, that it was sent to me and Mary Boc. And I have no recollection of when I had it or whether I looked at it. It apparently went into the file marked "Egrie input."
I had input files from a number of people, but I didn't — I have no recollection of looking at this collection of documents in preparing the text that you're referring to in Column 28. I may have discussed this with Dr. Egrie. She seems to recall talking to me about it. That doesn't sound unreasonable since, apparently, she and a coworker, Dr. Lane, did this work together.
Q: In fact, in Exhibit NYD it states, and we looked at this earlier, "On page 22 of the Egrie input document, results of SDS-PAGE gels are summarized in a way which

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parallels the description in the '933 patent."
Do you find that?
A: I — yeah, I see that. I agree with it.
Q: My question is: Doesn't that refresh your recollection that when you prepared the information in Paragraph 28, Column — lines 33 to 50, you, in fact, used the information from page 22 because, in fact, the information is parallel, comes out just the same way; isn't that right?
A: Does it indicate that I used it? It indicates it's the same information. I mean, I got that information from someone, Dr. Egrie, Dr. Lin, Dr. Lane. And this NYD says it's parallel information.
Q: It says that it's summarized in a way that parallels the description in the patent. It doesn't say there's parallel information. It says it summarizes in a way that parallels the description in the patent.
And my question is: Doesn't that refresh your recollection that in fact, you had page 22 in front of you when you wrote that information in the patent?
A: No. No. This — I didn't prepare NYD, I'm sorry, but I agree with it. Now, sitting here essentially as counsel for Amgen, I agree with that statement made by other counsel for Amgen.
Q: That is, summarized it in a way that parallels the way it's summarized in the patent?

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A: I think that's accurate.
Q: But having seen that, you don't have any reason to believe that you actually used that to write it so it turns out in that fashion?
A: No, I don't. What you see here in Column 28 is something that was constructed by information given to me and passed through Dr. Lin, and that's it.
Q: What, if at all, do you attribute the parallelism to that's referred to in this memo?
MR. KNOX: Your Honor, this Mr. Casebeer, there's no foundation for that question since Mr. Borun already testified he did not see this memo or have any role in it, apparently.
THE COURT: It's not necessary to argue every objection unless — until I've made a ruling.
The objection is overruled. He may answer if he can.
A: I'm sorry, I've lost the question.
THE COURT: He's asking you why you think that, why it's so. Why does the patent summarize it in the way it is summarized there in 2400, if you know?
THE WITNESS: Okay. Well, your Honor, I just agreed with the statement today and I can give you my construction of this document today in comparing it to this one, as an attorney. I didn't have page 22 in front of me

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when I wrote this.
THE COURT: I understand that's your — wait. I understand that's your position. But he's asking you why the parallelism, and I'd like to hear your explanation today, if you can give me any.
THE WITNESS: Sure. Your Honor, it's — it suggests a stepwise kind of experimental result where you have three things, none of them are equal to each other, okay, and they line up, the three of them. So you have one that's clearly the heaviest or the larger molecular weight, that means it doesn't go as far on the gel, then you have two others. The first one is the Chinese hamster ovary stuff. And you have two others and they aren't the same.
So you've got, like, three steps. They're — each of the others is different from the Chinese hamster ovaries.
Then on page 22, it goes on to address the difference between urinary and COS cell material after neuraminidase treatment to say that the urinary and COS cells are different.
So that's also consistent with it. But, your Honor, that's really a construction I'm doing here for you today.
THE COURT: I appreciate it. And I understand that's what Mr. Schwartz was asking and I just allowed him

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to have it.
Go ahead, Mr. Schwartz.
Q: A couple of brief questions, a couple on Exhibit 2400, and we'll move on. Just look at page 6 for a minute. We talked a little bit about that.
Under the summary, that says, "Gene's EPO is 3400 — 34,000 MW, Lot 82 EPO is 35 to 36K." That's a reference to the molecular weight of the different EPOs; isn't that right?
A: That's what I would read today.
Q: In daltons, one is 34,000, the other is approximately 35 to 36?
THE WITNESS: Your Honor, just for your information, we're looking at page 6 of 2400, and Mr. Schwartz has called my attention to a little bit down the page, heading "Summary," and it's the second sentence that he's read to me. And he's asked me if I think that's a reference to molecular weight in daltons, and I said that as I read this, it's a fair characterization.
Q: The second point of it is the difference in molecular weight is most probably a difference in the extent of glycosylation. And my question is: Do you have any recollection of being told that at that time?
A: In November of '84?
Q: That's right.

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A: No.
Q: Never learned any of this in that time; right?
A: Not in that time frame. This document came up in the interference and —
Q: I'm just asking for that time frame. Your answer is no?
A: My answer is no, sir. Sorry.
Q: And that's, presumably, if I go through any of the other detail, it will probably be the same answer, I guess; right? You don't recall anything in this document?
A: I don't recall having this document or reading anything in this document when I was preparing the November '84 application. I had, obviously, information that this development relates to, that's what I used to prepare the graph.
Q: Thank you. Now, I believe going on in the patent to the remainder of Column — of that column, Column 26 — I'm sorry, Column 28, there's then information starting at line 51 concerning carbohydrate analysis; correct?
A: Yes. This is carbohydrate analysis, starting at Column 28, line 51 and going across the next column.
Q: That's right. And it would be fair to say, wouldn't it, that when you go to Column 29, in your conclusion, "Glycoprotein products provided by the present invention," and so forth, that information in that paragraph is really

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directly supported and directed to the preceding column — preceding paragraph, that's the conclusion that flows from Column 28 starting at line 29; isn't that right?
A: Probably 28, line, let's say, 33.
Q: Thirty-three, I'm sorry.
A: Yeah, that's a fair statement that this summary at the top of Column 29 addresses the previously mentioned characterizations, yes.
Q: That's right. And there came a time when you learned that the information in Paragraph 50 — in Column 28, starting line 51 to the end was wrong; isn't that right?
A: There came a time when I found out that the hexose value for the recombinant product was probably wrong, and that the fucose value for both the recombinant and the urinary product was probably wrong.
Q: That's right. And that time was probably no later than 1990, 1991 — isn't that right? — in and around that time frame?
A: That's a good estimate. It was in the context of submissions in the inference.
Q: Now, you never did anything to correct that in this patent; isn't that right?
A: No. Those are the values that we had when it was written in 1984 so, I mean, you can't go back and change things.

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Q: Now, you filed a number of continuation applications based on this patent, on that application; isn't that right?
A: That's right.
Q: And in fact, each of the patents in suit is based on a continuation application filed subsequent to 1991; isn't that right?
A: Mr. Schwartz —
Q: I'll give you —
A: I would agree with you subject to correction.
Q: I can't keep all of these in my head. This might help.
A: Can I agree with you, subject to correction, or should I just figure out the colors and...
Q: No, basically, to go through it quickly, I mean, it just shows that the five patents in suit are in orange, and at least the last applications were filed in either '95, four of them, and one of them in '93. That's the simple point.
A: Well, that's what this shows.
Q: I'll represent that's accurate, okay?
A: Okay.
Q: Based on that, isn't it correct that when you filed each of those continuation applications, you never did anything to take out this incorrect carbohydrate data; isn't that right?

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A: Well, at least some of those I didn't file, but, no, there were no — it's called a continuation application. The specification stays the same as it was and has the same information that we had in 1984.

Q: And so when you decided to get additional applications based on that disclosure, you didn't correct what you knew then to be a mistake; isn't that right?

A: It wouldn't be a continuation application, then. If there were changes in the data, then that would be a continuation-in-part application. So that's not a continuing attempt to secure patent protection based on the same information that was filed in 1984.

Q: The reason, the consequence of that, of filing it as a continuation application, is filing it with data known to be wrong — isn't that right? — at least with respect to that paragraph? Isn't that what you did in at least four of the five?

A: The reason for filing the continuation application is to reserve the original filing date. And at the original filing date, there was no knowledge that this information was wrong. This was the best information we had.

So when you file a continuing application, you preserve the original, the original date. So in other words, so that's what we had in 1984.

If we wanted a new date, we had a new invention

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and we wanted to add some other kinds of information, that would have an effective date of when you filed that.

Q: I don't want to argue with you about it. I take it from what you're saying, you viewed this as an appropriate use of the patent laws?

A: No, absolutely.

Q: There's no doubt that you were aware that that information was false when these continuation applications were filed; isn't that right?

A: No, it's not false. It's the information we had. I can't go back — I can say it's wrong, but I can't go back and say it was false.

Q: As of the date you filed the continuation application, each of which was later than 1991, you knew that as of 1993, '95, what you were putting in it to rely on going back to an early date was incorrect data; that's all I'm asking?

A: I knew that the hexose value for the Chinese hamster ovaries analysis was incorrect probably, even though that's what Dr. Lin gave us. And I knew that the fucose value was incorrect for both the Chinese hamster ovary product, and the urinary EPO as of the point in time that you said, sometime certainly by 1990.

These applications were filed later than 1990, they all relied back to 1984. And at the time in 1984 when

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that information went in, it was correct.

Q: Isn't it correct that in other countries of the world, when you filed later applications, you corrected that data?

A: No. It occurred in South Africa that in the context of this proceeding, our South African counsel, when advised that the hexose values and fucose values were incorrect, said take it out.

And in Europe, in the appeal, when the European Board of Appeals were advised that those were incorrect, they said, not just attorneys, the European Board of Appeals said, Well, get it out of there.

Q: So at least in Europe and in South Africa, that information ended up being taken out of the counterpart package; isn't that right?

A: The South African counsel advised it and the European Patent Board of Appeals, the highest tribunal in Europe said, Oh, yeah, take it out, it didn't have any effect.

Q: Isn't it correct that you made numerous corrections to the '933 patent? In other words, you filed certificates of correction with all sorts of different corrections; isn't that right?

A: Those are corrections in the text and they fall into two parts. One set, you know, things that we had in there originally that were wrong, typographical errors, and also errors that the patent office made in the printing process.

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So that's a Certificate of Correction, goes — doesn't go to any substantive change in the patent, doesn't say white is back, black is white. It just says this word is misspelled.

Q: What you're saying is that you didn't believe it would be appropriate to change that information by Certificate of Correction?

A: No, that's the information we had. I mean, there was nothing wrong with that information when it was put out.

Q: Even though by the time you filed continuation applications you knew it was wrong; right?

A: When we filed the continuation application, we asked for our November 1984 date. And as of November 1984, that was the best information we had. It was only during the interference that Dr. Lin's raw data came in and it could be determined that Dr. Yu made a mistake, the person trusted to do this analysis at Yale University.

Q: Isn't it correct that you believed if you changed that information you'd lose your early filing date; isn't that what you told me?

A: With respect to a claim, for example, that went to those specific data points. If I had a claim that then said with the hexose — a recombinant product with the hexose ratio vis-a-vis urinary of 15.09, and I wanted to change that to 1.62 or something like that, I'd only be

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entitled to that later date for the 1.62. I don't have any claims like that.

Q: So at least as to that, you'd agree that it would be a problem; right?

A: No, it's not a problem. You're only entitled to the date you put it in.

Q: I understand what you're saying.

Now, I'd like to go to the prosecution of the '933 patent for a moment, and I'd like you to look at Exhibit NWP, which I believe has been admitted as 2131 — I guess 2161.

Do you find that?

A: I have that. Yes, I do.

Q: That's an amendment and your response that you submitted in connection with the parent application or one of the applications in the chain of '933; right?

A: I think — I'll take your word for it.

Q: Sure. You're welcome to look at that.

A: I'll agree with that subject to correction.

Q: Okay. And on page 4 is an example of a claim pending there, but claim 87 which has the phrase, "Having glycosylation which differs from that of human urinary EPO."

Do you find that?

A: On page 4, which is —

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Q: 909 at the bottom.

A: Document AM27020909, the text there of claim 87 has the wording, "and having glycosylation which differs from that of human urinary erythropoietin," so it means that it was in claim 87 originally, that's why it's not underscored. The new stuff is underscored. The old stuff is in brackets.

Q: If I didn't make it plain at the beginning, this is an amendment that you prepared on or about the date it bears, and namely, February 16th, 1995; correct? It says it on page 12.

A: I believe that's right.

Q: And going on from there, on page 8 you discuss — on page 6, I'm sorry, you discussed the rejection of claim 87. Do you find that?

A: Prior rejection before the amendment, right.

Q: That's correct. You have a reference to the rejection under Roman Numeral II.

Do you find that?

A: Yes. Second full paragraph says —

Q: Exactly. And then going on to page 8 and 9, you say at the bottom of page 8 and top of page 9, "As confirmed by the Takeuchi article cited by the Examiner, the glycosylation of recombinant EPO products is different from that of urinary EPO. The fact that recombinant EPO is

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inevitably different in its glycosylation from urinary EPO is manifest from the attached copy of the January 1994 expert statement of Dr. Richard Cummings," so forth; right?

A: That's what it says, yes.

Q: And so that's what you were arguing to the examiner at that time, isn't it; that recombinant EPO is inevitably different in its glycosylation from urinary EPO? Correct?

A: Different, that's "inevitably." I think that's probably Dr. Cummings' word in the attachment.

Q: It's your word in the amendment, isn't it? It's your word in the argument?

A: Well, I'm referring to Dr. Cummings' statement.

Q: You wrote those words. That's what you said, isn't it?

A: Yes, I did.

Q: Thank you.

And you attached Dr. Cummings' declaration?

A: Yes, I did. It was a declaration that he prepared for Europe.

Q: And I mention parenthetically there's been some question about whether the declaration was attached or not. As far as I'm concerned, it was attached and it's there, and we don't have any quarrel with that.

A: I think the examiner referred to it in the subsequent action, so it was there.

Q: I did say that to cut away any underbrush or squabbling

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which awakened me about 11:00 last night.

A: I'm sorry.

Q: I take it in making this argument, as of this time, you still didn't know anything about Exhibit 2400, the Egric input; is that correct?

A: No. I think this was sent in in February of '95, and I said I knew about the existence of the document prior to 1995.

Q: I take it, though, that you never brought to the attention of the examiner the information in the Egric document that we went through earlier; isn't that right?

A: The examiner had that information in the form of — this document was in in the interference, and the issue of similarities and differences between urinary and recombinant was an issue in the interference cited favorably to Amgen.

THE COURT: Mr. Borun, Mr. Borun, wait. Wait a minute. Wait a minute. Mr. Borun, when you say "this document" was in in the interference, to what document do you refer?

THE WITNESS: The document that we have been referring to as the Egric input document, your Honor.

THE COURT: Thank you.

THE WITNESS: That's Trial Exhibit 2400, was an exhibit in the interference.

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Western analysis," and goes and gives you some analysis.
If you turn to Figures 50-20 and 50-26, Figure 50-20 is the analysis. And the ultimate conclusion here is that the R-HuEPO migrates identically to the pure urinary EPO with an apparent molecular weight of 36,000 daltons.
Do you find that?
A: I find the last sentence on page 0898, not the last sentence, the penultimate sentence says that.
Q: And it's correct, is it not, that you didn't provide this specific information to the patent examiner in connection with the amendment as we've been talking about for the last half hour or so; isn't that right?
A: This wasn't an attachment to Dr. Cummings'.
Q: That's correct, it was not. You didn't provide it separately; isn't that right?
A: Is the data that's referred to part of one of the papers, the Browne publication, for example?
Q: Not that I know of. As I understand it, this was a submission to the FDA made in September 1995.
A: It's data, it's scientific data.
MR. CASEBEER: Your Honor, may I interrupt? If I could ask Mr. Schwartz to keep his voice up.
THE COURT: Sure.
MR. CASEBEER: It's very hard to hear back here.
THE COURT: Thank you. And you can feel free to

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move in the courtroom, sir, because the focus is only on the witness. So you can come closer.
MR. CASEBEER: Thank you, your Honor.
Q: And I'll represent to you that the data which is the subject of this exhibit has been already established in this lawsuit to be Lot 82 EPO. This is a comparison of CHO, which was the recombinant EPO used by — in the commercial product and Lot 82.
A: Well, I know that in this or a preceding application, there was comparison by Western analysis of Lot 82 and CHO material by Dr. Strickland. And it went in as the Strickland declaration. If this is the same stuff, it was before that.
Q: My question is: Did you bring this to the attention of the examiner in connection with the amendment we've been talking about; yes or no?
A: I already said I have no recollection of seeing this document before, and no recollection of it being an attachment to Dr. Cummings' —
Q: The answer is no; correct?
MR. CASEBEER: Mr. Schwartz, I didn't hear —
Q: The answer is no as to this document in that declaration?
A: This document, to my knowledge, is not a part of that declaration.

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Q: Thank you.
A: The data might be in the publications referred to in the declaration.
Q: But as you sit — well, let's leave it at that. The document isn't a part of it; is that correct?
A: Yes.
Q: And would you look, please, at Exhibit 2163? And this is just further on in the prosecution of the continuation application which issued as the '933.
Do you find that?
A: I'll accept your representation of it; correct.
Q: Sure. And basically, what this amendment shows is that you were then prosecuting claims 180 and 181 which ultimately became claims 1 and 2 of the '933 patent.
Do you find that? It's on page 2.
A: I — that's a suggestion here. Yes, I believe that's true. I'm looking at Exhibit 8EC and claims that are in Column 38 and claims 1 and 2 appear to be as set out on the second page of this document, 2163, as claims 180 and 181.
Q: And in going back to page 3, what you say, in effect, is you compare what we now looked at as new claim 100 to claim 87 which we were talking about in the prior application; correct?
A: Right.
Q: And then you go on to argue on page 5 further that at

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least the patentability as to the second of those claims; right?
A: I'm sorry, are you —
Q: If you go on top of page 5, it says, "New product claim 101," the second one which we're talking about, finds written support at page 64, line 20 through page 65, line 3 where glycosylated COS and CHO cell products were noted to have higher SDS-PAGE molecular weights than the human urinary isolate, molecular weights that the glycosylated products being the same, is that right?
A: Yes.
Q: And that was an argument which ultimately eventuated in claim 2 of this patent; right?
A: It's not an argument, it's a citation to support this specification.
Q: That's right.
A: The issue is whether or not these limitations are supported in the specification.
Q: That's right. And as a consequence of that argument, those claims issued, correct, and became claims of the patent?
Well, strike it.
The next thing that happened is the claims issued?
A: If you say so.
Q: Yes. Thank you.

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A: This is deposited December of 1995, and the patent issued in August of 1996.
Q: I'll represent to you that as I read the file history, that's the last thing that happened before they issued. If I'm wrong, someone will correct me, but I don't think there's any dispute about that. All I'm really doing is tying up what we've been talking about earlier, the earlier argument.
I can take those away, if you like. I'm going to go on to another topic.
A: Should I keep the '933?
Q: I think that's probably a good idea.
Now, I'd like to talk a little about the application that eventuated — this is the — why don't you take a look at Trial Exhibit 2165. And this is an amendment, I guess it's an interview summary is what it is. And this is a record of an interview that you attended with Mr. Watt and Examiner Martinell.
Do you find that?
A: This top thing is the — is the document generated at the patent office by Dr. Martinell. I believe it was essentially concurrently with the — with the interview. In other words, the — he had a word processor, he had a macro that had this form on it, and he filled in the blanks and generated this document at the end of our interview.

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That's the top page.
Q: Sure.
A: The subsequent pages are what appear to be some claim form drafts. And then the next two pages are — three pages are what's called a terminal disclaimer, where the applicant agrees that upon issuance of claims under consideration, the patent — any patent that issues will extend only so long as some other patent already in existence. So that —
Q: Let me show you one other document which is — a third preliminary amendment which you prepared at in or about — or I believe you prepared in or about December 1966 — 1996, I'm sorry.
Do you have that?
A: This is about six months after — six months before — oh, I'm sorry. This is filed December of '96, so it was a few days after the interview which is referred to in the interview summary of Exhibit 2165.
Q: That's right. I'd like you to turn to page 9 of the second document.
A: Yes.
Q: And in the third full paragraph, it states that, "Applicant notes that claims 69, 70 and 71 all differ in scope from glycoprotein claim 1 of U.S. 5,547,933 in specifying that the claimed subject matter comprises the

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mature human erythropoietin sequence of Figure 6." And in the footnote, it says, "Support to the reference mature sequence is found in the specification at page 48, lines 33 to 35."
Do you find that?
THE COURT: Mr. Schwartz, I don't find it. What page?
MR. SCHWARTZ: Looking at the document which says page 9, of Exhibit 2166.
THE COURT: Thank you.
MR. SCHWARTZ: On the bottom, there's a little 9.
THE COURT: I find it. Thank you. I have it.
THE WITNESS: It's the third paragraph, your Honor.
THE COURT: Thank you.
MR. SCHWARTZ: I've read him the third full paragraph plus the footnote.
THE COURT: And I have it.
A: The first sentence and the footnote.
Q: The first sentence of the footnote, that's right.
A: No, the first sentence of the third paragraph, plus the footnote.
Q: That's right. And I'd like to show you Exhibit 2167, and that's the reference in the specification to which you were referring; isn't that right? Page 48, lines 33 to 35.

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A: Well, is it your representation that is what I was referring to?
Q: I'm asking you.
A: This is a Choate, Hall fax, so I don't know.
Q: I'm representing that those are pages 48 and 49 of the specification as filed.
A: You're telling me those are.
Q: Yes, I am.
A: Well, if they are, then ask me a question.
Q: Having that in hand, is that what you were referring to?
A: The footnote refers to page 48, lines 33 to 35, and you've represented to me that the second page of 2167 is the page 48 that I was referring to. So —
Q: Now, at the time you made that argument, you knew that the mature EPO — that mature EPO expressed in CHO cells was 165 amino acids long; isn't that right?
A: That's correct.
Q: And you also knew that in the patent that it was said to be 166 amino acids; isn't that right?
A: No, that's not what it says.
Q: What does it say?
A: The codes for potential mature sequence of 190 — well, 193 amino acids, 27 of which are processed off at the front, and Lord knows what's processed off at the back.

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Q: As far as you're concerned —
A: The gene codes for it. And I'm — and in Chinese hamster ovary cells, it was later discovered, as — that the product is processed through 165, at least predominately. In other cells, it might not be. In other cells, it might be left alone at 166.
Certainly it's that way in yeast cells. Yeast cells don't process it off, 166 amino acids. Ah, I believe that — it's been represented that hamster kidney cells don't process off 166. There may be cells that process off more than the 166 amino acids. But 166 is the starting point that was known at the time of filing.
Q: And as time went on does that change?
A: No, it still holds, it goes for 166.
Q: And as time went on, it became known for different products that at times it was chopped off in different ways, right? 165 —
A: At least with respect to CHO cells, it was determined first by Genetics Institute in publications that are in this record, and the record of this prosecution, and then later challenged by others that a CHO cell product terminates with the 165th amino acid.
Q: So based on that, as far as you were concerned, it was appropriate to continue to process this claim in this fashion; right?

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A: This claim, set forth in this way, would cover, in my mind, 166, 165, whatever the process format is in the particular COS cell.
Q: Given that understanding, that was your basis for pursuing it at this time; correct?
A: I'm not sure I understand that question, but I think the answer is yes. You're asking me my understanding of the scope of this claim and this claim is —
Q: That's right.
A: — claim 69, that appears on page 7 of 2166?
Yes, that's a fair statement. The mature EPO amino acid sequence of Figure 6 means the mature or processed form. If maturation doesn't involve cutting off the signal, and it doesn't get cut off or doesn't all get cut off. If it involves other cuts, you know, as long as he used that.
Q: Thank you.
MR. SCHWARTZ: Your Honor, I'm about to start another topic. I can do it now, or I would just as well take our 15 minutes now.
THE COURT: We will take the 15 minutes now. We'll stand in recess for 15 minutes until about five minutes of 12:00. We'll recess.
THE CLERK: All rise. Court is in recess.
(Recess.)

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THE COURT: Can you hear me there in Chicago? You can hear me there?
MR. CASEBEER: Yes, your Honor.
MR. SCHWARTZ: Yes, your Honor.
MR. CASEBEER: Can you hear us?
THE COURT: Let's continue.
THE CLERK: Court is in session.
DIRECT EXAMINATION (Cont'd)
(BY MR. SCHWARTZ:)
Q: Mr. Borun, I would like to show you three documents which have been marked as Trial Exhibit AHa, AHb and 2410. Just give them to the witness. Looking first at AHa, Mr. Borun, I believe you were in the courtroom when we discussed this with Dr. Lin. Do you recall that? This is the portion of the original specification? Do you find that in red brackets?
A: Yes.
Q: And there's the phrase monkey origin DNA in monkey host cells in culture and human DNA.
A: You're looking at AHa, last page, with the 47 at the bottom and 48 at the top, correct?
Q: Right. That's right.
A: I have that page, yes.
Q: That's right. And looking, looking at AHb.
A: AHb.

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Q: Yes. And Page 117.
A: 59 at the bottom, 117 —
Q: Exactly.
A: — at the top, is that right?
Q: That's it.
And what it shows is that in the first application the phrase "human DNA in" appears, correct?
A: Yes.
Q: And it's highlighted —
A: In green.
Q: In green, that's correct.
And that phrase no longer appears in the second application, correct?
A: Well, the sentence has been changed in two ways. "Actually" has been inserted in the phrase —
Q: Correct.
A: — or the fragment, sentence fragment "human DNA in" no longer appears in AHb.
Q: And those represent changes you in fact made; isn't that right?
A: They do not — the addition of the term "actually" is a change that I intentionally made. The deletion of the term "human DNA in" is not a change that I made.
Q: Well, sitting here today you have no recollection one way or another as to how that occurred?

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that expression was not as good as in, as in COS cells, that's why the COS cell was picked to put in the application. That was Dr. Lin's testimony.

Q: And my question is, does that, as best you can recall, does that accurately, accurately reflect the discussion which you held with Dr. Lin on that subject at that time?

A: No.

Q: It does not. Tell me in what way you disagree with what Dr. Lin testified?

A: I wasn't aware of there being any picking. I wasn't aware of there being any human cell expression work at that time. I was aware of the intention that I provided to Dr. Lin, to Dr. Brown and others that I worked with on that project, that whenever a revision to the patent application was to be made, that is, whenever continuation in part application was to be filed, the best mode for practicing the invention had to be disclosed. So, that sounds, the part of Dr. Lin's testimony that you just quoted to me sounds like the result of a discussion concerning putting in the best data, but I was not aware that a picking had been done.

Q: I'm not sure I understand your answer. Is it your answer that you never had that conversation with Dr. Lin as he testifies?

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A: I don't think he testified that I, that he had a conversation with me. I think that — he said he picked data to give to me.

Q: That's why that, he says that's why the COS cell was picked to put in the application. And I take it that as far as you're — do you agree with that?

A: I don't know, that's his testimony that he picked it to put in.

Q: That's right. And —

A: But I was unaware of the picking process that he was describing.

Q: And he also testified that the human work wasn't included because the results from that was not as good as the COS work. Do you recall that discussion or that part of any discussion?

A: I had no discussion with him about human work.

Q: So you had — so it's your testimony that you knew nothing about human work at the time?

A: That's correct.

Q: Is that correct?

A: That's correct.

Q: When did you first learn about human work?

A: I think it was in the context of the interference where for purposes of putting in supportive declarations on priority Dr. Brown described that work. So we're talking about around 1989.

Q: So many years after the filing date of the parent application?

A: That's correct.

Q: Now, going on briefly to the, some events in the European opposition. Would you look, please, at Exhibit 2306a.

THE COURT: Mr. Schwartz, do you think you're going to be done with this witness by 1:30?

MR. SCHWARTZ: With difficulty, your Honor. I'm trying, I'm going to try to push it together and move it along as best as I can.

THE COURT: I didn't mean that critically. I just, we just have to make our plan.

MR. SCHWARTZ: I have that painfully well in mind and I'm doing what I can.

MR. CASEBEER: Your Honor, this is Craig Casebeer. I also have some questions of the witness.

THE COURT: Well, it's your witness so you'll have the burden of having him produced. The important thing is to get Mr. Schwartz's examination. You can handle the production of him.

Go ahead, Mr. Schwartz.

Q: Do you have that document?

A: Yes, I do.

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Q: Now, looking at Page 45 there's a paragraph that, in the middle starting at Line 35, the same as what we looked at is in the first parent application using the phrase human in human. Do you find that?

A: That's near the back of the exhibit.

Q: That's right.

A: It has production number AM27001250 and it says 45 at the bottom?

Q: That's right. Do you have that?

A: I have that.

Q: And so you would agree that as far as the European application that the same phraseology that we looked at earlier for the parent, the actual parent of the patents-in-suit appears, right?

A: I'm sorry, the —

Q: The words human in, human DNA in don't appear in that, in that portion, the same as in the ultimate patents-in-suit?

A: I believe that's correct. It never was part of the European application.

Q: That's right. That's right.

And I believe that you at least had some involvement in this prosecution, right?

A: Yes.

Q: Yes. And looking at, looking now at Exhibit QR,