

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

AMGEN’S MOTION IN LIMINE REGARDING FLAVELL NO. 3: TO
PRECLUDE RICHARD FLAVELL FROM OFFERING OPINIONS BASED ON A
CLAIM CONSTRUCTION THAT IS INCONSISTENT WITH
THE COURT’S CLAIM CONSTRUCTION OF THE ‘933 PATENT CLAIM
TERM “NON-NATURALLY OCCURRING”

As held by the Federal Circuit, the source limitation “non-naturally occurring”
“only excludes human EPO from specific sources.”1 Specifically, the term “limit[s] only
the source from which the EPO is obtained, not the methods by which it is produced.”2
Consistent with the affirmed construction of “non-naturally occurring,” this Court’s July
3, 2007 Markman Order construed “non-naturally occurring,” as it appears in the asserted
‘933 claims, to mean “not occurring in nature.”3 Contrary to this construction, Roche’s
expert, Richard Flavell, construes “non-naturally occurring” to require “that the claimed
erythropoietin glycoprotein has a unique glycosylation patterns that differ from EPO

1 Amgen Inc. v. Hoescht Marion Roussel, Inc., 314 F.3d 1313, 1329 (Fed. Cir. 2003).

2 Id. at 1330 n.5.

3 D.I. at 32.

products that occur in nature such as urinary EPO and EPO derived from plasma.”⁴

Based upon this false construction, Dr. Flavell then argues that Amgen has presented no reliable evidence that the epoetin beta in Roche’s product differs in structure from either urinary EPO or plasma or serum EPO.⁵ Dr. Flavell’s opinion improperly reads a structural limitation into “non-naturally occurring” that contradicts this Court’s construction and improperly transforms that source limitation into a structural limitation. Dr. Flavell should not be permitted to present opinions at trial that ignore and contravene this Court’s construction and this Court should preclude him from doing so.

Based on the foregoing, Amgen requests that the Court preclude Dr. Flavell from offering any opinions based on the improper construction of the term “non-naturally occurring.” Specifically, Dr. Flavell should be precluded from offering the opinions set forth at paragraphs 149-159 of his May 11, 2007 Report.

⁴ 5/11/2007 Flavell Report, ¶ 149 (at p. 72). Excerpts from Dr. Flavell’s May 11, 2007 Report referenced in this Motion are attached as Exhibit 2 to the Declaration Of Linda Sasaki-Baxley In Support Of Amgen’s Motions Regarding The Testimony Of Richard Flavell, filed herewith.

⁵ Dr. Flavell’s assertion is patently false since Amgen has thoroughly demonstrated at trial that mammalian cell-produced EPO clearly differs in structure from naturally-occurring sources. In addition, Dr. Flavell all but admits that his entire opinion is mere speculation by concluding that “*For all anyone knows* there may be other naturally occurring EPOs that are indistinguishable from epoetin beta...” *Id.* at ¶ 159 (at p. 78)

Dated: October 15, 2007

Respectfully Submitted,

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(emphasis added).

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 15, 2007.

/s/ Michael R. Gottfried
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