

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.

\* \* \* \* \*

MARKMAN HEARING

BEFORE: The Honorable William G. Young,  
District Judge

APPEARANCES:

DUANE MORRIS LLP (By Michael R. Gottfried,  
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- and -

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Plaintiff

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April 17, 2007

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| <p style="text-align: right;">Page 74</p> <p>1 you.</p> <p>2 What does the patent tell us? If we look at the</p> <p>3 specification as Dr. Torchilin did and brought to the</p> <p>4 Court's attention exactly what the specification has to say</p> <p>5 about this, if we look at the specification, the</p> <p>6 specification is very clear that a diluent, an adjuvant or a</p> <p>7 carrier can be in combination -- I'm sorry -- can be in</p> <p>8 combination with or together with the erythropoietin. And</p> <p>9 he points out that standard, that the patent describes</p> <p>10 standard diluents such as serum, human serum albumin and</p> <p>11 saline, both of which one of ordinary skill in the art would</p> <p>12 readily recognize are complexed with, bind to, adhere to,</p> <p>13 attach to human EPO.</p> <p>14 So, you know, once again, when we deviate from the</p> <p>15 tried and true analysis that the Federal Circuit has laid</p> <p>16 down and this Court has mastered for construing claims,</p> <p>17 looking at the claim language, looking at the specification,</p> <p>18 looking at the prosecution history, and asking ourselves,</p> <p>19 now, does the claim necessarily require this limitation that</p> <p>20 the defendant is trying to read into the claim.</p> <p>21 THE COURT: What do you say to her use of the word</p> <p>22 mammals in place of humans in your proposal?</p> <p>23 MR. DAY: Well, I think it's a question of what the</p> <p>24 plain meaning of pharmaceutical composition is. And we</p> <p>25 believe that the plain meaning of pharmaceutical composition</p> | <p style="text-align: right;">Page 76</p> <p>1 proposal?</p> <p>2 MR. DAY: Because of the word comprising, to make</p> <p>3 clear that as, when you construe the word comprising that</p> <p>4 you must have at least one of these. That doesn't mean you</p> <p>5 can't have them all. That's the effect of comprising.</p> <p>6 But the claim requires -- what does the claim</p> <p>7 require? The analytical issue for the Court is what does</p> <p>8 the claim require. It requires that there be at least --</p> <p>9 THE COURT: Excuse me.</p> <p>10 MR. DAY: -- an adjuvant, a diluent or a carrier.</p> <p>11 THE COURT: Yes. But doesn't the word "or" carry</p> <p>12 that, that meaning?</p> <p>13 MR. DAY: That there can be more than one? Not</p> <p>14 necessarily.</p> <p>15 THE COURT: I see.</p> <p>16 MR. DAY: I'm just trying to make it clear.</p> <p>17 THE COURT: Containing --</p> <p>18 MR. DAY: That --</p> <p>19 THE COURT: Well --</p> <p>20 MR. DAY: -- the effect of the word comprising is</p> <p>21 that there can be more than one. That's the effect of the</p> <p>22 word comprising. In giving that word meaning in this</p> <p>23 construct that's why I put at least.</p> <p>24 THE COURT: All right, thank you.</p> <p>25 Here's, here's what we're going to go with for now.</p>  |
| <p style="text-align: right;">Page 75</p> <p>1 is a composition that's administered to humans.</p> <p>2 Dr. Flavell, defendants' expert, agrees. In his expert</p> <p>3 report he says a pharmaceutical composition is a composition</p> <p>4 that's suitable for administration to humans.</p> <p>5 THE COURT: Well, I mean now at least, so the</p> <p>6 television tells us, we have all sorts of pharmaceutical</p> <p>7 compositions being administered by veterinarians to animals</p> <p>8 of all sorts. And I had thought we were talking about</p> <p>9 mammals here. Is that a mistake?</p> <p>10 MR. DAY: Is it a mistake that we're talking about</p> <p>11 mammals? Well, in the context of a pharmaceutical</p> <p>12 composition --</p> <p>13 THE COURT: You think so.</p> <p>14 MR. DAY: Pardon me?</p> <p>15 THE COURT: You think so.</p> <p>16 MR. DAY: Well, I think, I think the specification,</p> <p>17 the specification -- we're talking about column 33. In</p> <p>18 particular in column 33 there is that very famous sentence</p> <p>19 that your Honor knows very, very well. That sentence refers</p> <p>20 to mammals. No question about it. But it doesn't talk</p> <p>21 about pharmaceutical compositions. When we get to</p> <p>22 pharmaceutical compositions the specification is very</p> <p>23 clearly talking about patients.</p> <p>24 THE COURT: Why did you put the word at least a</p> <p>25 diluent, adjuvant or carrier in your proffer, in your</p>   | <p style="text-align: right;">Page 77</p> <p>1 I'm going to construe the term as a composition suitable for</p> <p>2 administration to humans containing a diluent, adjuvant or</p> <p>3 carrier. As to this, as well as these other matters, I'll</p> <p>4 take what's argued under advisement.</p> <p>5 All right. Now, then we come to the '868 patent,</p> <p>6 claim 2 and the '933 patent, claim 8 wherein said cells are</p> <p>7 CHO cells. I don't see why we need the derived here. I am</p> <p>8 disposed to go with a cell from the ovary of a Chinese</p> <p>9 hamster. That's the language. I don't think we need to add</p> <p>10 in anything. The claim said host cells are CHO cells. It</p> <p>11 seems to me a cell from the ovary of a Chinese hamster. And</p> <p>12 that is what I propose to do, but I'll hear you, Mr. Day,</p> <p>13 because you have a different position. I don't know what</p> <p>14 derived from adds.</p> <p>15 MR. DAY: I think derived from is true to the</p> <p>16 specification. And let me, again, I'm not trying to read</p> <p>17 limitations into the claim. I'm trying to be true to the</p> <p>18 specification.</p> <p>19 And I'm not quite sure what defendants are arguing.</p> <p>20 And there may be no issue or no dispute here for us to</p> <p>21 resolve. But it appeared from the last submission that the</p> <p>22 defendants made they were suggesting that, the fact that the</p> <p>23 cell was taken from a Chinese hamster ovary meant that the</p> <p>24 cell must be in the form that it would be found in a Chinese</p> <p>25 hamster ovary.</p> |