

EXHIBIT 12

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

* * * * *

AMGEN, INC. *

Plaintiff, *

vs. *

CIVIL ACTION

No. 97-10814-WGY

HOECHST MARION, et al *

Defendants. *

* * * * *

BEFORE THE HONORABLE WILLIAM G. YOUNG
UNITED STATES DISTRICT JUDGE
HEARING

A P P E A R A N C E S

DAY CASEBEER MADRID WINTERS & BATCHELDER LLP
20400 Stevens Creek Boulevard, Suite 750
Cupertino, CA 95014
for the plaintiff
By: Lloyd R. Day, Jr., Esq.

DUANE, MORRIS & HECKSCHER LLP
One International Place, 14th Floor
Boston, Massachusetts 02110
for the plaintiff
By: Dennis D. Allegretti, Esq.

Courtroom No. 18
1 Courthouse Way
Boston, Massachusetts 02210
December 15, 1999
2:35 p.m.

APPEARANCES, CONTINUED

MARSHALL, O'TOOLE, GERSTEIN, MURRAY & BORUN
6300 Sears Tower, 233 S. Wacker Drive
Chicago, IL 60606-6402
for the plaintiff
By: Edward M. O'Toole, Esq.

CHOATE, HALL & STEWART
Exchange Place
Boston, Massachusetts 02109
for the defendants
By: Robert S. Frank, Jr., Esq.
Eric Marandett, Esq.

FISH & NEAVE
1251 Avenue of the Americas
New York, New York 10020
for the defendants
By: Kenneth B. Herman, Esq.
Herbert F. Schwartz, Esq.
Doug Gilbert, Esq.

CAROL LYNN SCOTT, CSR, RMR
Official Court Reporter
1 Courthouse Way, Suite 3507
Boston, Massachusetts 02210
(617) 330-1377

1 '349 claims that refers to the productivity of the cell line
2 as determined by radioimmunoassay.

3 THE COURT: It is.

4 MR. DAY: And in this case there is no dispute
5 and there can be no dispute that defendants have informed the
6 FDA that with respect to their cells, the activity, the
7 productivity of their cells when determined by an assay called
8 ELIZA is determined to be in excess of 2,000 units of EPO per
9 24 hours.

10 Now, defendants are uniquely in possession of their
11 cells. In August and September we asked them to produce their
12 cells. They haven't produced their cells to us. We still
13 don't have their cells. So we are forced to rely upon their
14 documents.

15 We have put before you evidence that establishes when
16 compared to a claim limitation which says in Claim 1 that
17 their cells must have a productivity of one hundred units per
18 48 hours as measured by radioimmunoassay, that their cells
19 produced over 2,000 units in 24 hours when measured by ELIZA.

20 And we have put before you the validation studies
21 that were submitted to FDA and accepted by FDA as establishing
22 that the results obtained by ELIZA assay and a
23 radioimmunoassay are equivalent.

24 And we have put before you the declaration of an
25 expert that establishes that in his opinion he would expect if

1 anything the radioimmunoassay results to be higher than the
2 ELIZA results.

3 THE COURT: What do you say to Dr. Treco who
4 says that the comparison is difficult if the assay uses
5 different antibodies?

6 MR. DAY: I say, Your Honor, that doesn't pass
7 the Celotex red face test. When the defendants are uniquely
8 in possession of the information to come forward and to prove
9 to you what the actual attributes of their product are that
10 are relevant to the claim and they refuse to do so and they
11 refuse to produce the cells to us so we can do so, they have
12 failed to rebut the facts in this case. And they are uniquely
13 in possession of it.

14 And may I remind you, Your Honor, please don't
15 forget, we filed our motion for summary judgment over a month
16 ago. I think I saw two days ago a surreply. So they had a
17 month after their opposition. I don't see any evidence, none
18 in that surreply that establishes that their cells do not have
19 that level of productivity. They simply are hiding behind
20 speculative assertions and nothing more.

21 THE COURT: All right. Let me hear them on that
22 issue.

23 MR. HERMAN: Your Honor, I think what we just
24 heard is evidence that this is a premature motion. It isn't
25 that we have refused to produce our cells. Discovery is

1 ongoing and if they're properly requested, I will be happy to
2 give them to them.

3 THE COURT: Well, let's not horse around. He's
4 requesting them. When will they have them?

5 MR. HERMAN: I can't tell you, Your Honor,
6 because I'm on the production, but I would think they can have
7 them as soon as possible.

8 THE COURT: What does that mean? Tomorrow?

9 MR. HERMAN: A week maybe.

10 MR. DAY: Your Honor, excuse me --

11 THE COURT: Well, wait a minute. Let me stick
12 with him.

13 A week? That seems like a long time. How about
14 Monday? They're ordered to be produced by Monday.

15 MR. HERMAN: Monday it is, Your Honor.

16 THE COURT: All right. Now, but the rest of the
17 force of your argument may slow me down quite a bit.

18 You're saying we are not ready here.

19 MR. HERMAN: What I am saying, Your Honor, in
20 addition to the fact that arguing that we haven't given the
21 cells is not a reason for summary judgment.

22 Summary judgment requires the Court to take all
23 inferences in favor of the nonmoving party. Dr. Treco had
24 said that these are not equivalent tests or at least that
25 there is a difficulty in equating them.

1 The patent sets forth a test. It's Amgen's patent
2 after all. And they haven't tested the cell. I believe the
3 RIA test that they're relying on are not the test done in the
4 patent anyway. And so what they're putting together is a
5 series of this must be equal to that and that must be equal to
6 this and, therefore, it follows as night and day that we win.

7 And I believe that that's not appropriate on summary
8 judgment, Your Honor. You give them the cells, they can test
9 them and we can fight about the tests.

10 THE COURT: Give them the cells and I will take
11 it under advisement.

12 Let me ask another question.

13 MR. DAY: Your Honor, may I just briefly
14 respond?

15 THE COURT: You may.

16 MR. DAY: Just to put this in perspective, we
17 did request the cells in August. We requested them in
18 September. We were told that the defendants didn't have
19 control of them. We would have to subpoena their contract
20 manufacturer. We subpoenaed the --

21 THE COURT: You'll have them Monday.

22 MR. DAY: Thank you, Your Honor.

23 THE COURT: Now -- and these are direct answers.
24 And, believe me, I appreciate it. Let's go to this, which I
25 think is a little outside claim construction.