

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

EXHIBIT 5

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,
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

<p style="text-align: right;">Page 18</p> <p>1 and impartial, most impartial trial I can. I cannot ignore 2 the fact that there's been this related litigation to which 3 I've paid a great deal of attention over time and have 4 various views about these things both factual and legal. 5 One of the things I wrestled with first time out of the box 6 was the fact that, and I'm not asking you to concede this, 7 but this is really a seminal patent; in other words, when 8 this patent application was filed, the original patent now, 9 it most assuredly was on the cutting edge. And, therefore, 10 when it came to be examined by the Patent Office those 11 officers did not have the background that, for instance, 12 some slight but patentable advance in the mechanical arts 13 would have. It didn't, it didn't have a significant body of 14 prior art. I know we're going to find prior art, we're 15 going to wrestle around with that. And Amgen quite 16 properly, as any patent draftsman would do, drafted its 17 claims as broadly as it could and patents issued. And even 18 first time out of the box there was various uncertainty on 19 the part of this Court about whether Amgen had been granted 20 a patent beyond what, its claims went beyond what in fact it 21 had taught. Because TKT had a different way of doing it, 22 much further upstream, but it was within, as I ruled, and by 23 and large have been affirmed, as I ruled the claims of the 24 patent spoke. There it all is on the record. But I had 25 various -- the parts on which I've been reversed are the</p>	<p style="text-align: right;">Page 20</p> <p>1 it to me and a jury, about these DNA strands than we knew 2 when this patent application was filed. But I'm not clear 3 what difference that makes. 4 Now, is that helpful? Go ahead. 5 MS. BEN-AMI: Well, there, there was a lot to that 6 and I don't know if I wrote it all down. But let me say 7 this. We'll get to what the prior art was in another day 8 and we'll get to -- 9 THE COURT: Right, of course we will. 10 MS. BEN-AMI: -- how seminal this was and why Amgen 11 did what it did. 12 THE COURT: Exactly. Exactly. 13 MS. BEN-AMI: So for the sake of this argument, 14 I'll accept what your Honor said without being bounded, if 15 that's okay. 16 THE COURT: It is, absolutely. 17 MS. BEN-AMI: Okay. So let's think about it for a 18 minute. Amgen filed a group of patent applications. They 19 knew what the DNA sequence was. 20 THE COURT: Well, they thought they knew. 21 MS. BEN-AMI: That was the '008 patent. Right? 22 That's the -- 23 THE COURT: All right. 24 MS. BEN-AMI: So this is not a situation where 25 we're taking away from Amgen its seminal discovery, if you</p>
<p style="text-align: right;">Page 19</p> <p>1 parts where I was expressing disquiet. And, in fact, I went 2 so far in the most recent, though, though TKT didn't get 3 anything out of it, to explore this whole doctrine of, 4 reverse doctrine of equivalents. And then to say, well, in 5 this case it doesn't, it doesn't apply. That's what I 6 thought. Then they come out with Phillips. 7 Now, Phillips may not be the best case for this 8 proposition. But one of the things that I read from 9 Phillips was that when you're dealing with a seminal patent 10 you really do have to look -- you have to take the 11 specifications along with the claims to, better to 12 understand what the patent applicant is in fact teaching the 13 public. I'm sure there are other cases that say that, but 14 Phillips was the one that, because we were all interested in 15 what it would tell us to look at in this whole law-facts 16 problem in doing Markman construction. So that's in my 17 mind. 18 MS. BEN-AMI: Well -- 19 THE COURT: Are you saying here, and I'll try to -- 20 are you arguing that -- it's not in the specifications. So, 21 I don't think you're saying their specifications didn't 22 teach how to do it. In this respect, they did teach how to 23 do it. It works. It's just this 166 cleaves off. 24 Now, yes, we know a great deal more as we're going 25 to go into this trial today, and we'll see if you can teach</p>	<p style="text-align: right;">Page 21</p> <p>1 call it that, by saying they continued to try to get bigger 2 and bigger and bigger and they got so big that they claimed 3 something they didn't invent. Or that -- 4 THE COURT: What do you mean they got bigger and 5 bigger and bigger? 6 MS. BEN-AMI: In other words, the original claim of 7 the '008 is the DNA sequence. And they knew what the DNA 8 sequence was and they claimed it. Right? Then they go 9 ahead and they say we're claiming human EPO. That they had 10 not sequenced. So they didn't know what that was. Other 11 than its three-dimensional total package of structure. 12 And that's what I'm saying to your Honor. I want 13 to be clear about this. I'm not saying you must define 14 human EPO as being limited to the 166 amino acids. I'm not 15 saying that. Quite frankly -- 16 THE COURT: And that's not true in the real world. 17 MS. BEN-AMI: I'm not saying that. I think that 18 the patent is ambiguous because they did not know. But what 19 I'm saying is, if you're going to do an analysis that says 20 it's a specific amino acid sequence then it has to be 166. 21 The alternative approach, which I think takes into 22 account somewhat more of your views on seminal patent, how 23 do you deal with it, is to say human EPO must be everything 24 that is human EPO. It must be the amino acid sequence, it 25 must be the secondary structure, it must be the tertiary</p>

<p style="text-align: right;">Page 22</p> <p>1 structure, it must have the three-dimensional structure, it 2 must be human EPO.</p> <p>3 What Amgen's construction is -- and I can go 4 through this in more detail, because that was the next part 5 of my presentation -- what Amgen's construction is it's only 6 the specific amino acid sequence of 1 to 165.</p> <p>7 THE COURT: I follow you.</p> <p>8 MS. BEN-AMI: No glycosylation, no secondary 9 formulation, no tertiary structure, no three-dimensional 10 conformation. And what I'm saying is it can't be 1 to 165 11 alone. If it's going to be human EPO, it means human EPO, 12 then it's got to be all human EPO. Where --</p> <p>13 THE COURT: Well, I don't know that your proposed 14 instruction -- construction is helpful here. I have to 15 explain this to a jury. And I take that very seriously. If 16 you want this construed -- and, you know, I'm not going to 17 be tautological. Human EPO is human EPO. That doesn't mean 18 anything, to a jury. And at one time it didn't mean 19 anything to me.</p> <p>20 MS. BEN-AMI: Well, your Honor, our construction 21 says it has to have all the structure of human EPO, which 22 is, and we can continue going through, I will show you that 23 the patent tells you what these various structures are.</p> <p>24 THE COURT: Well, now, not, not in your first slide 25 here. It doesn't say all the structure.</p>	<p style="text-align: right;">Page 24</p> <p>1 such as, your Honor.</p> <p>2 THE COURT: Well, it is including them. You would 3 be happy, though, if I simply said human erythropoietin was 4 a protein having the structure of human EPO.</p> <p>5 MS. BEN-AMI: Yes, the total structure of human 6 EPO.</p> <p>7 THE COURT: Well, the structure. All right.</p> <p>8 MS. BEN-AMI: I think, your Honor, when it says 9 such as the amino acid sequence, that's saying if you just 10 have the amino acid sequence that's not, and I don't believe 11 that's correct.</p> <p>12 THE COURT: Grammatically you may be, you may be 13 right there.</p> <p>14 All right, let's hear from Mr. Day and we'll be 15 back to you.</p> <p>16 Mr. Day, she made some headway here. What -- how 17 do you feel about a protein having, human erythropoietin is 18 a protein having the structure -- maybe we should call it 19 DNA structure, if that means anything -- having the 20 structure of human erythropoietin.</p> <p>21 MR. DAY: That would be an erroneous construction, 22 your Honor.</p> <p>23 THE COURT: Okay. I'll hear you.</p> <p>24 MR. DAY: And your Honor was right to go to 25 Phillips. And the reason you're right to go to Phillips is</p>
<p style="text-align: right;">Page 23</p> <p>1 MS. BEN-AMI: It says the structure. It says the 2 structure that would be produced in mammalian cells as of 3 the invention date.</p> <p>4 THE COURT: Well, I --</p> <p>5 MS. BEN-AMI: It's not the amino acid sequence, 6 it's the structure of human EPO.</p> <p>7 THE COURT: Well, suppose we were to take Amgen's 8 then and say a protein having the structure of human EPO 9 such as the amino acid. Just have the same such as.</p> <p>10 MS. BEN-AMI: So it no longer says amino acid 11 sequence. It says --</p> <p>12 THE COURT: Well, I'm just talking here.</p> <p>13 MS. BEN-AMI: I understand in theory.</p> <p>14 THE COURT: So what do you think about that?</p> <p>15 MS. BEN-AMI: If it had all the structure of the 16 human EPO.</p> <p>17 THE COURT: Well, I'm not saying all. A protein 18 having the structure of human EPO, such as the amino acid 19 sequence of EPO isolated from human urine.</p> <p>20 MS. BEN-AMI: No, I don't think that's right, your 21 Honor. Because such as is now saying if you only have the 22 amino acid sequence that's out.</p> <p>23 THE COURT: That's an embodiment-- that's an aspect 24 of it.</p> <p>25 MS. BEN-AMI: That's including them rather than</p>	<p style="text-align: right;">Page 25</p> <p>1 because the process of claim construction is a highly 2 structured analysis. It's not a walk through the forest. 3 It begins with a very structured set of principles that have 4 been repeatedly laid out by the Federal Circuit to guide a 5 Court through the difficult question of figuring out what 6 does a claim mean. And the Court well appreciates the 7 mantra. Judge Michel laid it out very clearly in Medtronic. 8 You start with the claims. You look at the other claims in 9 the patent. You look at the specification. You look at the 10 prosecution history. You don't begin where Ms. Ben-Ami 11 began with an expert report that hasn't even been submitted 12 to the Court.</p> <p>13 THE COURT: Well, try -- what do you say about my 14 reading of Phillips? Do you think that's right?</p> <p>15 MR. DAY: Pardon me?</p> <p>16 THE COURT: What do you say about my reading of 17 Phillips? Do you think that's right?</p> <p>18 MR. DAY: Yes, I do think that's right. I think 19 that Phillips, if I understand your point correctly, I think 20 Phillips says that in the case of a seminal patent where you 21 have a pioneering patent, which is what these patents are --</p> <p>22 THE COURT: Well, she may give you '008.</p> <p>23 MR. DAY: She will disagree.</p> <p>24 THE COURT: But the others in her view you're just 25 getting bigger and bigger.</p>