EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

Civil Action
No. 05-12237-WGY

AMGEN, INC.,

Plaintiff,

v.

F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GmbH and HOFFMANN-LA ROCHE, INC.,

Defendants.

DAILY TRANSCRIPT OF HEARING IN RE OBVIOUSNESS-TYPE/ DOUBLE PATENTING (Volume 1)

BEFORE: The Honorable William G. Young, District Judge

1 Courthouse Way
Boston, Massachusetts
October 1, 2007

A P P E A R A N C E S

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PROCEEDINGS - 2:03 P.M.

THE CLERK: All rise. Court is in session, please be seated.

THE COURT: All right, I do think I'm prepared to proceed. I don't require an opening as to this, and I am counting the time, but I don't preclude one either.

So, counsel, who's going to take the lead here?

MS. CARSON: Your Honor, I'm going to take the lead on behalf of Roche.

Before we begin, though, just to kind of talk a little bit about the structure, we would like to reserve 45 minutes of Roche's time so that we can cross Dr. Lodish who we expect probably to give testimony on behalf of Amgen.

THE COURT: Well, of course you can. But in a way it's in your hands. You have two hours of time in a total four hour presentation. So you proceed as you see fit.

MS. CARSON: And we were assuming that you were giving two hours to Roche and two hours to Amgen.

THE COURT: You're absolutely right.

MS. CARSON: Okay.

THE COURT: But it's your burden, so you go first.

MS. CARSON: So Roche would like to begin by calling Dr. Thomas Kadesch to the stand.

THE COURT: He may be called.

THE CLERK: Right up here, sir.

MS. CARSON: Your Honor, before I begin with Dr. Kadesch, I just want to point out that we have two obviousness/double patenting theories, Number 3 and Number 4, and we're going to begin with Dr. Kadesch's testimony which is relevant to Theory 4.

THE COURT: Thank you.

THE CLERK: Sir, would you raise your right hand.

Do you solemnly swear that the answers you will give to this Court will be the truth, the whole truth, and nothing but the truth, so help you God?

THE WITNESS: I do.

THE CLERK: Please be seated.

MS. CARSON: Your Honor, may I proceed?

THE COURT: Of course.

MR. DAY: Your Honor, I would just like to object that we received no expert report from Dr. Kadesch addressing this subject. And to the extent that a report --

THE COURT: Well, this is jury waived and I'll be sensitive to that.

Well, though, that does raise a question. How can we get his opinions if there's no report? I would never have let you do that before the jury.

MS. CARSON: And, your Honor, Dr. Kadesch did put in a total of three expert reports and this was among the

issues that he addressed --

THE COURT: Oh.

MS. CARSON: -- in his expert report.

THE COURT: All right, fine. So long as we have --

MS. CARSON: And we'll be handing you the color coded expert reports.

THE COURT: That's fine. And you'll hand them to the plaintiffs as well, I'm sure. Yes.

THOMAS R. KADESCH

DIRECT EXAMINATION

BY MS. CARSON

Q Good afternoon, Dr. Kadesch. Would you please introduce yourself to the Court.

A Yes. My name is Dr. Tom Kadesch. I am Professor of Genetics at the University of Pennsylvania, and currently serve as the chair of the department.

Q And could you describe what you do in your position as Professor of Genetics at the University of Pennsylvania?

A Well, I've got three major responsibilities. One is to teach; the second is to run a research lab; and the third is to administer the department.

Q And the research lab that you run, what is the focus of your research?

A The focus of my research is the regulation of gene expression and protein expression.

Q How long have you studied protein expression?
A Well, I've been at the University of Pennsylvania since 1984, but I started when I was a postdoctorate fellow at Stanford.
Q Could you please briefly describe your educational background for the Court?
A Yes. I got B.S. in biochemistry from the University of California at Santa Barbara in 1975. In 1980 I got a Ph.D. in biochemistry from the University of California at Berkeley. Then I did post-doctoral work with Dr. Paul Berg at Stanford for three years, and then I started my job at Penn in 1984.
Q And who is Dr. Paul Berg?
A Dr. Paul Berg is a Nobel Laureate. He won the Nobel Prize around 1980. Often considered by many to be one of the fathers of recombinant DNA technology.
Q What kind of work did you do in Dr. Berg's laboratory?
A Well, we were very much involved in developing recombinant DNA technology and the ability of that technology to express genes in cells.
Q Now, do you understand that you're providing testimony in this proceeding from the point of view of a person of skill in the art in the 1983-1984 time frame?
A Yes, I do.
Q And what qualifications in your opinion would a person

of ordinary skill in the art in that time frame possess?
A Well, somebody of ordinary skill would have a Ph.D. or an M.D. and typically two years of research lab experience in addition to that.
Q And did you consider yourself to be one of ordinary skill in the art in the 1983-1984 time frame in recombinant DNA technology?
A Yes, I did.
Q What opinion are you here today to provide to the Court?
A My opinion has to do with the double patenting issue which is, given the '698 patent, the '349 patent claim 7 is obvious.
Q Now --
MR. DAY: Objection, your Honor; it's outside the scope of his report.
MS. CARSON: Your Honor, red report, Paragraph 12.
THE COURT: Well, I'll tell you we're going to save time here and I'm not going to entertain those objections. But to the extent that it is claimed to be outside the report, counsel will have time enough to set that out in a brief, and I have the reports and I'm not going to, I'm simply not going to consider anything that's not in the report. That way we'll move along more smoothly. I will not consider it unless it's here in the report.
MR. DAY: Your Honor, may I be heard for just one

second on that. It's simply not in the report, that's the point.

THE COURT: Oh, I understand that. I understand that. So here's what we're going to do. I'm going to sit here, I'm going to listen to it, I'm going to take notes on it, and then you're going to submit a brief saying, because you have daily copy, the following testimony is not in the report. And I'm going to then -- and they of course will say, oh, yes, it is, here it is. And I'm then going to look at those portions of the report and if it's not in the report, I'm not considering it. I'm capable of doing that and that's how I'll do it.

MR. DAY: Thank you.

MS. CARSON: Your Honor, in view of the way you're proceeding, it's also in yellow Paragraph 8 and blue Footnote 3, Pages 8 through --

THE COURT: Well, they're going to attack it. It will be your opportunity then to tell me where it is and I will look at it. But, bottom line, claim 7 of '349 is invalid?

THE WITNESS: Yes.

THE COURT: In view of '698?

THE WITNESS: Yes.

Q Are you aware that the Court --

MS. CARSON: I'm sorry, your Honor, may I proceed?

THE COURT: You may.

Q Are you aware that the Court has provided definitions for certain claim terms in this case?

A Yes.

Q And have you reviewed the Court's definitions in this case?

A Yes, I have.

Q And how did the Court's claim definitions come into play in you coming to your opinions?

A I considered them when I came to my opinions, yes.

Q Now, have you reviewed the '698 and the '349 patents and claims in coming to your opinions?

A Yes, I have.

Q So --

MS. CARSON: TK-9, please.

Q So, let's start by looking at claim 4 of the '698 patent, and this is claim 4 that's taken from Trial Exhibit 3.

MR. DAY: Your Honor, I object. This claim's not in suit.

THE COURT: No, the claim's not in suit, but this is the one that is supposed to be, or I take it that invalidates or aids in invalidating '349 claim 7.

MS. CARSON: That's correct, your Honor.

THE COURT: Yes.

MS. CARSON: This --

THE COURT: I understand. You may proceed.

MS. CARSON: Dr. Kadesch's opinion was offered before Amgen's response.

THE COURT: I have it in mind. I'm trying to save you time.

MS. CARSON: Okay. Thank you.

Q Can you tell me what your understanding of claim 4 of the '698 patent is?

A Yes. It's a process of producing erythropoietin in vertebrate cells.

Q Now, if we could look at TK-3.

And this is -- if you could tell me what your understanding of claim 7 of the '349 patent is?

A Yes. If you actually read it, a process for producing erythropoietin comprising steps of culturing vertebrate cells.

Q Now, in your opinion, what is the difference between claim 4 of the '698 patent and claim 7 of the '349 patent?

A Well, first of all, claim 7 of the '349 patent is dependent upon claims 1 through 6. Shown here is claim 1 for an example. And in claim 1 they talk about growing those cells and obtaining, actually measuring the amount of erythropoietin that's produced in those cells.

MS. CARSON: Okay. So if we could have TK-4.

Q So, Dr. Kadesch, if you compare claim 7 as you've now read it in light of claim 1 of the '349 patent with claim 4 of the '698 patent, can you tell me in your opinion what the differences are between these two claims?

MR. DAY: Excuse me, your Honor. If I understand, you don't wish me to object that these are outside the scope?

THE COURT: I do not. And your rights against the report are fully saved in the manner that I've said.

MR. DAY: Thank you.

MS. CARSON: May I proceed, your Honor?

THE COURT: You may.

Q So, Dr. Kadesch, if you could look at claim 7 of the '349 patent as you've now read it in light of claim 1 and compare it to claim 4 of the '698 patent, can you tell me in your opinion what the differences are between these claims?

A Well, in this particular case, highlighted in yellow are two aspects or two phrases within the claims. Basically a process of producing erythropoietin, glycosylated erythropoietin in claim 4 of the '698, and a process of producing erythropoietin, claim 7 in the '349 patent.

MS. CARSON: If we could have TK-5.

Q Again, this is a comparison of the same two claims, if you could continue your discussion.

A Yes. Both involve the use of vertebrate cells.

Q If we could have TK-6.
A And this basically is to say if you grow those vertebrate cells under appropriate nutrient conditions.
Q And if we could look at TK-7.
A So, in the '698 patent you have, basically, the way in which these, the erythropoietin is produced, promoter DNA, other than the human erythropoietin promoter in claim 4, and nonhuman DNA sequences controlling transcription in claim 1 of the '349.
Q Now, the '349 claim 7 which you've been reading in light of claim 1 of the '349 patent recites an amount of erythropoietin. What is that amount?
A The amount in this case is a value that they describe as a hundred units of erythropoietin using radioimmunoassay.
Q And what is radioimmunoassay?
A It was a standard assay used at the time, one of many assays that are used to measure the amount of protein.
Q And when you say standard, what do you mean by that?
A Well, someone of skill in the art in 1983 or 1984 would have certainly known about the RIA assay, radioimmunoassay.
Q Now, the '349 claim 1 says that these vertebrate cells are making a hundred units of erythropoietin by radioimmunoassay.

Do you have an opinion as to whether one of skill in the art, it would have been obvious to one of skill in

the art to make that level of erythropoietin using the process that's claimed in claim 4 of the '698 patent?

A Yes, that would have been obvious.

Q And can you explain your opinion?

A Well, the manner in which the Amgen scientists, the process that they used to generate this amount of erythropoietin involved a process called gene amplification. The gene amplification, simply put, is when you put a selected pressure on one gene, if another gene is linked to it, then that other gene will become amplified along with the DHFR gene that's being selected for. And so this is a way, a very convenient way of increasing the number of copies of the gene in the cell, but any gene that's linked to it, such as erythropoietin, would also be amplified and therefore you would express more of that gene product as well.

MR. DAY: Your Honor, I object and move to strike as irrelevant; not comparing the claim to the claim.

THE COURT: No, overruled; that may stand. I'll give it such weight as it its due.

Ms. Carson, I'll proceed as I have stated. I have very much in mind their motion to preclude the testimony of this witness in its entirety and their reference to the expert reports here. Just understand you're going to have to deal with that at some stage. But you proceed.

MS. CARSON: Thank you, your Honor.

Q Yes, you mentioned amplification. If you would turn in your book to Exhibit NUK.

A I don't know where it is. I'm sorry.

THE COURT: It's the penultimate tab in the book.

Q It's all the way in the back, almost the last.

A Okay.

MS. CARSON: Thank you, your Honor.

A Yes, I got it. Thank you.

Q Can you tell the Court what this is?

A Yes, this is a copy of a manuscript, first page of a manuscript by -- I'm sorry -- by Gordon Ringold.

THE COURT: I don't mind it being put up even though it's not yet in evidence. I'm reading it here as the presiding officer.

MS. CARSON: Thank you, your Honor. You can put it back up.

THE COURT: Society trusts us to be able to do this, and I work very hard to retain that trust.

Q Dr. Kadesch, can you tell us what this paper is?

A Yes, this is a paper that was published by Gordon Ringold at Stanford University basically describing what I just told you, namely, that if you take, if you amplify a dihydrofolic reductase gene in cells carried on in plasmid you can co-amplify a gene that's linked to it, in this case,

the XGPRT gene, which is a gene produced normally in E.coli. And so, this paper demonstrates that you can amplify the DHFR, the dihydrofolic reductase gene, co-amplify the XGPRT gene, and get higher level expression of the XGPRT gene.

Q And what is the date of this reference?

A 1981.

Q And the journal that this appears in, what is your opinion of the Journal of Molecular and Applied Genetics?

A The Journal of Molecular and Applied Genetics is a journal that is composed of peer-reviewed manuscripts. So to get a manuscript published in that journal it has to be considered by your peers and it has to be considered to be not only scientifically sound but of some impact.

MS. CARSON: Your Honor, I offer NUK into evidence as prior art.

THE COURT: Any objection?

MR. DAY: Yes, I object on relevance rounds, your Honor. There's nothing about amplification in either of the two claims.

THE COURT: What do you say to that?

MS. CARSON: Your Honor, the claims that are impacted by the double patenting assertions do talk about amplification, but moreover, you can consider for double patenting what was known in the prior art and this is evidence of what was known in the prior art that could be

done to achieve the levels that are claimed in claim 7 of the '349 patent.

THE COURT: Well, respectfully, I don't follow. I don't -- it has nothing to do with amplification.

MS. CARSON: The amplification relates to the levels of expression that are recited in the '349 claims. So, the issue is, if you practice the process of claim 4 of the '698 patent, you may or may not get a hundred units of erythropoietin, but you will certainly get it if you apply the well-known technique that was clearly taught in the prior art and is referenced in the patent specification of amplification.

THE COURT: All right. I guess I have a problem here, and here's my problem.

I am satisfied that the Federal Circuit considers this issue matter of law. And what I say I do say with respect, they do so in their rather sloppy and undefined view that they state the things are matter of law when what they really mean is that they're matters for the judge to determine.

Now, one way to approach this is as simply as matter of construction, which is, which is for me and which, though mentally there are some problems with it, that's how I do a Markman hearing. So I compare the two claims and I listen carefully to your arguments, I construe the claims of

the two patents, and then as matter of law I rule whether one is patentably distinct from the other. And having done it that way, I'm perfectly content that the Federal Circuit review my ruling de novo.

You've asked for an evidentiary hearing on this and in an excess of caution I've given it to you. And at least in my mind that would permit me in this complex area, where I don't have much guidance from the Federal Circuit on obviousness/double patenting, I'm using the Markman by analogy and what they did in Festo by analogy. It seems to me I would be helped by getting expert testimony. And so I'm getting it, for a few hours anyway. But now you want to introduce actual evidence to bolster that testimony, I take it. And I think somewhere I should draw the line.

I'll hear you.

MS. CARSON: I think that even in a Markman hearing if you were to construe the claims, you still have to consider what that construction would mean to one of skill in the art.

THE COURT: Correct.

MS. CARSON: And what this reference provides is the context as to what one reading the elements of claim 4 of the '698 patent would have in their mind as they're reading that because that's the obviousness/double patenting inquiry.

THE COURT: Right.

MS. CARSON: Not do they claim the same thing, that's same invention double patenting.

THE COURT: Well, same invention double patenting is, has the relationship to obviousness/double patenting as anticipation has to obviousness, correct? It is the epitome --

MS. CARSON: It's the same thing, yes. They're claiming the same invention.

THE COURT: No, I'm excluding this. I'm excluding it. NUK.

MS. CARSON: And just as an additional point on this reference for your Honor's consideration, even under Federal Circuit law prior art can be considered in conjunction with claim construction.

THE COURT: I've construed the claims. And the record is what it is and I'm stuck with it. And thus far, I have no reason to reconsider it.

MS. CARSON: Thank you, your Honor. May I proceed?

THE COURT: Of course.

Q So, Dr. Kadesch, how does this paper by Dr. Ringold -- actually let's just back up.

MS. CARSON: So, if we can go back to TK-13. I'm sorry, back up to TK-7.

Q You walked through these claims individually and pointed

out the similarities between the claims and we talked about amplification. When you take everything together, can you explain to the Court your opinion regarding the obviousness of claim 7 over '698 claim 4?

A Yes. If you look at claim 4, it's for, I mean, to put it in simple language, it's a process of making erythropoietin using promoter DNA other than human erythropoietin promoter DNA. And claim 1 pretty much is the same thing, nonhuman DNA sequences. And as I said, the only difference really is that you decided to measure the amount of erythropoietin you're making in claim 1 in the '349 patent as opposed to claim 4 in the '698 patent.

Q So, in your view, is there anything unexpected about the result that's claimed or what's claimed in claim 7 of the '349 patent?

A No, there's nothing unexpected. It was all in the art, and generating that amount of erythropoietin would have been expected.

MS. CARSON: Roche has no further questions for Dr. Kadesch.

THE COURT: Thank you. Any questions?

MR. DAY: Oh, I have a few, your Honor.

THE COURT: Go ahead.

CROSS-EXAMINATION

BY MR. DAY

Q Dr. Kadesch, you do not work on EPO, do you?

A No.

Q And you've never studied the EPO gene, have you?

A No.

Q You've never produced a recombinant EPO protein, have you?

A No.

Q You've never conducted experiments relating to the production of a recombinant EPO protein, have you?

A No.

MS. CARSON: Objection; vague.

THE COURT: Overruled.

Q Your peers would not consider you to be an expert regarding processes for production of EPO, would they?

MS. CARSON: Objection.

A No.

THE COURT: Overruled. Your answer?

A No.

Q You have no experience with CHO cells that have been genetically engineered to produce recombinant protein, do you?

A That's correct.

Q And you've offered no opinions on EPO glycosylation,

have you?
A No.
MS. CARSON: Objection.
THE COURT: Overruled.
Q By 1984 it was known that EPO was a secreted glycoprotein, correct?
MS. CARSON: Objection; outside the scope.
THE COURT: Overruled.
A I believe that's true.
THE COURT: And my usual approach to scope stands. This is the only time I'm going to hear from this witness in this jury waived proceeding. Let's get everything he has to say.
Q By 1984 it was known that many secreted proteins like EPO must undergo post-translational modification such as glycosylation in order to be biologically active, correct?
MS. CARSON: Objection; no foundation.
THE COURT: Overruled.
A I believe that's true.
THE COURT: He can answer if he knows.
Q And, for example, it was known that protein misfolding could compromise or even eliminate in vivo biological activity, correct?
A That's correct.
MS. CARSON: Objection; no foundation.

THE COURT: Overruled.

Q With regard to EPO specifically, the in vivo biological activity can be compromised due to misfolding or inappropriate post-translational modifications, right?

MS. CARSON: Objection; no foundation.

THE COURT: Overruled.

A I believe that's true.

Q In 1984 it was known that misfolding or deglycosylated EPO may have no biological activity, right?

MS. CARSON: Objection; no foundation.

THE COURT: Overruled.

A I believe that's true.

Q In fact, it was known that changes in glycosylation can reduce or eliminate in vivo biological activity for EPO, correct?

MS. CARSON: Objection.

A I don't know the answer to that question.

Q You do know, however, that the absence or removal of a particular sugar, terminal sialic acid, from the EPO protein will eliminate biological activity, correct?

MS. CARSON: Objection; vague, no foundation.

THE COURT: Overruled.

A I don't know the answer to that question.

Q You had your deposition taken in this case, correct?

A Uh-huh.

Q Let me hand you a copy of your deposition.

MR. DAY: Do you want to pass them out, please.

Q If you would turn to Page 276 of your deposition. I'm going to point you to Lines 13 to 16.

MS. CARSON: I'm sorry, Mr. Day, which lines?

MR. DAY: I said 276, Lines 13 to 16.

Q Question: Do you have an understanding of the removal of sialic acid when using erythropoietin biologically inactive?

Answer: That's my understanding, yes.

So what is the significance of that particular statement?

Well, the fact that you can remove sugars and you could not alter the readout of an RIA, but you dramatically inhibit the readout in a bioassay.

Did you give that testimony, sir?

A Yes, I did.

MS. CARSON: Objection.

THE COURT: Overruled.

Q Now, CHO cells do not naturally produce human erythropoietin, do they?

A They do not.

Q And one of ordinary skill in the art in 1983 or '84 would have understood that whenever you take protein outside

of its natural environment, that is, you take it outside of the cell that naturally produces that protein, one always has to be aware that a protein, if it's produced in its nonnatural environment, may misfold, correct?

MS. CARSON: Objection; vague, and no foundation.

THE COURT: Overruled. If he knows.

A One would have to take that into consideration, yes.

Q Okay. In fact, you're aware that some CHO cells produce biologically inactive recombinant human EPO, aren't you?

MS. CARSON: Objection; no foundation.

THE COURT: Overruled.

A That would be the interpretation of some of the data presented in the patent, yes.

MR. DAY: Thank you. No further questions.

THE COURT: Anything more for this witness?

MS. CARSON: Just one question, your Honor.

REDIRECT EXAMINATION

BY MS. CARSON

Q Dr. Kadesch, if you could look at your deposition testimony that Mr. Day just examined you on on Page 276. And I believe Mr. Day directed your attention to Line 16 through 18.

A Yes.

Q Okay. Can you tell me whether you were discussing EPO generally there, or was that in the context of a specific

article that was being marked at that deposition?

A Well, if you look on the previous page it's clear that that was in reference to a particular article that I was reading from.

THE COURT: Just, just so I'm clear, I'm going to back to something as I think it through. As you understand it, nonnaturally-produced human EPO runs the risk of being misfolded?

THE WITNESS: All proteins run the risk of being misfolded.

THE COURT: All right. And human EPO produced in the human body runs the risk of being misfolded?

THE WITNESS: That's correct.

THE COURT: I see. All right. Go ahead. If there's nothing else, that's fine.

MS. CARSON: Roche has no further questions.

THE COURT: Nothing else --

MR. DAY: No, sir.

THE COURT: -- Mr. Day?

You may step down.

(Whereupon the witness stepped down.)

THE COURT: Is that it for Roche's presentation?

MS. CARSON: That's it for Roche's evidentiary presentation. I would like to take the remainder of the time to present oral argument on both Theory 4 and Theory 3.

THE COURT: I'll, I'll proceed that way. That's, that's fine. I understand that. And I'll give you the time that we've allotted. And, therefore, Ms. Ben-Ami.

MS. BEN-AMI: I'm just segueing. Mr. Suh is going to carry the burden on this, your Honor. I did just want to point out a couple of things to you.

I would cite to your Honor the In re Longi case, 759 Fed. Circuit 887, 1985 case from the Federal Circuit, applying doubt patenting, obviousness-type/double patenting where specifically prior art references were considered with the claims for the double patenting.

And there are cases -- there's also MPEP cites on this I can read to your Honor. The MPEP Section 804, Paragraphs 8.36, 8.37. So this was the reason that we were presenting the view that you can look at the prior art. You take the claims of the, that you're looking at for the double patenting, and you apply the prior art plus the claims, and that is our understanding of the law. So I didn't want to, you know, let your Honor think that there are not cases that say this. There are cases that are quite specific out of the Federal Circuit that do say you do consider the prior art.

THE COURT: Happy to receive that specific argument. And I have no doubt about the authenticity of NUK. For the moment, I adhere to my ruling.

Mr. Suh.

MS. CARSON: Actually, your Honor, before we turn to, Mr. Suh's going to take care of obviousness/double patenting Theory 3, I was going to finish addressing Theory 4.

THE COURT: That's fine. It's one of the advantages of time limits. I'm comfortable that this will end at a specific time, and let's do the work together.

I'll hear you, Ms. Carson.

MS. CARSON: So, your Honor, this Theory 4 again is the assertion that Roche has made from the outset of this litigation, that the '933, the '349 and the '422, those are two product claims and one process claim, are obvious over the process claims of the '868 and the '698 patent.

And so, the first thing that I wanted to address -- RB-1.

Amgen's taken the position that we didn't raise this theory or preserve this theory, and we raised it as early as our amended answer and we maintained it throughout our pretrial memorandum. So, I wanted to dispense with that right out of the box.

The next thing that I wanted to talk to the Court about is, I want to explain why the language of 35 U.S.C., Section 121 makes it clear that Roche can in fact rely on the '868 and the '698 patents as obviousness/double

patenting references against the '933, '422 and '349 patents. And I want to, to illustrate this point, I'm going to look at the language of 35 U.S.C. 121 and then walk the Court as quickly as possible through the prosecution history just to show the Court how these patents came into existence.

So if I can have RB-2.

35 U.S.C. Section 121 says that a patent that issues on an application with respect to which requirement for restriction has been made, or an application that's filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application.

So, the question that we have to ask is did the '868 and '698 patents issue on an application to which a requirement for restriction was made, or did it issue on an application that was refiled as a result of a restriction requirement.

And what I want to illustrate to the Court today is that in the case of the '868 and the '698 patents, it did not issue, those patents did not issue on an application that a restriction was made on nor did those patents issue from an application that was filed as a result of a restriction requirement.

And so, if we can RB-3.

This is a very complicated family history of the patents-in-suit. But if you look to the far left side, serial number 675,298, that's your original application that resulted in the '008 patent. It's on that '298 patent where the restriction requirement happened. And in that restriction requirement the Patent Office restricted the claims to a series of separate groups. And so the separate groups that were -- so, this is the application that the restriction requirement was issued in.

The '008 patent issued from that application. So if you look at the statute, you would say that this is a patent that issued on an application in which a restriction requirement was made. This is your patent, the '008.

So, the '008 patent we could not rely on as a reference assuming consonance was maintained, and it's our position that it was not, but your Honor has, has already ruled on that in summary judgment.

So, now the question is, is this patent application, which is the application from which the '868 and the '698 patent issued, was this application filed as a result of the restriction requirement. Because that's the other, the other bar to using these patents as a reference, if this application was filed as a result of a restriction requirement.

And what I want to walk you through is the fact

that this was not filed as a result of a restriction requirement. As a matter of fact, the application that gave rise to the '868 and the '698 patents was voluntarily filed to encompass process claims that could have been prosecuted into the '008 patent.

And could I have RB-4.

Now, the Manual of Patent Examining Procedure explicitly tells you that if the applicant voluntarily files two or more applications without a restriction requirement 35 U.S.C. 121 does not apply.

So, if we can go to the next slide which is RB-5.

So, the next series of slides that we're going to walk through are going to show you as you walk through the prosecution history and the application that was filed that gave rise to the '868 and the '698 patents that that application was filed voluntarily, directed to claims that could have been prosecuted to result in the '008 patent, and that it was a voluntary decision by Amgen.

So, if I could have the next slide.

So, this is a time line of how, what we're going to walk through. The '298 application, that's what resulted in the '008 patent. This is where your restriction requirement happened. The claims that were to DNA and the claims that were to process were put into Group II. They belonged together. The Patent Office says you get one patent on

process claims and DNA claims. So that's the restriction requirement that happened.

Amgen prosecuted the DNA and the process claims in Group II like the Patent Office told them to do and at some point they just voluntarily canceled their process claims. And Amgen actually has explained why they voluntarily canceled their process claims. They canceled them because they weren't getting them allowed quickly enough, so they decided to take those Group II claims out of the DNA claims and pursue them elsewhere.

And I'm going to illustrate this with portions of the file history. They voluntarily dropped their process claims in 1987, March of 1987. The '008 patent issues without their process claims. And then in October of 1987, now they file a new application and now they're going to go back after the process claims again.

If I could have the next slide.

So, here's the restriction requirement that occurred in the '298 application where the examiner grouped the claims in six different groups and they said that the DNA claims belong with the process claims.

And could I have the next slide, please.

So claims 61 through 72, these were process claims, along with DNA claims, where Amgen decided to pursue way back when when that restriction requirement was first

issued.

If I could have the next slide.

And this is just a slide to illustrate that claims 69 through 72 were directed to a process for production of a polypeptide having all or part of the structural conformation of EPO where you grow under nutrient conditions host cells that have been transformed, et cetera.

So these are the process claims that the Patent Office told Amgen belonged with their DNA claims as part of Group II and that they should all be prosecuted together.

Can I have the next slide.

Now, after prosecuting those claims for a while, along with the DNA claims, Amgen decided to voluntarily cancel these process claims out of the application.

And if I could have the next slide.

And what Amgen told the Court in the offer of proof that they recently filed, they said, although they initially elected all of the Group II claims, which included DNA host cell and process claims for further prosecution in the '298 application, they later canceled those process claims after it became apparent that the PTO would not allow issuance of those claims. So they were in a hurry, they wanted to get the DNA claims, so they voluntarily pulled the process claims out.

Can I have the next slide. Next slide, please.

All right. So now where we are is -- and it might help to go back very quickly to the time line, which is RB-6.

So, where we are on the time line right now is, Amgen has voluntarily canceled their process claims. The '008 patent issues here. Now, it's October 1987 and they file the '179 application. Now, this is the application that we have to focus on. The question becomes is this application filed as a result of a restriction requirement, because that's the only other way that Amgen could have the benefit of 35 U.S.C. Section 121.

So, if we can go to RB-13, please.

Okay. So here is the initial filing of the '179 application. This is the application that we're looking at to find out whether or not it was filed as a result of the restriction requirement. It was a request for filing in continuation. Amgen canceled claims 2 through 60.

And if we could go to the previous slide just to see what that is.

So in canceling claims 2 through 60, these are the original claims that were restricted in the first application, they were left with one DNA claim. So, they had one DNA claim from Group I.

Now, if I could have slide RB-14.

However, at the same time -- so you would say,

okay, well, they filed this as a result of the restriction requirement, they were going for Group I, not Group II claims. But that's not what happened. Because on that same day, the same time that they canceled those claims and left the one DNA claim, they also canceled the DNA claim at the exact same time and they inserted new claims 61 through 64. And those were claims that were directed to processes for producing erythropoietin.

So, all they did was, through a series of simultaneous amendments, they now are prosecuting claims in the '179 application that are two, Group II process claims that they should have pursued in the application that led to the '008.

So this application was not filed as a result of a restriction requirement. This application was filed because Amgen decided that they wanted to produce, to pursue process claims later on when they thought they could get them and they could get their DNA claims earlier.

This application, these are process claims, they're added to the '179 at the same time that Amgen files the application. So this application is not filed as a result of a restriction requirement.

And the same series of events occurred for the '698 application. They did the exact same thing. They canceled all the claims except for claim 1, and at the same time they

canceled claim 1 and they added process claims.

And I realize that this is a complicated series of events and a lot of maneuvers. But if the Court goes through this file history with the help of the slides that we've handed up, the Court will see that Section 121 does not say that we are prohibited from using the '868 and the '698 patents as a reference against the '933, '349 and the '422 patents.

Now, just due to time constraints, I can't go into how if you look at those claims of the '868, it's a process for making glycosylated erythropoietin polypeptide that has the in vivo biologically active. The '933 claims are product-by-process. You use the process to get the product. So, it's hard to believe that these claims could possibly be patentably distinct.

And really the only question here is, can we use the '868 and the '698 as a reference patent against the '933 and the '349 and the '422. And the answer is a resounding yes. Yes, we can. And once the Court gets past that question and recognizes that 121 offers Amgen no protection whatsoever, then it becomes abundantly clear that there's obviousness-type/double patenting going on. And the evidence is all in the record from Dr. Lowe and now from Dr. Kadesch.

THE COURT: Well, let me ask you -- let me just

follow this -- I understand that argument, and let me try to follow it out.

You say that there is no way they could get protection, or more narrowly, they should not have the protection of 121. Therefore, the '698 patent should be construed as matter of law to render the related claims in the patents-in-suit obvious. As matter of law, right?

MS. CARSON: Well, I think as your Honor pointed out, they say as matter of law but it's an issue for the Court to decide. Because as Ms. Ben-Ami just pointed out, you can in obviousness-type/double patenting determination consider what was known in the prior art.

THE COURT: Okay. I appreciate your consistency. And therefore, when we, when we tease out this aspect of the case as I have chosen to try it, a result, the result for which you argue is that I would determine, whether I call it a finding by the judge or whether it's a ruling by the judge, that certain of the claims in issue are obvious by virtue of this prosecution history. Right?

MS. CARSON: You -- yes, your Honor. What our argument is is that if you take certain of the claims of either the '698 or the '868 and you look at the asserted claims, those claims are obvious over the claims of the '698 and the '868.

THE COURT: Yes. Let me see here.

Well, what is your position as to the '179 application? Is it your position that it contained both claims that were the result of a restriction requirement and claims not subject to any restriction?

MS. CARSON: Your Honor, because everything was done at the exact same time it never actually contained claims that would be to a nonelected invention, because everything happened at the same time.

THE COURT: All right. But as I -- I see.

MS. CARSON: And, your Honor --

THE COURT: Let me say it back to you to see if I have got it.

They filed claims subject to a restriction requirement. At least claim 1 was.

MS. CARSON: Yes.

THE COURT: All right. They -- you say claim, claims 2 through 60 were not because it was they who had voluntarily ceased the prosecution of those claims.

MS. CARSON: Claims 62 through 72, or something like that.

THE COURT: All right. Then they drop all those claims, they drop the one claim that they, is, is subject to a restriction requirement.

MS. CARSON: Right.

THE COURT: They substitute on the same day claims

62, inserting 62 through what?

MS. CARSON: Seventy -- 61 to 72.

THE COURT: Sixty-one through 72. Which you say are not subject with, to a restriction requirement.

MS. CARSON: Right. They were process claims that belonged to --

THE COURT: Are they consonant with the restriction requirement as the law uses that term?

MS. CARSON: They're dead on in Group II. They belonged in Group II. They track the language of what should have been in Group II. They're process claims. They're what the Patent Office said you should be prosecuting with your DNA claims.

And, your Honor, there's a point that I would like to make. Because if you take -- Amgen can say to you, well, when we filed the '179 we had a claim 1 and that was subject to a restriction requirement, so the '179 and any patent that issued from it should be immunized by 121.

THE COURT: Oh, no, Ms. Carson, whatever my other failures, you've made an argument I understand. And I'll be asking them about it and we'll hear what their response is.

MS. CARSON: Okay. Thank you, your Honor.

THE COURT: Now, before we turn to Mr. Suh, I need about five minutes, to change reporters, and I need five minutes. It seems to me that this would be a good time,

because I'm just counting the time, and I don't want to interrupt your argument.

So we'll take a five minute recess at this time. We'll recess.

THE CLERK: All rise. Court is in recess.

(Recess.)

THE CLERK: All rise. Court is in session, please be seated.

THE COURT: Mr. Suh?

MR. SUH: Good afternoon, your Honor.

THE COURT: Go right ahead.

MR. SUH: As my colleague, Ms. Carson, explained, I will be dealing with the obviousness-type/double patenting Theory Number 3, which is the theory that's based upon the earlier issue and now expired '008 patent, and that those claims render the asserted claims in the '868 and the '698 patents invalid. And with respect to this theory, your Honor, I don't think there is any dispute anymore that Section 121, the restriction requirement safe harbor, applies. I believe that Amgen has now agreed to that.

And I also wanted to make the point with respect to the 121 restriction requirement that my colleague, Ms. Carson, talked about, that that is still Amgen's burden to prove.

THE COURT: What's Amgen's burden of proof?

MR. SUH: To show that the Section 121 safe harbor actually applies as a defense to double patenting.

THE COURT: Oh, I follow that. All right.

MR. SUH: And the reason why we're giving, as we can call this argument, with respect to ODP Theory Number 3, is because your Honor actually allowed the jury to hear some evidence on ODP Number 3 through Dr. Lowe.

THE COURT: Yes. And you have every right to rely on the full record that's been prepared in the case. When I got it in my mind that I was going to determine this myself, I thought that -- I didn't -- it might be confusing to the jury to start striking things out, we're just not going to mention that any further. Those arguments as they are today are going to be directed to me.

MR. SUH: Yes, your Honor.

THE COURT: But the record is what it is.

MR. SUH: In addition to Dr. Lowe, there were issues that did overlap from what Dr. Lin actually testified yesterday, which actually bear on ODP Theory Number 3. But before I actually lay that evidence out, I'd like to actually go to the file history, because I think this is a good point where it lays out, again, the fact that there is no restriction requirement issued here. And I'd like to go to what Ms. Carson published as RV12.

Your Honor, this is the 1986 restriction

requirement from the parent applications of all the patents in suit. And your Honor, if we look at Group II, that group is the group whereby the claims of the '008 patent issue, and that group is also the claims that the '868 patent claims issued, and the '698. So those were all within the same restriction group. They were never separated out. That's why there is no 121 issue with respect to the '008 as opposed to the '868 and the '698.

Now, I think this particular time period is very relevant, late '80s. I think we should go back 20 years ago, this was before any of the patents in suit had issued. Amgen had their '008 patent, and they were faced with their first commercial and legal challenge with respect to EPOGEN.

Amgen sued a company by the name of Genetics Institute in the District of Massachusetts before Judge Saris. But at the same time, they were involved in a very bitter interference fight in the patent.

THE COURT: Which they win.

MR. SUH: And that's exactly why I think that with respect to ODP Theory Number 3, the things that they actually said in those patent interferences are directly contradictory to their position here today. And I'm going to go through that with you.

THE COURT: Well, I'm interested in that, because is it not true that if I adopt either of the arguments that

you and your colleague, Ms. Carson, have made in this lawsuit, I will be making rulings of law contrary to the agency officers that have looked to these matters?

MR. SUH: Absolutely not, your Honor.

THE COURT: I won't be. I'm not -- not that that frightens me, or will cause me to stay my hand, but it's something. So, and you're saying not at all.

MR. SUH: Absolutely not.

THE COURT: That if I adopt the arguments that you and she have made, the record as against some claim that different hearing officers are reaching inconsistent positions as matter of law, won't lie.

MR. SUH: No. I'll tell you why. Because our position is that Amgen is judicially estopped because they're trying to actually contradict the findings that these judicial bodies and the Patent Board actually adopted. They argued it, the patent office adopted it, and now they want to change their minds. I'm going to go through that with you right now.

In the late '80s, there were three interferences that Amgen was involved with against Genetics Institute.

THE COURT: Well, Mr. Suh, I want to hear this. At the same time, if I count the time now, you're at an hour, and Roche is an hour ten minutes out of their two. So you've got five more minutes before you're into the 45

minutes you want to reserve for Lodish. And much as I could direct, and the like, I'm not likely to. I'm prepared to use the full four hours.

Now, I'm not -- I just want you to figure out how you want to do it. That's all.

MR. SUH: I understand. I'll go through this very quickly.

THE COURT: Go ahead.

MR. SUH: Those interference decisions involved three sets of inventions. One interference was called the '096 interference, and that involved the actual claim. The count of that interference was an actual claim to the now expired '008 patent. That was claim 2.

There was also another interference, and that was -- that involved 102097 interference. That count was the claim that became the '868 and the '698 patent. So we have these two separate counts, your Honor. And that was being contested before the Patent Board.

Now, Amgen caught a break in the late '80s because Judge Saris actually came out with a finding which said that Amgen was the first to clone the EPO gene before GI. So what did Amgen do, your Honor? It took that district court decision, went to the Patent Board and said, Patent Board, you should recognize this decision. You should recognize the decision because the count in the interference was to be

'008, and the litigation was also involving the '008.

And to a certain extent that makes sense, but Amgen didn't stop there because there was another interference and that involved the '868 claim. And what Amgen did there was it said this decision on the '008 claims should also be used, it should also be dispositive on the '097 interference.

And how did they make that argument, your Honor? They made that argument by saying that the '008 claims and the claims that became the '868 and '698 patents were the same invention. And their words were, These are merely different manifestations of the same invention.

THE COURT: Well, why would they ever say that?

MR. SUH: Because they wanted to bootstrap the opinion that Judge Saris made on the '008 and use that as judicial authority in order to win their other interference. And they made those arguments, and they made these arguments in this interference brief, which I'd like to offer into evidence.

THE COURT: Well, I don't know -- why don't I take judicial notice of it. I'm disposed to receive it.

MR. SUH: And your Honor, this is not only did they make the arguments, and this is answering the question that you asked, they made these arguments and the Patent Board accepted it. They agreed with them. They said that for

purposes of priority, the '097 interference that dealt with the '698 and '868 patent and the other interference, '008, are identical based upon the arguments that Amgen made.

THE COURT: And so this is rather straightforward argument. So you say, Having said that, that is a classic judicial estoppel. They said that, they got the advantage of that before the administrative board, now they can't say something else here.

MR. SUH: Absolutely. Because that was 20 years ago. And now what happened in 2004, the '008 patent expired, and in 2006 Amgen sued Roche. And when we answered that pleading, we said double patenting, '008 patent. As soon as we said that, they ran away from their statements that they made 20 years ago. And the arguments that they give are three-fold. They said, Well, you're really taking those statements that we made out of context. Well, your Honor, we can provide you the briefs. We're not taking anything out of context.

The other argument that they're making is that, Well, these were really arguments that Genetics Institute was making. And your Honor can actually take a look at the briefs and see that Amgen actually adopts the position by GI in order to take advantage of Judge Saris' position.

So we're not asking you to overturn anything that Judge Saris did. We're not asking you to overturn anything

that the Patent Board did. As a matter of fact, those stay exactly the same. And it's Amgen that wants to actually go back and change history.

THE COURT: I understand the argument. Is that Roche's presentation?

MR. SUH: Yes, your Honor.

THE COURT: Very well. Mr. Day, I, again -- I'm sorry.

MR. SUH: And, your Honor, may I please move this particular interference brief into evidence?

THE COURT: I'm not accustomed to taking briefs as evidence, but since this is a judicial estoppel claim, I'm going to receive it. We'll give them letters here, so we don't foul up -- does this have letters?

MR. SUH: Yes. GUK.

THE COURT: GUK. I'll consider it in this proceeding.

All right, Mr. Day, I'm a little --

MR. SUH: I'm sorry, your Honor, one last thing. May we please also allow you to have judicial notice of the interference decision, which I also have a copy of?

THE COURT: Yes. Does it have letters?

MR. SUH: Yes, it does. CAD.

THE COURT: CAD will be considered in this.

All right. Mr. Day, I'm not going to have

arguments about directed findings, but really you can spend your time as you see fit. You can either take them on legally right now, you can call witnesses. They've reserved 45 minutes, and we'll use it up however. And you may proceed as you see fit.

MR. DAY: Thank you, your Honor. And before I begin, I apologize to the Court, but I did misspeak this morning. I said that Dr. Varki was our last witness. I believe that Dr. Lodish will also be testifying in our case, but very briefly. He will be our last witness. I just wanted to bring that to the Court's attention.

I'm going to use my time today for argument, your Honor, and we're going to be calling Dr. Lodish as a witness on Thursday afternoon.

THE COURT: And that's fine.

MR. DAY: I think it's probably best simply to follow the order in which Roche has presented its arguments. So I'm going to begin with Theory Number 4. Is it okay if I refer to these as Theory 4 and Theory 3?

THE COURT: It is. And a question I wanted to put to your side, since we're going to argue is, I would like to see the legal -- this can be done by brief -- but the legal landscape and gloss that's put on the word "consonance." Because you've got this single application from which various patents flow, and as I understand the law, for them

to have any benefit from an earlier restriction, your conduct must be consonant with that restriction.

First, isn't that a correct statement of the law?

MR. DAY: Yes.

THE COURT: And, therefore, I'd like --

MR. DAY: So it must maintain consonance.

THE COURT: Fine. I'd like to see -- and my statement is to both sides. In the limited time we have, I'd like to see that develop by the decisions of courts either controlling or persuasive. But now I'll hear your argument.

MR. DAY: I think the two controlling decisions here that your Honor's going to want to look at are Symbol in the Federal Circuit -- let me give you the citation to that case, if I could. My eyes are shot. It's Symbol Technologies versus Opticon, 935 F. 2d 1569. You might want to particularly look at 1579 to 80. Then, of course, Applied Materials versus Advanced Semiconductor Materials, 98 F. 3d 1563, 1567 to 69.

And the principle around consonance, just to address the point, since the Court's raised it, the principle around consonance is that the important concept is that the patent, as issued, must have claims that maintain consonance with the original restrictional requirement. And what Applied Materials establishes is that doesn't mean that

during prosecution you can't amend the claims, it doesn't mean you can't go in and out of consonance during prosecution. That's okay. It's all right that different claim sets move in and out of these applications.

What matters is from measuring from the beginning point, was it an application filed in response to a restriction requirement; and the endpoint, at the end when the claims issue, did they maintain consonance as issued. That's the key thing. And that's what Applied Materials establishes. And that's why I commend both of those decisions to the Court.

I think that there are a couple of preliminary points that I want to talk about with respect to Theory 4 that Ms. Carson made light of, but I don't think are quite as superficially disposed of as Roche would have the Court believe. First of all, Roche provided no discovery within the time limits for any of these defenses. They were served, as our brief proffered last week showed, written interrogatories requiring answers by the discovery cutoff set by the Court, April 2nd. No responses identified these defenses.

Secondly, when Roche served their expert reports four days later on their validity defenses, they had one, two, three, four, five expert reports on obviousness-type/double patenting.

Could I have Slide D253 up, please?

They had five different experts offer initial expert reports on April 6 who covered ODP. Those are the first five listed: Lowe, Blobel, Harlow, Kellems, Sofocleous. Kadesch didn't discuss anything about ODP in his expert report. All these amended reports, from April to June, and none of them, none of them said anything about this. And the only thing that we got were two sentences in the last report of Kadesch, two sentences in the last report of Kadesch that said the '698 claim 4 was rendered '349 claim 7 invalid for double patenting. Not obviousness-type/double patenting, double patenting.

THE COURT: But I guess I don't understand here, to this extent. There's much to what you say about Kadesch, I've looked at that. And if they want to say something more about that, fine. But Mr. Suh's argument is entirely -- I mean, he supports it by matters as to which I could take judicial notice, but it's entirely matter of law. A question of judicial estoppel. Ms. Carson's --

MR. DAY: As to Theory 3 --

THE COURT: Just hear me so you can deal with it.

Ms. Carson's argument, though she put on Kadesch, she doesn't really need Kadesch because there's no doubt I can look at the patents and the prosecution history. I do that in Markman. That's for me, however we characterize it,

and it's my duty, I think, to do that.

So it's not a question of failure to provide evidence. Rather, it is what I make of the evidence. She could still win if I disregard Kadesch and disregard Lowe. Even if they say anything about this, and I'm not clear they do.

MR. DAY: No, she couldn't.

THE COURT: At least in my mind she could.

MR. DAY: No, she couldn't.

THE COURT: Why not?

MR. DAY: Because this is an -- this is an affirmative defense of Roche.

THE COURT: She says, though, that you bear the burden of coming within 121.

MR. DAY: 121 is simply a safe harbor to the defense. But it's still a defense of Roche. And Roche still has to mount the defense, and they have to give us notice of the defense, and they have to make disclosure of the defense in discovery, and they have to give us a reason to believe, before trial, that they're going to try this issue to the Court.

THE COURT: And you say it doesn't even rise to that level.

MR. DAY: That's right. I'm saying there's a waiver here that the Court should pay attention to because

of the Court's strict scheduling orders, and what the Court has required the parties to abide by and adhere to in this case. What standard does the Court here set for pretrial disclosure of a defense. That's the issue.

And when they don't disclose the defense in their interrogatory responses, and don't disclose the defense in any of their expert reports, they don't disclose the defense in their '282 statement, they don't provide any notice of defense right up until their pretrial brief served on the eve of trial, is that fair notice of a defense that entitles them to raise this? That's the issue I raise.

So let me turn to the issue that Ms. Carson raises.

Could I have Slide D255.

And that issue is, if the Court decides that, okay, well, we'll skate on that, we'll let them get by with that, and now Mr. Day, you tell me, do you have a safe harbor defense that otherwise takes this out.

I'm sorry, did I get D255? Is that what this is? Well, let me show you what I want.

(Whereupon counsel conferred.)

MR. DAY: So this is Section 121 and it's Section -- this is Section 121, verbatim, but I've broken it out logically to help parse the language of the statute so that it's easier to understand what the statute says.

The statute says that a patent issuing, and there

are two alternatives, on an application with respect to which a requirement for restriction under this section has been made, or, on an application filed as a result of such a requirement -- that's this case, that's what we're dealing with here -- shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application, or against the original application, or any patent issued on either of them, if the divisional is filed before the issuance of the patent on the other application.

Could I have 225, please?

THE COURT: I'm following.

MR. DAY: So there are two requirements. The two requirements are, first of all, that the later-issued patent must arise from an application that was filed as a result of a restriction requirement. That's what Symbol Technologies and Applied Materials applied to.

THE COURT: Well, she accepts that, and her parsing of the history is that this --

MR. DAY: She wants you to second-guess what happened, right?

THE COURT: Second-guess what happened, she says it was a fast shuffle. It didn't happen that way.

MR. DAY: No, it happened exactly -- it happened exactly as she said it happened, but that's not a fast

shuffle.

THE COURT: That's a fair response.

MR. DAY: Okay. The way it happened was that Amgen, in response to a restriction requirement, filed an application that contained one single claim that was not in the elected group, just as the patent office requires it to do. It followed the patent office practice and procedure. It filed one claim, it filed a filing fee for one claim, and then consistent with, just as Applied Materials and Symbol Technologies teaches you, it was free to amend that application all the way until the point of final issuance, so long as the claims that issued out of the final application, so long as the claims that issued maintained consonance.

THE COURT: And -- I just have to ask a basic question. I understand the word "consonant," and I'll check these cases as to the laws. That means, in other words, that the claims that ultimately issued fall within the original restriction requirement so that they gain the benefit of Section 121.

MR. DAY: It means so that they fall outside the elected claims within the original restricted -- restriction requirement. Let me explain. And I think we're probably saying the same thing, but I'm trying to be as precise as I can be.

THE COURT: And I'm asking.

MR. DAY: Could I have D259, first of all.

THE COURT: Well, they're outside in the sense that they're patentably distinct, but they are within the ambit of the original restriction requirement. Does that say it?

MR. DAY: Not quite, your Honor. Let me see if I can work on a phrasing that is accurate and clear.

We see here the restriction requirement. And this is the patent office restriction requirement that was imposed in the original '298 application. And it defines six groups of claims, and they're numbered there, Roman Numerals. And the patent office went on at the bottom, it says, "Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter restriction for examination purposes as indicated is proper." Amgen, you must elect one of these, choose one.

Amgen chose Group II. And as a result of choosing Group II -- could I have D219, please? -- Amgen, on the left, you have the '298 application, the next box to the right is the restriction requirement with the six groups of claims. Amgen chose for the '008 application, the '298 application, it chose Group II claims, Roman Numeral II, above the '008 and it prosecuted those Group II claims.

Amgen then filed two applications in response to the restriction requirement, the '179 and the '178, and both of those applications as filed contained one claim. Neither of those claims was within Group II. That's what the law required Amgen to do. That's why there were applications filed in response to a restriction requirement.

That was then Amgen's ticket to ride, if you will. From that point forward, Amgen was free to amend and put whatever claims in and out it wanted to, so long as whatever applications ultimately resulted from that, if the patent issued with claims that abided by the restriction requirements on the left, in other words, so long as the applications issued -- let's take a look at the '933 -- so long as there were no claims in the '933 patent that fell within Group II, it was entitled to the protection of 121 against any other application filed as a result of that restriction requirement.

THE COURT: Let me say it back so I understand it. In other words, to be consonant with means that the claims as issued in the patents resulting from the '179 application, had to be claims within Groups I, III, IV, V and VI, and not within Group II.

MR. DAY: Precisely.

THE COURT: All right.

MR. DAY: And as long as those claims are within

those nonelected groups, they are consonant with the restriction requirement.

So what happened is that Amgen filed two applications. It bought two tickets to ride. It said, We'll take two tickets to ride, thank you. Patent Office -- could have taken six, could have taken five, doesn't really matter. Because under Symbol and Applied, it has the freedom, once it buys a ticket to ride, it has the freedom to amend those applications and to divide them or file continuations. And none of the resulting applications, none of the resulting applications will be subject to ODP on any application that issues as a result of that restriction requirement. That's what the law means.

And so as long as Amgen maintained consonance, it gets the protection of 121. The '933 maintained consonance, the '422 maintained consonance, the '349 maintained consonance. The '698 did not and the '868 did not. Because the '698 and the '868 both included claims that fell within the scope of Group II. So they don't maintain consonance.

Therefore, those claims are not entitled to the statutory safe harbor of 121 protection. However, as the statute goes on to make clear -- could I have 261, please? Forget -- that's all right, never mind.

However, the fact -- the statute goes on to say, "The validity of a patent shall not be questioned for

failure of the director to require the application to be restricted to one invention." That point's not relevant to the point I want to make so let me simply withdraw it.

The fact that Amgen did not maintain consonance with the '698 and the '868 does not mean that it cannot establish that the claims are not subject to obviousness-type/double patenting. And, in fact, during the prosecution, I'll get to this when we address Theory 3, when we get at '868 and '698, in fact, during prosecution the claims were rejected by the examiner for obviousness-type/double patenting and Amgen overcame that rejection which heightens the presumption that these claims are valid.

So the point I want to make with respect to Theory 4, and I'm happy to close out on that, if I could just come back to, first of all, 225, and I'm going to end with 220. Get that ready, 225.

The point I want to make with respect to Section 121 is this Court has already determined as a matter of summary judgment that both the '178 and the '179 applications were filed as a result of restriction requirement. That determination has been made in Amgen's summary judgment. Roche is asking you to go back and revisit that judgment, and they're asking you now to determine, no, the '179 application was not filed as a

result of a restriction requirement.

And the fact that -- when the claims were filed, the fact that when the application was filed, that 120 demonstrates that it qualifies for 121 protection. In order to secure the protection, the patents at issue must have maintained consonance. And only those patents get the protection of 121. And that's what Symbol and Applied Materials and Gerber all establish.

Let me turn, if I could, to Roche's Theory 3, Mr. Suh's argument, if I could, your Honor.

The first point to understand about what Roche calls Theory 3 is, okay, let's clear the air here. Amgen is not arguing that it has a statutory safe harbor protection under 121 reduced claims, instead Amgen's arguing that these claims are patentably distinct, and the patent office has determined on multiple occasions that these claim are patentably distinct. And indeed it expressly determined that when it allowed the claim to issue.

Roche is asking the Court to unwind those decisions and to reverse them. And what's the background of this? I want to be clear about some of the factual background that Mr. Suh covered, and some of the factual background that he did not cover. And to do that, it's probably best to just put up a little bit of a time line. And I'm going to put up now -- now we can have D255.

And let me just explain this time line, because it's going to set the context for the prosecution history of this '868 and the '698 patents. As you see, the time line goes in sort of a U. This is Mr. Gottfried's idea, so I can give him full credit. We start off on the left, and what you see are the original applications in dark blue. These are the CIPs that were originally filed in December, February, September and ultimately in November 1984.

Going down, you see 7/3/86, you see in the yellow box the restriction requirement that we've been talking about. Then you see the '179 application, which is the application that ultimately resulted in the '868 and will result in the '698 applications as well. And you see in the 1987 to 1988 time period, just before that red box at the bottom which is the interference proceeding, Amgen was seeking allowance of this application in the patent office. It was seeking process claims in the patent office.

And the reason it was seeking process claims, and this is important to understand, is that there was, in addition to the GI case that was pending here in the District of Massachusetts, there was a parallel ITC proceeding in D.C. And in the ITC proceeding, Amgen was seeking to enforce its '008 DNA and host cell claims against the importation by Chugai of recombinant erythropoietin made in Japan and then being shipped into the United States.

The ITC held that you cannot stop the importation of product made in Japan because you do not have process claims to the manufacture of erythropoietin. And you do not have product claims to erythropoietin polypeptides or proteins. You only have DNA claims and you only have host cells containing DNA. And neither of those claims give rise to a process claim, which is what is required in order to stop the foreign manufacture and importation of infringement product.

So the ITC said your claims, your '008 claims don't extend to, they are patently distinct from and don't cover processes for the production of erythropoietin. And so Amgen was in the patent office before, in this case, the lower left-hand box there, Examiner Tannenholtz, trying to get process issued, because it needed the process claim in order to stop the importation of the infringing product.

Examiner Tannenholtz was resistant to allowing the claims because he was applying a law of a case decision called in re Durden on a theory that, well, the claims would have been obvious. Ultimately, he was persuaded that the law, the in re Durden, didn't apply, and that the process claims, that is, the claims using a novel starting material in a process to produce a novel product, was not obvious. And he withdrew his rejection. But when he withdrew his rejection, the claims went into the interference.

The patent office in the interference declared three separate interferences. And by rule, they must declare a separate interference for each separately patentable invention. They defined three different counts. Each count had to be patentably distinct. They defined a count to the '008 DNA and host cell claims, they said that's one invention. They defined a count to the process of making EPO glycoproteins, they said that was a separate invention. And they defined a count to EPO glycoproteins, the product themselves. They said that's a third invention. The three interferences were the '096 on the DNA, the '097 on the process, and the '334 on the product.

When the third interference was filed, GI filed a brief in the interference. Mr. Suh alluded to this, but I think mischaracterized Amgen's argument about this and what the brief actually said. GI filed a brief and they said, We should combine all these interferences into one. There's really just one invention.

This is what GI said. And in their brief they said the interferences should be combined because the counts all define different manifestations of the same invention. The motion was denied. And when the motion was denied, when the third interference was declared, the patent office acting commissioner -- and could I have D228, please? -- the acting commissioner of the Patent and Trademark Office, Jeffrey

Samuels, the examiner on the case, Howard Schain, and his supervisor, John Kittle, all signed this document saying while the subject matter of the three interferences is deemed to be patentably distinct, that subject matter is nevertheless related. Each of these inventions were separate. The three interferences were maintained as separate counts. And they denied the motion to combine because the subject matter was patentably distinct.

And as I pointed out -- D256, please -- the reason there were three interferences was because under patent office procedures, each count shall define a separate patentable invention. That's what the Manual Patent Examiners -- the MPEP requires. And it's not just the MPEP, but it's also by federal regulation. When there is more than one count, each count shall define a separate patentable invention. That's why there were three interferences.

Okay. So the first argument that Mr. Suh made to you, that Amgen said that these were different manifestations of the same invention, well, actually that was a statement made by GI. When GI filed that motion, Amgen opposed the motion and said, Suffice it to say, these are not the same invention, these are separate inventions.

Could we have that slide? Could I have D286?

This is what Amgen said in response to GI's

argument. "Fritsch contends on page 866 of its motion, the interference in terms of subject matter are essentially the same and the interference counts are different manifestations of the same invention. Fritsch has the burden of proof in support of its motion and the allegations made therein. Since Fritsch does not even attempt to supply any arguments or evidence in support of the bare allegation of same invention, it is apparent that it was not a serious contention. Suffice it to say that Lin contends that the two counts are not the same invention." So it's not Amgen that's saying that these are different manifestations of the same invention.

There was, in the interference, as Mr. Suh alluded to, another issue. It was the central issue in the interference. And that issue was the priority of inventorship; who was the first to invent here, and what happened in the course of the priority of the inventorship. And here again, I need to step back to set the stage.

THE COURT: Is that germane to this? In a way, I've gleaned that from the skirmishing that's going on, presentation to the jury.

MR. DAY: It's germane to my rebuttal of Roche's argument.

THE COURT: All right. Well, then I'll hear you.

MR. DAY: Because Roche is taking snippets from

interference briefs out of context and using them to create an impression that Amgen took a position that Amgen did not, and that the patent office reached a result that the patent office did not reach. And I simply want to set the context straight.

The issue both in the district court and in the interference was -- of priority inventorship, was defined by Fritsch this way. Fritsch argued, GI argued that they were the first to invent, recognizing that Lin had cloned the gene before them. Their argument was, Well, we conceived of a method of obtaining the gene before Lin back in 1982, and we were diligent in reducing it for practice. And even though we succeeded after Lin, because our conception was earlier in time, we were the first to invent it.

So Fritsch's argument was sort of a classic argument that has been applied in many areas of patent law, that the first to invent is the first to conceive followed by diligent reduction to practice. They argued that they were first to conceive back in 1982, and that in '82, '83, '84, they were diligent, and even though they cloned the gene a year after Lin, they were still ahead of him.

This court, the district court, rejected that argument and said in the context of DNA it's simultaneous concept reduction to practice. And the Federal Circuit --

THE COURT: When you say "this court," that would

have been Judge Saris?

MR. DAY: Correct, your Honor. I mean the District Course of Massachusetts.

THE COURT: But in Judge Saris' case. Go ahead.

MR. DAY: And obviously she was sitting as a magistrate at the time under this Court's supervision. I don't mean to suggest your Honor was involved, but I do mean to suggest it was the District of Massachusetts.

THE COURT: I just want reference to the opinion, and I understand. Go ahead.

MR. DAY: And the Federal Circuit affirmed and established a body of law which I've cited to you in our JMOL about simultaneous conception and reduction to practice and what is required in this area of the law to get to inventorship.

So Fritsch, nonetheless, not withstanding this, Fritsch continued to argue this in the interference. Because this was the -- this was their argument, this is what they were trying to ride. For that reason, Fritsch argued because conception, conception was what he was turning on, Fritsch argued that all of these counts should be determined by his date of his conception because the district court had already found in findings that the patent office was more or less bound by, the district court had already found that Lin cloned the gene first, Lin had

expressed the product first, Lin had developed the process for producing the product first, and had shown biological activity. All his dates were first. The only way Fritsch could get ahead of any of those dates was to argue conception as the basis for inventorship.

And what the Board of Interferences held in the interferences was they asked Fritsch, Do you concede, at final argument, do you concede that inventorship turns on who got the gene first? And Fritsch made that concession on the basis that, well, conception matters, and if I conceived of it first, I got it. The Board says, Well, that decides it because Lin was first on everything. There's no question. And that's why the interferences were all decided in favor of Lin, because Fritsch could not establish a date of reduction to practice for any of these that was ahead of Lin.

Finally, the last thing that comes out of the interferences, and is very important to understand, is that Fritsch had a final argument. They knew they were going to lose on it, on priority, and so they had a final argument. And the final argument was Lin's inventions were obvious. And they challenged the patentability of Lin's claims on the grounds that they were obvious.

That's why it's important to look at the entirety of the record in the interference and the entirety of the

briefs, because you need to understand what arguments Amgen made with respect to that issue.

And if I could have D310, please.

Fritsch argued that the process count would have been obvious. And here's what Amgen argued in response. "Furthermore, it was not obvious that in vivo biologically active recombinant human EPO could be made by the claimed process. Until Lin obtained the sequence, Browne used it in expression, and Egrie with Dukes found the product had in vivo biological activity. The process at best was only a wish."

So when you put the entire record in context, and you understand what -- and not just isolated snippets woven together in a very well-crafted way to present the appearance of an argument, when you take the entire record in context and understand what happened in the interference proceedings and what arguments were actually made, what they show you is it wasn't Amgen that was arguing that these counts were all different manifestations of the same invention. That wasn't Amgen's argument. Indeed, Amgen argued that these inventions were separate inventions.

It wasn't Amgen that argued that once you had the DNA it would be obvious to obtain a process for making a biologically active in vivo erythropoietin. In fact, Amgen argued exactly the opposite in the interference. And so

these patents came out of the interference in all three cases with priority assigned to Lin.

And the prosecution, if we go back to the time line now, please, and that would be 255, 255, and so prosecution resumed after the interference. And we're looking here at the time line that we were looking at earlier, the bottom. You see the interference is the red bar. When the interference concluded, all of these, the '008 was clear of the interference, the other applications now went back into examination, and in particular the '179 application went back into examination. And there was an ODP rejection issued in that case over the '008 claims. And the examiner said, Okay, you don't have 121 safe harbor protection because these claims are within Group II, and we think they're obvious over the DNA claims.

Lin responded to that obviousness rejection. And Lin made three arguments in response to the obviousness rejection. The first argument that Lin made was with respect to the ITC proceeding. He said, Look, the ITC has by virtue of the ITC decision and the Federal Circuit affirmance of that decision, it's already been determined that the '008 claims are patentably distinct from the process claims.

Second argument. The interference, in declaring two separate interferences, one for the DNA and one for the

process, the board at the patent office has already determined that these are patentably distinct inventions. But three, three, more fundamentally and more importantly, before the interferences were declared, we met and overcame the examiner's rejection for obviousness. And the reason that we overcame the rejection was on the basis of the evidence and the argument that we presented. And the evidence and argument that we presented in the course of that was to show that it would not have been obvious in 1983 or '84 to obtain a glycoprotein like EPO whose biological activity in the body, as you just heard from Dr. Kadesch, depends on the sugars. You just heard from Dr. Kadesch on the stand that if you remove a sialic acid --

THE COURT: Wait a minute. I'm following, but that -- I have nothing to say about that.

MR. DAY: No, this is the argument Amgen made. I'm simply recounting the argument Amgen made to the patent office.

THE COURT: All right. Well --

MR. DAY: I'm simply saying that Dr. Kadesch just now corroborated the argument.

THE COURT: Well, you're saying, Amgen, and I'm going to look at these materials with this in mind, you're saying, and I certainly haven't heard out of your mouth any admission of judicial estoppel.

MR. DAY: No.

THE COURT: All right. I'm interrupting you, only because --

MR. DAY: I will conclude by 4:00.

THE COURT: Well, I'm going to cut you off with five minutes and let you conclude sometime. But I'm following it so far, and I just need to plan for tomorrow.

So we're changing gears now. Now we're just talking about how the case is going to proceed tomorrow.

Tomorrow we will -- you may put on your additional two witnesses and we'll finish with this witness. And then you will rest.

Now, in a bifurcated proceeding -- or this isn't a fully bifurcated proceeding -- I do not require you to renew your motion for directed verdict. Under the Rules of Civil Procedure, you will save your rights for judgment not withstanding the verdict if you renew it at the close of all the evidence. Though, again, candidly, as a case management tool, I expect Roche may make a motion for directed verdict on the portion -- on the infringement portion that may be successful in whole or in part.

So you don't lose anything if you renew it tomorrow. But you may, though I'm not giving you any oral argument, you have to go right on.

MR. DAY: I plan simply to file some papers, your

Honor.

THE COURT: That's fine. So when that happens, I will say the first part's done, and working the break around it so I don't take a break between your two openings, and I doubt that will happen --

THE CLERK: And we have to swear in Francis.

THE COURT: Yes. We'll take that at the break. I will give my brief precharge on infringement, and the doctrine of equivalents, then there will be openings.

Now, since the burden of proof is on the other foot here, Amgen will open first, then Roche. You need not spend your time in opening, but you may. Amgen will call its first witness, and we'll roll right on.

MR. FLEMING: A point of clarification.

THE COURT: Yes.

MR. FLEMING: Under the '422, is the reverse doctrine of equivalents still available for Roche in this case?

THE COURT: No. I've given -- no.

MR. FLEMING: It wasn't clear, the reverse doctrine of equivalents.

THE COURT: That's interesting now, isn't it, because that's precisely the situation that arose in my original foray jury-waived. I had granted summary judgment as to infringement on the point. In the second trial, I

considered but rejected TKT's -- I don't know the answer to that.

MR. FLEMING: It would be useful for openings tomorrow.

THE COURT: It would be, wouldn't it?

MR. FLEMING: We, of course, have interpreted it that we still have it.

THE COURT: And I confess to you, Mr. Fleming, I was too quick a reaction. This is a new case, and only Amgen is bound. I don't -- boy, I exhaustively looked at that reverse doctrine of equivalents. I don't think that's much of a hope before the Federal Circuit, but that's not for me to say.

MR. DAY: Your Honor, could I be heard on that?

THE COURT: Yes.

MR. DAY: Just a couple of things. There is woefully little in Roche's expert reports to address this. And, moreover, if they are going to put on a reverse doctrine of equivalents case, then we should be allowed to tell the jury that the product literally infringes.

THE COURT: Well, we'll -- they only get to that issue if they find the product literally infringes.

MR. DAY: Well, you have found as a matter of summary judgment that the product literally --

THE COURT: I have ruled that --

MR. DAY: Yes, sir. I stand corrected.

THE COURT: -- the product literally infringes. Oh, I see the point.

And I do think that follows, Mr. Fleming.

MR. FLEMING: No, your Honor, because it's typically done in the alternative. Because the argument is should --

THE COURT: But they're not going to be asked. They're not going to be asked on the jury verdict slip whether claim 1 of the '422 literally infringes. No reference is going to be made to that at all. Why? I've ruled on the point and taken it away from them.

If you want a box on whether it infringes by the doctrine of equivalents, because as to the others, as to the others -- the way I expect many of these claims to come out, we're going to put both literal and equivalent infringement to the jury. And I have to tell them if it literally infringes, you don't have to answer doctrine of equivalents, leave it blank. If it does not literally infringe, you have to answer doctrine of equivalents.

So it does seem to me the logic is I have to tell them, I'll make it as mild as possible, but that it has been determined that as to this one it literally infringes. So you want to think about that and tell me tomorrow.

MR. FLEMING: First thing in the morning.

The second thing is as to the witnesses, now that Amgen has told us that they actually are putting Dr. Lodish on, which is contrary to what we understood, I understand he's going to be short, but they've given us quite an extensive disclosure about him. Can we get a really meaningful disclosure --

THE COURT: I expect people are going to --

MR. FLEMING: You have now ordered the exchange be followed in good faith.

THE COURT: You're not saying they don't. I wish they would, but my sovereign remedy for all this is the time limits. On Thursday, the 18th of October, this case will go to the jury. That discipline, and it is a necessary discipline in this case, and you're doing fine, is such that --

MR. FLEMING: No, I'm sorry, your Honor. Perhaps --

THE COURT: No, you made it clear. If they take a lot of time with Lodish, it's their time.

MR. FLEMING: No, sir, that's not my point. I beg your pardon, I was not clear. They say they're going to put Dr. Lodish on for invalidity for only a short purpose. They have given us in their written disclosure --

THE COURT: A bunch of stuff.

MR. FLEMING: He's got a tremendous amount of

reports. All we're asking for is a fair disclosure.

THE COURT: Yeah, I wish they would but I'm not ordering it.

Okay. I miscalculated the time on this segment, which doesn't count against the trial, but since I'm going to entertain more of this on Thursday afternoon, actually I had neglected Amgen's cross-examination of Dr. Kadesch. So Amgen has used up 55 minutes, and Roche has used up one hour and five minutes. Actually it's 55 minutes remaining, Mr. Suh.

MR. SUH: Thank you, your Honor. I wanted one last point. After we have submitted all the evidence on double patenting, Roche will present its brief on judicial estoppel as well as --

THE COURT: That makes perfect sense. I don't have to decide anything on Thursday afternoon, and at 4:00 on Thursday afternoon it is highly unlikely I'm going to decide anything. And, in fact, I backed into this thinking I had to make this decision before the case went to the jury. I don't think I do. Having taken it away from the jury, it's my determination. It will have the consequences that I determine that it has.

I thank you all. We'll recess.

MS. CARSON: Just to expand on what Mr. Suh said, we'll offer briefing on all the issues of double patenting.

THE COURT: Fine. Nine o'clock tomorrow we'll resume the jury trial. Thank you. We'll recess.

THE CLERK: All rise. Court is in recess.

(Adjournment.)

C E R T I F I C A T E

We, Donald E. Womack and Cheryl B. Palanchian, Official Court Reporters for the United States District Court for the District of Massachusetts, do hereby certify that the foregoing pages are a true and accurate transcription of our shorthand notes taken in the aforementioned matter to the best of our skill and ability.

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