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In the Matter of:

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

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- MR. DAY: His mike was off. [1]
- THE WITNESS: Would you like me to repeat the last
- [3] answer, your Honor?
- MR. SCHWARTZ: I think he would, Mr. Borun.
- THE COURT: Mr. Knox, wait a minute. We're not
- [6] doing too well here.
- Mr. Knox, is the systems person or the top person
- [8] out there in Chicago, can you do something for Mr. Borun's
- [9] microphone? I can't hear him.
- MR. KNOX: All right, your Honor. [10]
- THE WITNESS: Your Honor, the technical person has
- [12] placed another microphone in front of me. Is that better?
- THE COURT: It is much better, sir. Thank you,
- [14] Mr. Knox.
- Go ahead, Mr. Schwartz. [15]
- Q: You also represented Amgen in a number of foreign
- [17] patent applications; correct?
- A: I represented them in dealing with foreign agents and
- [19] attorneys. I am not licensed to practice in any foreign
- (20) country.
- Q: And but Paragraph 6 -[21]
- [22] THE COURT: Wait a minute.
- Mr. Knox, now we can't hear Mr. Schwartz [23]
- MR. KNOX: We're working on that right now.
- THE COURT: Thank you. I heard him well before, [25]

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- [1] but couldn't hear Mr. Borun.
- THE WITNESS: That's because I have his
- [3] microphone.
- MR. SCHWARTZ: We'll see if we can find a way to
- 151 get both of us
- THE COURT: You can approach him, Mr. Schwartz, if
- [7] it helps you.
- Isn't technology a wonderful thing?
- MR. SCHWARTZ: I'm just waiting, your Honor, while
- [10] he's trying to get it going.
- Is that any better? [11]
- [12] THE COURT: It is. Go ahead.
- MR. HALEY: Thank you. [13]
- Q: And in Paragraph 6.7 on page 5, you say you were
- [15] directly involved in the application in the way in which
- [16] you mentioned in that paragraph; is that right?
- [17] A: Yes, that's correct.
- Q: Also, you represented Amgen in a number of their [18]
- [19] litigations; isn't that correct?
- [20] A: Yes, I have
- [21] Q: And including that, you're one of the trial counsel for
- [22] Amgen in this lawsuit; is that right?
- A: Yes, sir, I have an appearance in this case.
- Q: And you also appeared as their counsel in the Chugai
- [25] litigation?

- A: Yes, I did. [1]
- Q: And also Amgen-Chugai interference? [2]
- [3] A: That's correct. That's noted in Paragraph 6.8.
- Q: Thank you Now, I'd like you to to show you two [4]
- [5] documents. One of them is a handwritten document that has
- [6] been marked admitted into evidence as Exhibit 2400, and
- another is a document which has been marked for
- (8) identification as NYD, a —
- THE COURT: Mr. Schwartz, you've got to talk right
- [10] into the mike, sir, I can't hear you.
- [11] Ask that question again.
- [12] Q: The first document is Exhibit 2400. Do you have that?
- [13] A: Yes, I do, Mr. Schwartz.
- Q: And the second document is marked for identification as
- [15] NYD and it's the first five pages of the submission that
- [16] Amgen made in this lawsuit entitled, "Amgen's Submission of
- [17] Gels Showing that Amgen's EPO Has a Higher Molecular
- [18] Weight," and so forth.
- A: I have Exhibit NYD, which is a submission, plus eleven [19]
- [20] or twelve attachments.
- [21] THE COURT: Mr. Schwartz, I've only got one mike
- [22] that I can rely on here. You go over and stand by
- [23] Mr. Borun and conduct your investigation your inquiry
- [24] from there, if you would. It's just too difficult to hear
- [25] you.

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- Now, here's what I've got. You've shown him two
- [2] documents, Exhibit 2400, and Exhibit For Identification
- [3] NYD, and you have directed him to the first five pages of
- [4] NYD.
- MR. SCHWARTZ: That's correct, your Honor. Can
- [6] you hear me better now?
- THE COURT: Much better. Pick up there.
- Q: Now, I'd like you to look first at page 2 of NYD. And
- [9] the first full paragraph states: Document constituting
- [10] TX2400, in paren, the Egrie input document, appears to
- [11] indicate in November of 1984 Dr. Egrie provided the
- [12] attorney who prepared the November 30th, 1984 patent
- [13] application with copies of SDS-PAGE gels accompanied by her
- [14] analysis of the data TX2400, see Tab 1.
- [15] Do you find that?
- [16] A: Yes, I do.
- Q: And my question is: Isn't it correct that you're that 1171
- [18] attorney?
- [19] A: Uhm, I'm the attorney who prepared that application,
- [20] yes.
- Q: And you're the attorney referred to in that
- [22] paragraph isn't that right? in that sentence; where
- [23] it says, Dr. Egrie provided the attorney who prepared it,
- (24) that's you?
- A: I think that's what's referred to.

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- Q: Do you have any reason to doubt that it's you? [1]
- A: No. I didn't prepare this submission.
- Q: That wasn't my question. My question is: Do you have

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- [4] any reason to doubt you're the individual referred to in
- [5] that sentence?
- A: Reading that sentence here for the first time, I have
- [7] no reason to doubt that I'm the attorney being referred to,
- [8] because I prepared that application.
- Q: Thank you. [9]
- Now, going back to or going first to [10]
- [11] Exhibit 2400, it says on the top, Mike Borun and Mary Boc
- [12] thought the simplest thing to do was to Xerox the relevant
- [13] excerpts for you, notebooks and so forth.
- Do you find that?
- A: I see that, yes. [15]
- Q: And who was Mary Boc? [16]
- A: Mary Boc is an attorney who, in 1984, was an associate
- (18) with my firm.
- Q: And the next page is another note which ends with a [19]
- [20] handwritten note, "Things requested by MFB."
- Do you find that? The next to the last line. [21]
- A: I find that, yes. [22]
- Q: You're the "MFB"; isn't that right? [23]
- A: I would assume so, that Mary Boc is referring to me. [24]
- Q: And on the next page where it says on the right, "Egrie 1251

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- [1] input," do you find that?
- A: That's right.
- Q: That's in your handwriting; isn't that so? [3]
- A: Yes. That handwriting is her printing actually, tab of
- [5] a manila folder.
- THE COURT: Wait a minute now. Wait a minute.
- [7] Wait a minute.
- MR. SCHWARTZ: I'm sorry.
- THE COURT: The best microphone that's there [9]
- [10] appears to be that flat speaker microphone. Now,
- [11] Mr. Schwartz, you're doing much better, I can hear you, now
- [12] that you worked in close. I hear Mr. Borun less well, but
- [13] I hear him adequately. But if you touch that microphone
- [14] with your paper -
- MR. SCHWARTZ: What I'll try to do is move it
- [16] closer to Mr. Borun and further from me.
- [17] THE COURT: Fine, but don't touch it. That's the
- (18) one
- MR. SCHWARTZ: I've moved it closer to him and [19]
- [20] further from me. Can you hear me still?
- THE COURT: Yes, I can.
- Now I have a question of substance. Your last
- question to him referred to oh, I see, it's the tab here
- where it has "Egrie input." Pick up there. I'm with you.
- Q: That's in your handwriting; correct? [25]

- [1] A: That's my printing, yes
- Q: That's your file folder? [2]
- r31 A: That's a file folder that I -
- Q: One of your file folders, that's right. [4]
- And going back to NYD, a page we were looking at, [5]
- [6] the second full paragraph says the following: On page 22
- [7] of the Egrie input document, the results of SDS-PAGE gels
- [8] are summarized in a way that parallels the description in
- [9] the '933 patent, Column 28, lines 33 to 50 in pertinent
- [10] part under the title, COS, CHO and native EPO, different
- [11] size of neuraminidase digestion product, Dr. Egrie
- [12] explained that the size of Gene's standard, standard
- [13] urinary EPO, is approximately equal to the size of COS-cell
- [14] produced EPO, and so forth.
- 1151 Do you find that?
 - A: I find that text, yes.
- (17) Q: Now, would you look, please, at Exhibit 3, if I hand it
- [18] back to you.

[16]

- BEC, I'm sorry. Do you have that, Mr. Borun? [19]
- [20] A: Yes, I do, BEC.
- [21] Q: That's one of plaintiff's exhibits. And turn to Column
- 22 28 for a moment.
- (23) A: I have it, yes.
- [24] Q: That's the material that's referred to in page 2, isn't
- [25] it, starting at line 33 of Column 28, "A preliminary

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- [1] attempt was made to characterize," et cetera?
- A: Page 2 of NYD appears to refer to Column 28, lines 33
- [3] to 50 of the '933 patent, which you just handed to me.
- [4] Yes, that's the reference.
- Q: That's right. And it also talked about page 22 of
- [6] 2400, and that's what I'd like to look at next.
- Page 22, I'm sorry.
- A: That's the page numbered -
- Q: Numbered -191
- [10] A: — numbered at the top?
- [11] Q: Hand-numbered at the top, 22. Do you find that?
- [12] A: Yes, I do.
- Q: And that's headed at the top, Roman Numeral V. Do you
- [14] see that? "COS, CHO and native human EPO differ in their
- (15) size and neur" -
- A: Neuraminidase.
- Q: That's better "digestion products," right? And (17)
- [18] under the note, the first entry is, "Size of Gene's
- standard approximately equal to size of COS-produced EPO as
- [20] was seen in prior Section 4."
- [21] Do you find that?
- (22) A: I'll take your word for it that the word at the end of
- [23] the line in the middle of the page there is "section."
- Q: That's how I read it.
- A: Okay. That appears to be what's being referred to

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- Q: And the work you were doing at that time, "Gene's
- [3] standard," is Dr. Goldwasser's pooled EPO; isn't that
- [4] right?

m in -

- A: It's my understanding that Gene's standard referred
- [6] to it's my understanding now that Gene's standard refers
- [7] to material that Dr. Goldwater Goldwasser obtained as a
- [8] pool of urine from aplastic anemia patients.
- Q: And going back to Column 28 of the patent, line 40,
- [10] when you wrote, "The pooled source human urinary extract,"
- [11] that's a reference that to Gene's standard; isn't that
- (12) right?
- [13] A: Well, I wouldn't connect it to Gene's standard,
- [14] because but I was referring to pooled source urinary
- (15) erythropoietin.
- Q: And the only isn't it correct that the only one you
- [17] had been told about at that time was the one that came from
- [18] Dr. Goldwasser?
- A: The time being November of 1984? [19]
- (20) Q: That's correct.
- A: I believe that well, it's my recollection that the
- [22] information I got from Dr. Lin and his coworkers about
- [23] carbohydrate analysis or characteristics was involved a
- [24] reference to material from Dr. Goldwasser.
- Q: Thank you.

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- A: I didn't use the word "standard," but -**[13**
- Q: I appreciate that, but the pooled source human urinary
- [3] extract was the material received from Dr. Goldwasser; is
- 141 that correct?
- A: I don't recall being aware that Amgen had any other
- [6] pooled source urinary EPO product.
- Q: Other than this? Other than what it told you it had
- [8] gotten from Dr. Goldwasser?
- A: I'm pretty sure I understood that it was
- 1101 Dr. Goldwasser's material.
- Q: Thank you. [11]
- Now, it then goes on to say in the next line of [12]
- [13] page 22, "Size of CHO cell materials is larger than COS or
- [14] Gene's standard."
- [15] Do you find that? That's the very next line.
- A: Okay. [16]
- Q: And then it says, "CHO is " looks like
- [18] "- approximately equal to Lot 82 EPO."
- A: It looks to me like "CH" stands for "carbohydrate,"
- [20] then SDS, then there's a wavy line. It doesn't say
- [21] approximately, it's a wavy line, which isn't approximate,
- [22] to Lot 82 EPO.
- Q: It says as seen in Section 3? [23]
- [24] 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 [1]
- [2] there's a Roman Numeral III right at the top there.
- Q: And that says, "Heterogeneity of native human urinary
- [4] EPO." Do you find that?
- A: Yes.
- Q: And that says, "Comparison of EPO from two different
- [7] patient sources"; correct?
- A: Yes, it does.
- Q: And the first source is identified as Gene Goldwasser's
- [10] EPO. Do you find that?
- A: Yes. F1 11
- Q: And that's the pooled EPO we've been talking about; [12]
- [13] isn't that right?
- A: Well, I only understood there to be -
- Q: One pooled EPO? [15]
 - A: One source of EPO, and that was the pooled EPO.
- Q: And then right under, it says, "Lot 82 urine was
- [18] provided by Kirin Brewery from Kirin Brewery from
- [19] Japan."

[25]

- [20] Do you find that? It says the material was
- [21] purified to homogeneity at Amgen, by Amgen and Kirin
- [22] scientists jointly?
- A: Urine was provided by Kirin Brewery, it looks like,
- [24] "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
- [2] Amgen and Kirin scientists jointly." That's what it looks
- is like to me.
- Q: And isn't it correct that that's the Lot 82 EPO which
- [5] is referred to on page 22 that we talked about a few
- [6] minutes ago?
- A: I have no reason to doubt that that's that these are
- [8] references I mean, the same Lot 82 and Lot 82.
- Q: Now, you say, going back to Column 28 of the patent,
- [10] that these studies indicated that the CHO-produced EPO
- [11] material had a somewhat higher molecular weight than the
- [12] COS I expression product. Do you find that?
- [13] A: Yes.
- [14] Q: And the CHO-produced EPO is the EPO that's the
- [15] recombinant EPO that was the subject of Example 12 of the
- (16) patent; right?
- A: Example 10. I believe the CHO-produced EPO material
- [18] that was referring here is this is the material obtained
- [19] from Chinese hamster ovary cells as described in the
- [20] immediately before preceding text of Example 10.
- Q: That's right. And the COS-1 expression product, that [22] was the — that was the material of both human and monkey
- [23] made in COS cells that was described in the patent; is that
- A: Now, this, the COS-1 material here is using human it

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- [1] says in the third line —
- [2] Q: Yes.
- [3] A: line 35, third line of the paragraph, it says,
- [4] "Conditioned medium," so it's the stuff outside the cells
- [5] growing in the medium, "of COS-1," and these are monkey
- [6] cells, "and CHO," those are Chinese hamster ovary cells,
- [7] "expression of the human EPO gene."
- (8) Q: So that was human and COS cells: correct?
- (9) A: That's correct, that was human and COS cells.
- [10] Q: And you're reporting here that EPO and CHO had a
- [11] somewhat higher weight than EPO and COS; right?
- [12] A: That's right.
- [13] Q: And then you say the COS was, in turn, slightly larger
- [14] than the pooled source human urinary extract?
- [15] A: That's correct.
- [16] Q: And going back to Note 1, it said, "Size of Gene's
- [17] standard is approximately equal to the size of COS-produced
- [18] EPO."
- [19] Do you find that?
- [20] A: You're going back to page 22 of 2400?
- [21] Q: That's correct.
- [22] A: Middle of the page where it says "note," and it says
- [23] "approximate EPO," yes.
- [24] Q: That's correct. And it refers back to Paragraph 4 of
- [25] this document; correct?

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

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- [1] A: That would be consistent.
- [2] Q: And ---
- [3] A: Paragraph 4 doesn't I'm sorry. I'm sorry.
- [4] Q: Paragraph 4 is on page 17. Are you looking at page 17?
- [5] A: Have we looked at that before?
- [6] Q: I don't believe we have. And what it says in
- [7] Paragraph 4 is: Recombinant monkey and human EPO produced
- [8] by COS cells have the same molecular weight as native
- [9] urinary EPO, Goldwasser's EPO. This result indicates that
- [10] the recombinant EPO is glycosylated to the same extent as
- [11] the native protein.
- [12] Do you find that?
- [13] A: I'm finding it, yeah.
- [14] Q: And so that's saying that at least the human EPO
- [15] produced in COS has the same molecular weight as
- [16] Goldwasser's EPO; correct?
- [17] A: That appears to be what this document says.
- [18] Q: That's right. And as I said, on page 22, it I read
- [19] from earlier, the reference would be approximately equal to
- [20] that paragraph; correct? We just looked at that.
- [21] A: Those are inconsistent.
- [22] Q: Why are they inconsistent?
- [23] A: They can't be the same and approximately equal.
- [24] Q: One says approximately equal to and one says the same.
- [25] A: Yes.

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 [1] Q: And can you point me to any other writing that you were
- [2] aware of at the time, other than 2400, that discusses the
- [3] specific issue to which I'm now talking about, which is why
- [4] the COS-1 product was, quote, slightly larger than the
- [5] pooled source human urinary extract here?
- [6] Do you have any writing in mind that you relied on
- [7] at that time?
- [8] A: No, not a writing. No.
- (9) Q: Nothing. Okay.
- [10] A: Not that I have nothing, I have no writing.
- [11] Q: You have no writing, that's right.
- [12] Now, it's correct, is it not, that in the
- [13] discussion of urinary EPO, in the paragraph we're talking
- [14] about, you make no reference to the Lot 82 EPO isn't
- [15] that right? or a single-source EPO? What I'm talking
- [16] about is Column 28, line 33 to line 50.
- A: No, I was referring to EPO obtained from, you know,
- [18] pooled urine from aplastic anemia patients.
- [19] Q: And that's all you referred to in this paragraph; isn't [20] that right?
- [21] A: That's all I knew about, yeah.
- [22] Q: That's all you knew about. So it's your testimony that
- [23] you never heard of Lot 82 EPO at the time you prepared the [24] application?
 - A: I have no recollection of knowing about Lot 82 EPO at

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- [1] the time I prepared the application, the November 1984
- [2] application. That's the text of which is in the
- [3] '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
- [6] knowledge of a Lot 82 or single-patient source EPO.
- Q: So you have no recollection of having ever gotten any
- [8] of the information which Joan Egrie says she sent you in
- [9] Exhibit 2400; isn't that right?
- A: I I don't as I said in my deposition, Dr. Egrie [10]
- [11] seems to recall giving it to me in person. I have no
- [12] recollection of that. It appears, from the front of 200.
- [13] that it was sent to me and Mary Boc. And I have no
- [14] recollection of when I had it or whether I looked at it.
- [15] It apparently went into the file marked "Egrie input."
- I had input files from a number of people, but I
- [17] didn't I have no recollection of looking at this
- [18] collection of documents in preparing the text that you're
- [19] referring to in Column 28. I may have discussed this with
- [20] Dr. Egrie. She seems to recall talking to me about it.
- [21] That doesn't sound unreasonable since, apparently, she and
- [22] a coworker, Dr. Lane, did this work together.
- Q: In fact, in Exhibit NYD it states, and we looked at
- [24] this earlier, "On page 22 of the Egrie input document,
- [25] results of SDS-PAGE gels are summarized in a way which

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- [1] 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
- [5] that when you prepared the information in Paragraph 28.
- [6] Column lines 33 to 50, you, in fact, used the
- [7] information from page 22 because, in fact, the information
- [8] 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
- [10] same information. I mean, I got that information from
- [11] someone, Dr. Egrie, Dr. Lin, Dr. Lane. And this NYD says
- [12] it's parallel information.
- Q: It says that it's summarized in a way that parallels
- [14] the description in the patent. It doesn't say there's
- [15] parallel information. It says it summarizes in a way that
- [16] parallels the description in the patent.
- And my question is: Doesn't that refresh your
- [18] recollection that in fact, you had page 22 in front of you
- [19] when you wrote that information in the patent?
- A: No. No. This I didn't prepare NYD, I'm sorry, but
- [21] I agree with it. Now, sitting here essentially as counsel
- [22] 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
- [25] it's summarized in the patent?

- [1] A: I think that's accurate.
- Q: But having seen that, you don't have any reason to
- [3] believe that you actually used that to write it so it turns
- [4] out in that fashion?
- A: No, I don't. What you see here in Column 28 is
- (6) something that was constructed by information given to me
- [7] and passed through Dr. Lin, and that's it.
- Q: What, if at all, do you attribute the parallelism to
- p) that's referred to in this memo?
- MR. KNOX: Your Honor, this Mr. Casebeer, there's
- [11] no foundation for that question since Mr. Borun already
- [12] testified he did not see this memo or have any role in it,
- [13] apparentiv.
- THE COURT: It's not necessary to argue every [14]
- [15] objection unless until I've made a ruling.
- The objection is overruled. He may answer if he 1161
- [17] can
- [18] A: I'm sorry, I've lost the question.
 - THE COURT: He's asking you why you think that,
- (20) why it's so. Why does the patent summarize it in the way
- [21] it is summarized there in 2400, if you know?
- THE WITNESS: Okay. Well, your Honor, I just
- [23] agreed with the statement today and I can give you my
- [24] construction of this document today in comparing it to this
- [25] one, as an attorney. I didn't have page 22 in front of me

[1] when I wrote this.

- THE COURT: I understand that's your wait. I
- [3] understand that's your position. But he's asking you why
- [4] the parallelism, and I'd like to hear your explanation
- (5) today, if you can give me any.
- THE WITNESS: Sure. Your Honor, it's it
- [7] suggests a stepwise kind of experimental result where you
- [8] have three things, none of them are equal to each other,
- (9) okay, and they line up, the three of them. So you have one [10] that's clearly the heaviest or the larger molecular weight,
- [11] that means it doesn't go as far on the gel, then you have
- [12] two others. The first one is the Chinese hamster ovary
- [13] stuff. And you have two others and they aren't the same.
- So you've got, like, three steps. They're each
- [15] of the others is different from the Chinese hamster
- (16) Ovaries
- Then on page 22, it goes on to address the [17]
- [18] difference between urinary and COS cell material after
- [19] neuraminidase treatment to say that the urinary and COS
- (20) cells are different.
- So that's also consistent with it. But, your
- [22] Honor, that's really a construction I'm doing here for you 1231 today.
- THE COURT: I appreciate it. And I understand
- [25] that's what Mr. Schwartz was asking and I just allowed him

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[3] Column 28 starting at line 29; isn't that right?

A: Probably 28, line, let's say, 33.

Q: Thirty-three, I'm sorry.

[15] urinary product was probably wrong.

[20] submissions in the inference.

[22] patent; isn't that right?

(8) characterizations, yes.

[1] directly supported and directed to the preceding column -

[2] proceeding paragraph, that's the conclusion that flows from

A: Yeah, that's a fair statement that this summary at the

Q: That's right. And there came a time when you learned

A: There came a time when I found out that the hexose

Q: That's right. And that time was probably no later than

[13] value for the recombinant product was probably wrong, and

[7] top of Column 29 addresses the previously mentioned

[10] that the information in Paragraph 50 — in Column 28,

[11] starting line 51 to the end was wrong; isn't that right?

[14] that the fucose value for both the recombinant and the

[17] 1990, 1991 - isn't that right? - in and around that time

A: That's a good estimate. It was in the context of

Q: Now, you never did anything to correct that in this

A: No. Those are the values that we had when it was

[24] Written in 1984 so, I mean, you can't go back and change

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- m to have it.
- Go ahead, Mr. Schwartz.
- Q: A couple of brief questions, a couple on Exhibit 2400,
- [4] and we'll move on. Just look at page 6 for a minute. We

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- 151 talked a little bit about that.
- Under the summary, that says, "Gene's EPO is
- [7] 3400 34,000 MW, Lot 82 EPO is 35 to 36K." That's a
- [8] reference to the molecular weight of the different EPOs;
- (9) isn't that right?
- [10] A: That's what I would read today.
- [11] Q: In daltons, one is 34,000, the other is approximately
- [12] 35 to 36?
- THE WITNESS: Your Honor, just for your
- [14] information, we're looking at page 6 of 2400, and
- [15] Mr. Schwartz has called my attention to a little bit down
- [16] the page, heading "Summary," and it's the second sentence
- 1171 that he's read to me. And he's asked me if I think that's .
- [18] a reference to molecular weight in daltons, and I said that
- [19] as I read this, it's a fair characterization.
- Q: The second point of it is the difference in molecular
- [21] weight is most probably a difference in the extent of
- [22] glycosylation. And my question is: Do you have any
- 1231 recollection of being told that at that time?
- A: In November of '84?
- Q: That's right. [25]

- A: No. [1]
- Q: Never learned any of this in that time; right? [2]
- A: Not in that time frame. This document came up in the (31
- [4] interference and -
- [5] Q: I'm just asking for that time frame. Your answer is
- [6] no?
- A: My answer is no, sir. Sorry. [7]
- Q: And that's, presumably, if I go through any of the
- [9] other detail, it will probably be the same answer, I guess;
- [10] right? You don't recall anything in this document?
- A: I don't recall having this document or reading anything
- [12] in this document when I was preparing the November '84
- [13] application. I had, obviously, information that this
- [14] development relates to, that's what I used to prepare the [15] graph.
- Q: Thank you. Now, I believe going on in the patent to
- [17] the remainder of Column of that column, Column 26 I'm
- [18] sorry, Column 28, there's then information starting at
- [19] line 51 concerning carbohydrate analysis; correct?
- [20] A: Yes. This is carbohydrate analysis, starting at
- [21] Column 28, line 51 and going across the next column.
- Q: That's right. And it would be fair to say, wouldn't
- [23] it, that when you go to Column 29, in your conclusion,
- [24] "Glycoprotein products provided by the present invention,"
- [25] and so forth, that information in that paragraph is really

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 - Q: Now, you filed a number of continuation applications
 - [2] based on this patent, on that application; isn't that
 - [3] right?

[25] things.

[18] frame?

[191

- A: That's right. [4]
- Q: And in fact, each of the patents in suit is based on a
- [6] continuation application filed subsequent to 1991; isn't
- [7] that right?
- A: Mr. Schwartz -(B)
- Q: I'll give you -
- A: I would agree with you subject to correction. F101
- [11] Q: I can't keep all of these in my head. This might help.
- [12] A: Can I agree with you, subject to correction, or should
- [13] I just figure out the colors and...
- Q: No, basically, to go through it quickly, I mean, it
- [15] just shows that the five patents in suit are in orange, and
- [16] at least the last applications were filed in either '95,
- [17] four of them, and one of them in '93. That's the simple
- 119 A: Well, that's what this shows
- [20] Q: I'll represent that's accurate, okay?
- A: Okay. [21]
- Q: Based on that, isn't it correct that when you filed
- [23] each of those continuation applications, you never did
- [24] anything to take out this incorrect carbohydrate data;
- [25] isn't that right?

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- A: Well, at least some of those I didn't file, but, no.
- [2] there were no it's called a continuation application.
- [3] The specification stays the same as it was and has the same
- [4] information that we had in 1984.
- Q: And so when you decided to get additional applications
- [6] based on that disclosure, you didn't correct what you knew
- [7] then to be a mistake; isn't that right?
- A: It wouldn't be a continuation application, then. If
- [9] there were changes in the data, then that would be a
- [10] continuation-in-part application. So that's not a
- [11] continuing attempt to secure patent protection based on the
- [12] same information that was filed in 1984.
- Q: The reason, the consequence of that, of filing it as a
- [14] continuation application, is filing it with data known to
- [15] be wrong isn't that right? at least with respect to
- [16] that paragraph? Isn't that what you did in at least four
- [17] of the five?
- A: The reason for filing the continuation application is
- [19] to reserve the original filing date. And at the original
- [20] filing date, there was no knowledge that this information
- [21] was wrong. This was the best information we had.
- So when you file a continuing application, you
- 1231 preserve the original, the original date. So in other [24] words, so that's what we had in 1984.
- If we wanted a new date, we had a new invention

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- [1] and we wanted to add some other kinds of information, that [2] would have an effective date of when you filed that.
- Q: I don't want to argue with you about it. I take it
- [4] from what you're saying, you viewed this as an appropriate
- [5] use of the patent laws?
- A: No, absolutely.
- Q: There's no doubt that you were aware that that
- [8] information was false when these continuation applications
- [9] were filed; isn't that right?
- A: No, it's not false. It's the information we had. I
- [11] can't go back I can say it's wrong, but I can't go back
- [12] and say it was false.
- Q: As of the date you filed the continuation application,
- [14] each of which was later than 1991, you knew that as of
- [15] 1993, '95, what you were putting in it to rely on going
- [16] back to an early date was incorrect data; that's all I'm
- [17] asking?
- A: I knew that the hexose value for the Chinese hamster [19] ovaries analysis was incorrect probably, even though that's
- [20] what Dr. Lin gave us. And I knew that the fucose value was
- [21] incorrect for both the Chinese hamster ovary product, and
- [22] the urinary EPO as of the point in time that you said,
- [23] sometime certainly by 1990.
- These applications were filed later than 1990,
- [25] they all relied back to 1984. And at the time in 1984 when

[1] that information went in, it was correct.

- Q: Isn't it correct that in other countries of the world,
- [3] when you filed later applications, you corrected that data?
- A: No. It occurred in South Africa that in the context of
- [5] this proceeding, our South African counsel, when advised
- [6] that the hexose values and fucose values were incorrect.
- [7] said take it out.
- And in Europe, in the appeal, when the European
- [9] Board of Appeals were advised that those were incorrect,
- they said, not just attorneys, the European Board of
- [11] Appeals said, Well, get it out of there.
- Q: So at least in Europe and in South Africa, that
- [13] information ended up being taken out of the counterpart
- [14] package; isn't that right?
- A: The South African counsel advised it and the European
- [16] Patent Board of Appeals, the highest tribunal in Europe
- [17] said, Oh, yeah, take it out, it didn't have any effect.
- Q: Isn't it correct that you made numerous corrections to
- [19] the '933 patent? In other words, you filed certificates of
- [20] correction with all sorts of different corrections; isn't
- (21) that right?
- A: Those are corrections in the text and they fall into
- [23] two parts. One set, you know, things that we had in there
- [24] originally that were wrong, typographical errors, and also [25] errors that the patent office made in the printing process.

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- So that's a Certificate of Correction, goes -
- [2] doesn't go to any substantive change in the patent, doesn't
- [3] say white is back, black is white. It just says this word
- [4] is misspelled.
- Q: What you're saying is that you didn't believe it would [6] be appropriate to change that information by Certificate of
- [7] Correction?
- A: No, that's the information we had. I mean, there was [9] nothing wrong with that information when it was put out.
- Q: Even though by the time you filed continuation [10]
- [11] applications you knew it was wrong; right?
- A: When we filed the continuation application, we asked
- [13] for our November 1984 date. And as of November 1984, that
- [14] was the best information we had. It was only during the
- [15] interference that Dr. Lin's raw data came in and it could
- [16] be determined that Dr. Yu made a mistake, the person
- [17] trusted to do this analysis at Yale University.
- Q: Isn't it correct that you believed if you changed that [19] information you'd lose your early filing date; isn't that
- [20] what you told me?
- A: With respect to a claim, for example, that went to
- [22] those specific data points. If I had a claim that then
- [23] said with the hexose a recombinant product with the [24] hexose ratio vis-a-vis urinary of 15.09, and I wanted to
- [25] change that to 1.62 or something like that, I'd only be

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- [1] entitled to that later date for the 1.62. I don't have any [2] claims like that.
- Q: So at least as to that, you'd agree that it would be a [4] problem; right?
- A: No, it's not a problem. You're only entitled to the [6] date you put it in.
- Q: I understand what you're saying.
- Now, I'd like to go to the prosecution of the
- [9] '933 patent for a moment, and I'd like you to look at
- [10] Exhibit NWP, which I believe has been admitted as 2131 I [11] guess 2161.
- Do you find that? [12]
- [13] A: I have that. Yes, I do.
- Q: That's an amendment and your response that you
- [15] submitted in connection with the parent application or one
- [16] of the applications in the chain of '933; right?
- A: I think I'll take your word for it. [17]
- Q: Sure. You're welcome to look at that. [18]
- A: I'll agree with that subject to correction. [19]
- Q: Okay And on page 4 is an example of a claim pending
- [21] there, but claim 87 which has the phrase, "Having
- [22] glycosylation which differs from that of human urinary [23] EPO."
- Do you find that?
- A: On page 4, which is -[25]

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- Q: 909 at the bottom. [1]
- A: Document AM27020909, the text there of claim 87 has the
- [3] wording, "and having glycosylation which differs from that
- [4] of human urinary erythropoietin," so it means that it was
- [5] in claim 87 originally, that's why it's not underscored.
- (6) The new stuff is underscored. The old stuff is in
- 77 brackets.
- Q: If I didn't make it plain at the beginning, this is an
- [9] amendment that you prepared on or about the date it bears,
- [10] and namely, February 16th, 1995; correct? It says it on
- [11] page 12.
- A: I believe that's right. [12]
- Q: And going on from there, on page 8 you discuss on
- [14] page 6, I'm sorry, you discussed the rejection of claim 87.
- [15] Do you find that?
- A: Prior rejection before the amendment, right. [16]
- Q: That's correct. You have a reference to the rejection
- [18] under Roman Numeral II.
- Do you find that? [19]
- A: Yes. Second full paragraph says -[20]
- Q: Exactly. And then going on to page 8 and 9, you say at [21]
- [22] the bottom of page 8 and top of page 9, "As confirmed by
- [23] the Takeuchi article cited by the Examiner, the
- [24] glycosylation of recombinant EPO products is different from
- [25] that of urinary EPO. The fact that recombinant EPO is

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- [1] inevitably different in its glycosylation from urinary EPO
- [2] is manifest from the attached copy of the January 1994
- [3] 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
- (6) that time, isn't it; that recombinant EPO is inevitably
- [7] different in its glycosylation from urinary EPO? Correct?
- A: Different, that's "inevitably." I think that's
- [9] probably Dr. Cummings' word in the attachment.
- Q: It's your word in the amendment, isn't it? It's your [10]
- word in the argument? [11]
- [12] A: Well, I'm referring to Dr. Cummings' statement.
- Q: You wrote those words. That's what you said, isn't it? [13]
- [14] A: Yes, I did.
- [15] Q: Thank you.
- And you attached Dr. Cummings' declaration? [16]
- A: Yes, I did. It was a declaration that he prepared for [17]
- [18] Europe.
- Q: And I mention parenthetically there's been some [19]
- [20] question about whether the declaration was attached or not.
- [21] As far as I'm concerned, it was attached and it's there,
- [22] and we don't have any quarrel with that.
 - A: I think the examiner referred to it in the subsequent
- (24) action, so it was there.
 - Q: I did say that to cut away any underbrush or squabbling

[1] 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
- [4] still didn't know anything about Exhibit 2400, the Egrie
- [5] input; is that correct?
- A: No. I think this was sent in in February of '95, and I
- [7] said I knew about the existence of the document prior to m 1995.
 - Q: I take it, though, that you never brought to the
- [10] attention of the examiner the information in the Egrie
- [11] document that we went through earlier; isn't that right?
- A: The examiner had that information in the form of -
- [13] this document was in in the interference, and the issue of
- [14] similarities and differences between urinary and
- [15] recombinant was an issue in the interference cited
- [16] favorably to Amgen.
- THE COURT: Mr. Borun, Mr. Borun, wait. Wait a
- [18] minute. Wait a minute. Mr. Borun, when you say "this
- [19] document" was in in the interference, to what document do
- (20) you refer?
- [21] THE WITNESS: The document that we have been
- [22] referring to as the Egrie input document, your Honor.
- THE COURT: Thank you.
- THE WITNESS: That's Trial Exhibit 2400, was an

[25] exhibit in the interference.

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