

**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.)	

**AMGEN’S MOTION *IN LIMINE* REGARDING FLAVELL NO. 6:
TO PRECLUDE RICHARD FLAVELL FROM OFFERING OPINIONS BASED ON A
CLAIM CONSTRUCTION THAT IS INCONSISTENT WITH THE COURT’S
CONSTRUCTION OF ‘868 CLAIM TERM “ISOLATED DNA SEQUENCE
ENCODING HUMAN ERYTHROPOIETIN”**

The Court has construed the claim “cells transformed or transfected with an isolated DNA sequence encoding human erythropoietin” to mean:

cells that have been genetically modified with isolated DNA containing genetic instructions for human erythropoietin or later generations of these cells that have inherited those instructions.¹

In so ruling, the Court rejected Roche’s argument that “purified” should be added to “isolated,”² and recognized that it had construed “isolating” “as not requiring ‘in pure form.’”³ Having omitted the term “purified” from the construction, the Court’s construction allows for, but does not require, that the “isolated” EPO DNA used to transfect the recited cells be “pure.”

¹ Memorandum and Order, dated July 3, 2007, p. 30.

² See *id.* at 29 (Table).

³ *Id.*

Contrary to this construction, Roche' expert, Richard Flavell, premises his non-infringement opinion of the '868 claims on a construction that the "isolated" EPO DNA used to transform Roche' CHO cells must be isolated and purified:

the cells Roche uses to create its epoetin beta reagent were not "transformed or transfected with an isolated DNA sequence encoding human erythropoietin." . . . [T]he cells used by Roche in the manufacture of CERA were not created using isolated and purified of DNA according to the claim limitation⁴

This opinion, however, is contrary to the Court's claim construction. It reads into the claim a limitation that does not exist. Moreover, it reads Dr. Lin's preferred embodiment out of the claims.⁵

Based on the foregoing, the Court should preclude Dr. Flavell from offering any opinion based on the improper construction of the term "an isolated DNA sequence encoding human erythropoietin."

Dated: October 15, 2007

Respectfully Submitted,

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By its attorneys,

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⁴ 5/11/07 Flavell Report at ¶73 (emphasis added). 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 See TX 1 at Figure 4 and col. 25:30-25:37 (showing that human EPO DNA, mouse DHFR DNA, viral promoter DNA, plasmid DNA, and carrier DNA are inserted in the CHO cells of Example 10)

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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 15, 2007.

/s/ Michael R. Gottfried
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