

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

AMGEN, INC.,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 05 CV 12237 WGY
)	
F. HOFFMANN-LAROCHE LTD.,)	
a Swiss Company, ROCHE DIAGNOSTICS)	
GMBH, a German Company, and)	
HOFFMANN LAROCHE INC., a New)	
Jersey Corporation,)	
)	
Defendants.)	

**PLAINTIFF AMGEN INC.’S MOTION FOR LEAVE TO FILE A
REPLY TO ROCHE’S OPPOSITION TO AMGEN’S BENCH
MEMORANDUM REGARDING EVIDENCE OF INFRINGEMENT OF ‘349 CLAIM 7**

Amgen respectfully requests leave to file a Reply to Roche’s Opposition to Amgen’s Bench Memorandum Regarding Evidence of Infringement of ‘349 Claim 7.¹ As grounds for this request, Amgen states that a reply is necessary to address certain arguments raised by Roche in its Opposition. Specifically, a reply is necessary to demonstrate that, contrary to the attorney argument that forms the sole basis for Roche’s Opposition, Dr. Lodish’s testimony and Roche’s own documents provide three separate and sufficient bases for a finding of infringement of ‘349 claim 7:

1. Dr. Lodish’s opinion that Roche’s cells are capable upon growth in culture of producing EPO in excess of 100 U per 10⁶ cells in 48 hours based upon his review of and reliance upon radioimmunoassay tests performed by Dr. McLawhon on Roche’s cells grown in culture by Dr. Kolodner.²

¹ A copy of Amgen’s Proposed Reply is attached hereto as Exhibit A.

² Trial Tr. 2452:19 – 2455:11.

2. Dr. Lodish's calculation based on data reported in Roche's BLA (Ex. 52) that Roche's commercial cells produce "in round numbers 1,500 units of EPO per million cells in 48 hours." This calculation was based upon an ELISA assay reported in the BLA which Dr. Lodish described as "a similar assay" to a radioimmunoassay – "both assays use an antibody to EPO which binds specifically to EPO to measure how much EPO is in the culture fluid" – and the results "would be very similar, if not identical."³
3. Roche's BLA shows that Roche follows the teachings of Example 10 in Dr. Lin's patents to make the EPO component of peg-EPO. Using these steps, the same cells described in Dr. Lin's Example 10 produced EPO well in excess of the production levels recited in the '349 claims.⁴ Since Roche follows these same steps, it would be more than reasonable for the jury to conclude that Roche's cells are capable of achieving the same "high level of expression of EPO" as Dr. Lin's cells.

Based on the foregoing, Amgen submits that a brief reply is necessary to more fully address the foregoing and will aid the Court in deciding this matter.

³ Trial Tr. 2449:23 -2451:15.

⁴ Trial Ex. 1, Col. 26, lines 43 – 65; Col. 28, lines 6-10.

Dated: October 14, 2007

Respectfully Submitted,

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By its attorneys,

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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 no agreement was reached.

/s/ Michael R. Gottfried
Michael R. Gottfried

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 and paper copies will be sent to those indicated as non-registered participants on October 14, 2007.

/s/ Michael R. Gottfried
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