

**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. 05-12237 WGY

U.S. District Judge Young

**ROCHE'S MOTION *IN LIMINE* TO PRECLUDE EXPERT TESTIMONY BY DR.
LODISH REGARDING THE CONDUCT OF DRS. LIN AND GOLDWASSER WHICH IS
SPECULATIVE, AND OUTSIDE HIS COMPETENCE AS AN EXPERT**

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October 2, 2007

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I. INTRODUCTION

Dr. Lodish should be precluded from testifying regarding:

- (i) the competence or state of mind of Dr. Lin and Amgen's patent attorneys; and
- (ii) Dr. Goldwasser's state of mind and the propriety of his actions.

II. ARGUMENT

The expected testimony of Dr. Lodish to which this motion is directed should be barred because it consists of mere speculation by Dr. Lodish and is outside his area of expertise and his personal knowledge. Fed. R. Evid. 602, 702, 703.

A. **Dr. Lodish Should Be Precluded From Testifying Regarding the Competence or State of Mind of Dr. Lin and Amgen's Patent Attorneys**

In his May 11, 2007 report, Dr. Lodish opines:

Of course, the fact that the inventions later described and claimed in Lin's subsequent patent applications were not obvious to Dr. Lin when he discovered that DNA encoding human EPO does not necessarily mean that his subsequent inventions would not have been obvious to a person of ordinary skill in the art. However, Dr. Lin was more than an ordinarily skilled artisan: he had the resources of a devoted research team and highly competent patent counsel, and he was highly motivated to describe and claim whatever inventions his discovery provided as soon as they were made. The fact that Lin did not claim such subsequent inventions in his earlier applications reflects the fact that such later inventions were not then obvious to a highly skilled and motivated scientist, such as Lin, let alone to a lesser scientist of only ordinary skill in the art.

(Rebuttal Expert Report of Harvey F. Lodish, Ph.D. ("Lodish II") at ¶ 187).

Dr. Lodish has no personal knowledge or expertise that would allow him to testify that "Dr. Lin was more than an ordinarily skilled artisan," that Dr. Lin's research team was "devoted," that Amgen's patent counsel was "highly competent" or that Lin was "highly motivated." Plainly, such subjective conjecture is precisely the sort of "expert" testimony that should be excluded under *Daubert*. See *Sutera v. Perrier Group of Am.*, 986 F. Supp. 655, 661 (D. Mass.

1997). Dr. Lodish should similarly be precluded from testifying about what Dr. Lin thought or believed at the time of his work on the subject matter of the patents-in-suit.

Likewise speculative and beyond Dr. Lodish's knowledge and expertise is his attempt to explain away certain deposition testimony of Dr. Lin. In one instance, Dr. Lodish states: "I suspect that Dr. Lin did not understand Roche's counsel's question." (Lodish II at ¶ 445).

Elsewhere, Dr. Lodish says: "it seems clear that Dr. Lin's belief . . . was that one did not know in advance whether any particular mammalian cell could glycosylate recombinant EPO in such a way so as to afford the protein with *in vivo* biological activity." (Lodish II at ¶ 448). Neither bit of conjecture about what Dr. Lin was thinking is appropriate expert testimony.

B. Dr. Lodish Should Be Precluded From Testifying Regarding Dr. Goldwasser's State of Mind and the Propriety of His Actions

In his May 11 report, Dr. Lodish also asserts: "Although Dr. Goldwasser testified that he believed that he was the only one that had purified urinary EPO in 1983, he did not testify that no one else could have obtained purified urinary EPO in 1983." (Lodish II at ¶ 216). Dr. Lodish should not be permitted to attempt to dilute Dr. Goldwasser's clear admission by overlaying his own interpretation of Dr. Goldwasser's testimony. Dr. Lodish's testimony should be limited to his own opinions and knowledge; he should not be recasting the opinions of others.

Dr. Lodish's May 11 report also states:

Both Drs. Lowe (¶ 52) and Kellems (¶ 48) observe that Dr. Goldwasser obtained and purified human EPO using funds from the National Institutes of Health (NIH). It is unclear what Drs. Lowe and Kellems are trying to imply by these statements, however, *to the extent they are suggesting that Dr. Goldwasser or Amgen did something improper, such a conclusion is completely unfounded.* So long as Dr. Goldwasser conducted the experiments described in his applications for funding by the NIH, there was no restriction on what he could do with his purified urinary EPO preparation, much less any requirement that Dr. Goldwasser provide his purified materials to a particular source. Drs. Lowe and Kellems have provided no evidence based on NIH policy or the terms of the grants that Dr. Goldwasser received that would establish otherwise. Because neither Dr. Lowe nor Dr. Kellems provides any more than an insinuation of impropriety, they have

provided no evidence in support of any conclusion that Dr. Goldwasser or Amgen behaved improperly. Moreover, neither Dr. Lowe nor Dr. Kellems has established that anyone other than Amgen ever asked Dr. Goldwasser for purified urinary EPO in the amounts that he supplied to Amgen. To the contrary, Dr. Goldwasser testified in his deposition that he supplied purified human urinary EPO to the NIH for distribution to any individual or entity that requested it.

(Lodish II at ¶ 222 (emphasis added)). Dr. Lodish's opinion that there was nothing "improper" about Dr. Goldwasser's work with Amgen and the NIH is wholly outside the scope of his expertise as a scientist. Simply put, Dr. Lodish is not competent to testify regarding the propriety of Dr. Goldwasser's actions.

III. CONCLUSION

For the reasons stated above, Roche respectfully requests that the Court grant Roche's motion in all respects.

CERTIFICATE PURSUANT TO LOCAL RULE 7.1

I certify that counsel for the parties have conferred in an attempt to resolve or narrow the issues presented by this motion and that no agreement could be reached.

DATED: October 2, 2007

F. HOFFMANN-LA ROCHE LTD,
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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) and paper copies will be sent to those indicated as non registered participants on the above date.

/s/ Thomas F. Fleming _____