# UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

AMGEN INC.,	)
Plaintiff,	) ) Civil Action No. : 05, 12227 WCN
v.	) Civil Action No.: 05-12237 WGY
	)
F. HOFFMANN-LAROCHE	)
LTD., a Swiss Company, ROCHE	)
DIAGNOSTICS GmbH, a German	)
Company and HOFFMANN LAROCHE	)
INC., a New Jersey Corporation,	)
Defendants.	) ) )

## AMGEN'S BENCH MEMORANDUM THAT IT IS IMPROPER FOR RICHARD A. FLAVELL TO OFFER OPINIONS THAT RESTATE ARGUMENTS REJECTED BY GRANT OF SUMMARY JUDGMENT THAT CLAIM 7 OF THE '349 PATENT IS DEFINITE

Roche's Dr. Richard A. Flavell should be precluded from describing to the jury opinions that this Court has presumably rejected as part of its grant of summary judgment that Dr. Lin's claims were Definite, Adequately Described and Enabled. As part of it response to Amgen's motion for summary judgment, Roche claimed that the phrase "U of erythropoietin ... as determined by radioimmunoassay" in claim 7 of the '349 patent was indefinite. As Amgen described in its Motion for Summary Judgment, Roche's argument was flawed because claim 7's reference to radioimmunoassay allowed one of ordinary skill in the art to measure the amount of EPO in a sample by RIA, calibrate the measurements to a known standard, and report the results

<sup>&</sup>lt;sup>1</sup> See Electronic Order of Aug. 27, 2007.

of that assay in "units" of EPO.<sup>2</sup> As Amgen described in its memorandum of law, Roche's own experts agreed with these contentions.<sup>3</sup>

Despite this grant of summary judgment that claim 7 of the '349 patent was definite, Roche's Dr. Flavell intends to recycle Roche's same arguments to the jury, claiming (1) "U of erythropoietin" was a measure of biological activity that cannot be measured by RIA; (2) that many standards for RIA were known at the time of the invention, each which would have reported different values of "U of erythropoiten;" and (3) RIA was incapable of distinguishing erythropoietin from materials that are not erythropoietin.<sup>4</sup> These are exactly the arguments that this Court has presumably already rejected when it granted summary judgment that claim 7 of the '349 patent was definite. Roche cannot now reargue them.

Furthermore, any claim by Roche that it is now arguing these same issues as to enablement should also be rejected. This Court's apparent rejection of Roche's flawed arguments as to indefiniteness relates just as much to any argument that these very same issues relate to whether claim 7 was enabled. Since the Court has already held that claim 7 of the '349 patent is definite, Flavell's opinions are irrelevant because it is the law of the case that "U of erythropoietin" could be measured by RIA, the applicable RIA standards would have been known to one skilled in the art; and RIA was capable of distinguishing erythropoietin from materials not erythropoietin. Accordingly, Dr. Flavell should not be able to offer these irrelevant opinions to the jury.

<sup>&</sup>lt;sup>2</sup> See Amgen's Memorandum in Support of Motion for Summary Judgment that Dr. Lin's Asserted Claims are Definite, Adequately Described and Enabled at 13 (Docket # 532).

<sup>&</sup>lt;sup>3</sup> *Id.* at 11–14, n. 28, & n. 32.

<sup>&</sup>lt;sup>4</sup> See Fourth Expert Statement of Richard A. Flavell, Ph.D. In Response to Various Arguments Raised By Amgen's Experts, ¶ 67. Attached hereto as Exhibit A to the Declaration of Daniel A. Curto in Support of Bench Memo ("Curto Dec.")

Dated: September 14, 2007 Respectfully Submitted,

> AMGEN INC., By its attorneys,

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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.

/s/ Michael R. Gottfried

Michael R. Gottfried