UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

Civil Action
No. 05-12237-WGY

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AMGEN, INC.,

Plaintiff,

v. MARKMAN HEARING

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

Defendants.

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BEFORE: The Honorable William G. Young,
District Judge

APPEARANCES:

DUANE MORRIS LLP (By Michael R. Gottfried, Esq.), 470 Atlantic Avenue, Suite 500, Boston, Massachusetts 02210
- and -
DAY CASEBEER MADRID & BATCHELDER, LLP (By Lloyd R. Day, Jr., Esq., Linda A. Sasaki-Baxley, Esq. and Jonathan Loeb, Ph.D.) 20300 Stevens Creek Boulevard, Suite 400, Cupertino, California 95014
- and -
McDERMOTT WILL & EMERY (By William G. Gaede, III, Esq.), 3150 Porter Drive, Palo Alto, California 94304
- and -
WENDY A. WHITEFORD, ESQ., Of Counsel, Amgen, Inc., One Amgen Center Drive, Thousand Oaks, California 91320-1789, on behalf of the Plaintiff

1 Courthouse Way
Boston, Massachusetts

April 17, 2007

A P P E A R A N C E S (Cont'd)

BROMBERG & SUNSTEIN LLP (By Lee Carl Bromberg, Esq. and Julia Huston, Esq.), 125 Summer Street, Boston, Massachusetts 02110

- and -

KAYE SCHOLER LLP (By Leora Ben-Ami, Esq., Howard Suh, Esq., Christopher T. Jagoe, Esq., Krista M. Rycroft, Esq., Thomas F. Fleming, Esq. and Jeanna Wacker, Esq.), 425 Park Avenue, New York, New York 10022, on behalf of the Defendants

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

Calling Civil Action 05-12237, Amgen v. Hoffmann-La Roche.

THE COURT: Well, good morning, counsel, and would counsel identify themselves for the record.

MR. DAY: Certainly, your Honor. Good morning. Rusty Day representing Amgen. And with me I have my partner, Linda Baxley, and Jonathan Lobe; also Bill Gaede from McDermott, Will and Emery, Wendy Whiteford from Agmen, and Mike Gottfried from Duane Morris.

THE COURT: Yes, speak up a little bit, Mr. Day --

MR. DAY: I will, your Honor.

THE COURT: -- when we get rolling.

Go ahead.

MS. BEN-AMI: Good morning, your Honor. Leora Ben-Ami from Kaye Scholer for La Roche. And with me are Howard Suh, Chris Jagoe, Krista Rycroft over there, Jeanna Wacker, Tom Fleming, all from Kaye Scholer; Julia Huston and Lee Bromberg from the Bromberg firm; and George Townsend from La Roche is sitting in the back there.

THE COURT: Well, good morning.

Now, we've got some time to work together. Let me sketch out the general parameters and I think they will be familiar to you.

Because this is going to be a jury case, as near as I can see, and because we are at the trial preparation stage that every day counts, I consider it incumbent on me at least tentatively to make constructions today unless I'm clearly at sea. You'll understand that the constructions that I make today are law of the case in the sense that they govern the further proceedings in this case, but I reserve my right to modify them for good and sufficient reason. Now, that -- and I think I have an obligation to explain my reasoning in writing. But, as we talk things through today, I am going to make every attempt to give you my best judgment about the claim constructions so that further proceedings may go forward intelligently and expeditiously.

Now, at my request you've all briefed this, what you're framing is a stare decisis issue, and maybe I was a little previous there. Maybe that's -- well, we'll see. We'll see. I need not say anything about it until we get rolling here. But it is a matter of interest to me.

We have a number of claims to be construed. But I would like to start with the concern about therapeutically effective, because that's been such a matter of analysis both in this Court and in the Federal Circuit in a related case. And with respect to the phrase in the patent at issue here, patents at issue here, it would seem that the language adopted by the Federal Circuit controls the construction

adopted by the Federal Circuit.

And, Mr. Day, I'm going to let you start with this. Here's why. You are a party to both the cases. I don't have to look at this as pure matter of law. You are litigating the issue. You have had, or Amgen here, not you, Amgen has had a chance to fully brief, try and the like. And the Federal Circuit's come up with what it's come up with, and it seems to me, though conceivably there are further appellate proceedings, that's not for me to say or consider, I'm bound by what the Federal Circuit has said.

Isn't that right?

MR. DAY: Yes.

THE COURT: Okay. Well, then if that's so, if we look at -- let's go to the language which most closely deals with therapeutically effective. Where's that?

MR. DAY: Perhaps your Honor is thinking of '933, claim 9, I believe, or --

THE COURT: Okay.

MR. DAY: I'm just trying to find the page. Claim 9.

THE COURT: Claim 9.

MR. DAY: Pharmaceutical composition comprising an effective amount of a glycoprotein product effective for erythropoietin therapy. Is that the --

THE COURT: Yes, that's it.

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MR. DAY: That's correct. She will, she will disagree. It has been many, many years since this invention was made and nobody has yet found another way to do what Lin did. So, in the case of a pioneering patent, then in a pioneering patent claims are ordinarily entitled to a broader scope. Amgen's claims are both broad and they are narrow. They are not uniformly broad. The impulse to claim broad is not unchecked. There is also a reason to claim narrowly, and Amgen claims narrowly as well.

THE COURT: To, to avoid anticipation.

MR. DAY: Not to avoid anticipation. By claiming narrowly, you can delimit what it is that an accused embodiment must have in order to infringe. If you claim a lot then the accused embodiment has to have all of those things. And that, of course, is what's going on here. Roche is trying to blow this claim out to include more and more things in the meaning of human EPO in order to argue we don't have this, we don't have that, we don't have that.

So you can claim both broadly and you can claim narrowly. So the question is in the context of this claim, '422, claim 1, where you have to look at the entire claim language, in the context of this claim what does the claim term human erythropoietin mean. That's the issue for the Court.

I have some binders, too, that I would like to hand

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up to the Court, if I may. Could you give them some to opposing counsel.

Okay. And these are simply the slides that I will be talking about.

The first thing that I want to illustrate for the Court is the difference in the claim construction that Roche proposes and Amgen proposes.

Amgen's construction is a protein having the amino acid sequence of human EPO, such as the amino acid sequence of EPO isolated from human urine.

Now, the question for the Court in considering that, is that consistent with the other claim language, is that consistent with the specification, is that consistent with the prosecution history, as to what that term human erythropoietin means in the context of the entire claim, '422, claim 1.

Roche's construction differs. And I've highlighted on the right what is importantly different about Roche's construction. First of all, they say it's not a protein. They say it's a glycoprotein. That means that it must have glycosylation. It has the amino acid sequence of erythropoietin isolated from human urine. So they agree with us about the amino acid sequence. This argument you just heard from Ms. Ben-Ami, which was not in their papers, was made for the first time this morning on oral argument,

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is predicated on an expert report not before the Court, is inconsistent with what they acknowledge. This --

THE COURT: Well, we're trying to get at the best construction.

MR. DAY: I understand.

THE COURT: You do have, you do have a problem with that position 166. I mean, her argument does resonate.

MR. DAY: No, we don't have a problem with that.

THE COURT: All right, tell me why.

MR. DAY: And the reason we don't have -- because these are -- this is human erythropoietin purified from mammalian cells grown in culture. And the cells cleave off the 166 amino acids. And Lin produced and made and had in his possession an EPO that was produced by mammalian cells grown in culture. So he possessed a 165 species of human erythropoietin when he filed his application.

THE COURT: But he didn't know it.

MR. DAY: Oh, did he, did he know it?

THE COURT: Well --

MR. DAY: He possessed it.

THE COURT: Well, let's just go back.

MR. DAY: But, no, your Honor, this is an important point.

THE COURT: Go ahead.

MR. DAY: You asked a very good question and it's

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an important point. But it's irrelevant. It's irrelevant whether he knew it. What is relevant is whether he possessed it and he taught others how to get the same thing. That it was later discovered to be 165 and not 166, not what he had deduced it to be, is irrelevant.

THE COURT: Well, I understand that's your position.

MR. DAY: Okay. The second thing is, that Roche seeks to add to this claim is having the structure that would be produced in mammalian cells as of the invention date.

Now, let me ask you to turn the page and I'll illustrate for you what the difference is first of all between these two constructions.

On the left you have a picture of Amgen's construction. Amgen construes human erythropoietin as referring to the amino acid sequence of human erythropoietin as isolated from urine. Roche construes human erythropoietin as referring not only to the amino acid sequence but also to all of the glycosylation that's attached to that sequence by the cells. And they say there is one structure. They call it the structure. And so there's only one such structure.

Now, what's wrong with Roche's construction? Why is it inconsistent with the other claims, with the

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THE COURT: Well, you may but --
MS. BEN-AMI: I won't go through everything, but I think there's a lot of points here and I think I really do need to discuss this a little bit more.
THE COURT: While you're getting set let me talk to the clerks.
MS. BEN-AMI: Okay.
(Pause in proceedings.)
THE COURT: Go ahead.
MS. BEN-AMI: Your Honor, when I say extensive it might still be brief. But I would like to start with this.
If you look at your screen, your Honor, this is what Amgen told you human EPO meant in the Markman hearing in the TKT case. Now, I'm not collaterally estopped and we can argue about what the meaning is in terms of claim construction. But Amgen was here before your Honor defining human EPO as a glycoprotein having a specific sequence of amino acids -- it doesn't say they're 1 through 165 -- and the ability to stimulate formation of red blood cells.
So Mr. Day is now telling you that human EPO isn't a glycoprotein. And if you want me to go through every slide here where the specification says it's a glycoprotein, and the testimony of Dr. Lodish and Dr. Goldwasser and everyone else, I can. But it's in your binder going through slide 21, slide 22. We can just go to slide 21 as

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representative.
This is Dr. Lodish's tutorial. EPO is a glycoprotein. Human EPO in the body is a glycoprotein. It's a glycoprotein. The way they got over obviousness was to say what's unique about this molecule is that it's an obligate, is a term they phrase, glycoprotein. And your Honor can look at all the slides so that we don't spend as time. But it is throughout the specification and throughout the prosecution history.
THE COURT: But suppose I, suppose I adopted that and said, but modified their definition and called it a glycoprotein, and then everything else the same, having the amino acid sequence. That doesn't get you anywhere.
MS. BEN-AMI: Well, I don't know if it gets me anywhere or not --
THE COURT: No, but you --
MS. BEN-AMI: -- but it's not what I think is right. I think it has to have the structure of human EPO.
THE COURT: All right, I understand.
MS. BEN-AMI: That's part of the structure. But it's not all of the structure.
THE COURT: All right. All right.
MS. BEN-AMI: Mr. Day really went through many of these points. But he said something that I think is incorrect here about the E.coli. I think that is earlier

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on. Can you -- he said, you know, they showed that with E.coli you wouldn't get glycosylation.
It's 153. Can I have that, please?
We must be very careful when we have a patent that is trying to trying to claim analogs and derivatives. And your Honor will remember that the Federal Circuit said they couldn't claim analogs, many years ago; that they didn't have sufficient description for analogs.
So we can't look at a specification that says I'm claiming EPO, I'm claiming analogs of EPO, I'm claiming parts of EPO, I'm claiming everything in the world, and then say all that means human EPO.
But let's look at this part of the prosecution -- of the specification where it says about making this E.coli product. It doesn't call it human EPO. It's called des Ala EPO.
THE COURT: Excuse me.
MS. BEN-AMI: That's all right.
THE COURT: Go ahead, Ms. Ben-Ami.
MS. BEN-AMI: I'm sorry, your Honor.
THE COURT: All right. But --
MS. BEN-AMI: This, this is important. Because when they talk about the E.coli product they're saying that E.coli product has not only 166 but it has an additional, an additional at the front.

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THE COURT: What is this I'm reading from now?
MS. BEN-AMI: This is the specification of the patent at column 33. Mr. Day just said to you, well, your Honor, it talks about making EPO in E.coli and they're not glycosylated. But what I'm saying when they talk about that E.coli, they're saying it's not human EPO. Because what they say is the expression product is -- I'll write it on the back here, your Honor -- the expression product of the specification at that point is Met -- I'm sorry -- Met-166. And then they say by processing the Met comes off so you're left with 166. And if it's not just the Met that comes off, amino acid 1 comes off as well. So now you have 165. But it's not the same 165 as human EPO. Because human EPO is 2 through 166. I mean, this EPO, I'm sorry, is 2 through 166. Human EPO --
THE COURT: Is 1 through 165.
MS. BEN-AMI: -- is 1 through 165.
THE COURT: Right.
MS. BEN-AMI: So now we have something that they're calling a variant, a des, whatever it says, right, product. And they're saying it's 167 or 166, or if it's 165, it's a different 165 than Amgen says EPO is.
THE COURT: Right.
MS. BEN-AMI: Human or otherwise.
THE COURT: Let me ask Mr. Day a question.