## UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

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

## [PROPOSED] AMGEN INC.'S REPLY TO DEFENDANTS' RESPONSE TO AMGEN INC.'S REPORT PURSUANT TO THE COURT'S MAY 11, 2006 ORDER AND MOTION AND MEMORANDUM FOR ADDITIONAL DISCOVERY

Amgen Inc. files this reply to the Defendants' Response to Amgen Inc.'s Report Pursuant to the Court's May 11, 2006 Order and Motion and Memorandum for Additional Discovery ("Roche Response") to correct the record with respect to the basis and scope of Amgen's claim for infringement and Amgen's request for limited discovery.

First, Amgen does not, and has not, conceded that "there was no current infringement." <u>See</u> Roche Response p. 3. Rather, Amgen's complaint expressly sets forth a claim for current infringement and seeks a declaration that Roche is "currently" infringing Amgen's patent. <u>See</u> Amended Complaint p.9, Prayer a. Amgen's claim is asserted based on its good faith belief that Roche has taken steps that fall outside the safe harbor of 271(e)(1), and which are, therefore, actions that give rise to a claim of current infringement. For example, paragraphs 26 and 29 of the Amended Complaint set forth allegations of

current infringement including, without limitation, the fact that Roche has taken specific steps to solicit potential customers, including large dialysis organizations, in an effort to solicit interest in the purchase of PEG-EPO once it obtains regulatory approval in the United States. Therefore, not only has there been no concession by Amgen as to the issue of current infringement, Amgen has sufficiently plead facts to support its claim such that Roche's motion to dismiss on this basis should be denied.

Second, the information sought by Amgen in connection with the Court's order is directly related to the question of whether Roche's actions fall outside of the safe harbor of 271(e)(1). This information is a subset of the information that Amgen has already requested in the International Trade Commission proceeding and which Roche is required to produce in that proceeding. Therefore, it is not burdensome or harassing to request that the same information be made available in this case pursuant to a protective order that is satisfactory to the Court. Having opened the door to these issues in filing its motion to dismiss, Roche should not be allowed to avoid compliance with the Court's order or prevent Amgen from presenting a full record to the Court.1

Accordingly, based on the forgoing, Amgen respectfully requests that the Court deny Roche's motion to dismiss or in the alternative grant Amgen's motion for additional discovery.

<sup>1</sup> Roche moved to dismiss pursuant to Rule 12(b)(1) and 12(b)(6). Roche's affidavits in connection with its Rule 12(b)(1) challenge the factual accuracy of the jurisdictional facts asserted by Amgen. In such situations, the First Circuit has held that "the court must address the merits of the jurisdictional claim by resolving the factual disputes between the parties," and that "[i]n conducting this inquiry, the court enjoys broad authority to order discovery, consider extrinsic evidence, and hold evidentiary hearings in order to determine its own jurisdiction." Valentin v. Hospital Bella Vista, et al., 254 F.3d 358, 364 (1st Cir. 2001).

June 9, 2006

Respectfully Submitted,

AMGEN INC., By its attorneys,

/s/ Michael R. Gottfried

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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 and paper copies will be sent to those indicated as non registered participants on June 9, 2006.

/s/ Michael R. Gottfried Michael R. Gottfried