

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

AMGEN, INC.,

Plaintiff,

v.

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

Defendants.

Civil
Action No. 05-CV-12237 WGY

**ROCHE'S BENCH MEMORANDUM NO. 1 THAT DR. ORKIN SHOULD BE
PRECLUDED FROM OFFERING OPINIONS ON TOPICS ABOUT WHICH HE
HAS EXPRESSLY DISCLAIMED EXPERTISE**

Amgen's expert, Dr. Orkin, should be precluded from offering opinions on the following topics, because, during his June 5, 2007 deposition, he either expressly disclaimed having expertise on such topics, represented that he had not sufficiently studied such topics to allow him to testify about them at trial, or represented (directly or through counsel) that such topics were outside the scope of his reports:

- protein expression and/or glycosylation

Q: [D]o you intend to provide any testimony at trial regarding such other aspects such as expression or glycosylation?

A: No. (Depo. Tr. 14:2-7¹)

Q: So expression or glycosylation are topics that as you sit here today, in view of the rebuttal expert statement that's been marked as Exhibit 1 and in addition your supplemental rebuttal expert statement, that you are not prepared without more study to testify about?

A: That is correct; without additional study I wouldn't be able to testify on them. (Depo. Tr. 14:14-22)

¹ As used herein "Depo. Tr." refers to the transcript of the June 5, 2007 Deposition of Dr. Stuart Orkin.

- peptide or protein sequencing

Q: And why are you not prepared to comment in depth on peptide sequencing in this case?

A: *That is outside my report, and it's also outside my primary expertise.*

Q: So you wouldn't consider yourself an expert in the art of protein or peptide sequencing, would you?

A: *I am not an expert in peptide or protein sequencing.* (Depo. Tr. 26:22 - 27:5 (emphasis added)).

- radioimmunoassay

Q: Doctor, to use an antibody in a radioimmunoassay for erythropoietin, it's necessary that the antibody is specific for erythropoietin; isn't that correct?

AMGEN COUNSEL: Objection. *This is way outside the scope of his expert report. Radioimmunoassays are certainly not something that he's an expert on.* (Depo. Tr. 107:1-23 (emphasis added)).

- Table 1 of the specification of the patents-in-suit

Q: Do you have an understanding of what's depicted in Table 1?

AMGEN COUNSEL: I object. *This is outside the scope of his report, so...*

A: Table 1 is a listing of sequences of peptides purportedly from human erythropoietin.

Q: And, Doctor, do you feel the subject matter of this table is outside the scope of your expert reports?

A: I would say it's peripheral, peripheral to my report.

Q: What do you mean by peripheral to your report?

A: In other words, my report deals primarily with whether or not one could have expected to clone cDNA for erythropoietin back in the 1981 to 1983 period...but I'm not prepared to comment in depth on peptide sequencing in this case. (Depo. Tr. 25:3-21).

- antibodies and their specificity

Q: So, Doctor, is it your testimony as you sit here today that you can contend that there were antibodies that were not specific enough to

determine if tumors or cells were producing EPO, but at the same time you have no idea whether those antibodies were specific enough to be used in a radioimmunoassay? (Depo. Tr. 107:25 - 108:6)

AMGEN COUNSEL: Objection, it's a compound question. Number two, *it's way outside the scope of his expert report. He's not an antibody expert*, and there's no basis for asking Dr. Orkin these questions. (Depo. Tr. 108:10-13 (emphasis added))

Under Rule 702, "the expert must be qualified; . . . the expert's testimony must be reliable; and . . . [the expert's testimony] must 'fit' the facts of the case." *See Sutera v. Perrier Group of Am.*, 986 F. Supp. 655, 661 (D. Mass. 1997). To be "qualified," the expert must have "knowledge, skill, experience, or education" on the matters on which he will testify. F.R.E. 702.

Even when an expert witness has been qualified with respect to certain limited subject matter, "a district court acts properly by excluding opinions that are beyond the witness's expertise." *Levin v. Dalva Brothers, Inc.*, 459 F.3d 68, 78 (1st Cir. 2006) (approving of the District Court's narrowing of issues on which expert was permitted to testify). Logically, it is proper for a trial court to preclude an expert witness from offering opinions in areas about which the expert has expressly disclaimed expertise. *Abbott Labs. v. Brennan*, 952 F.2d 1346, 1351-52 (Fed. Cir. 1991) (approving of the District Court's ruling that an expert who "had stated he was not an expert on patent royalties" could not testify as an expert on the issue of royalties.).

By his own admissions at deposition, Dr. Orkin is not qualified, as required by Rule 702, to offer reliable expert opinions on any of the above-mentioned topics, or represented that such topics were outside the scope of his reports. Roche therefore respectfully requests that the Court preclude Dr. Orkin from testifying as to any of the above.

DATED: September 26, 2007

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

By its attorneys,

/s/ Thomas F. Fleming

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) on the above date.

/s/ Thomas F. Fleming

Thomas F. Fleming