

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

AMGEN INC., )  
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 )  
 ) Civil Action No.: 1:05-cv-12237 WGY  
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 F. HOFFMANN-LA ROCHE LTD, a Swiss )  
 Company, ROCHE DIAGNOSTICS )  
 GMBH, a German Company, and )  
 HOFFMANN LA ROCHE INC., a New )  
 Jersey Corporation, )  
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**AMGEN’S MOTION *IN LIMINE* REGARDING FLAVELL NO. 8:  
 TO PRECLUDE RICHARD A. FLAVELL FROM OFFERING OPINIONS  
 THAT WERE REJECTED BY THIS COURT’S HOLDING THAT PEG-EPO  
INFRINGES CLAIM 1 OF DR. LIN’S ‘422 PATENT**

The law of the case doctrine and Fed. R. Civ. P. 56(d) bar Roche from arguing or presenting evidence that contradicts this Court’s order that peg-EPO infringes claim 1 of Amgen’s ‘422 patent. Roche’s expert, Richard A. Flavell, however, offers opinions in his expert reports that directly contradict the foundation of this Court’s order. Rule 56(d) prohibits Dr. Flavell from providing such testimony at trial. As set forth in Rule 56(d), where there has been a partial adjudication of facts, “the fact so specified shall be deemed established, and the trial shall be conducted accordingly.” Dr. Flavell should be precluded from offering any opinions that contradict facts adjudicated by this Court’s order of summary judgment.

The first opinion that Dr. Flavell offers that contradicts this Court’s order of summary judgment is that Roche’s peg-EPO is not a pharmaceutical composition comprising “human erythropoietin.” Dr. Flavell’s bases for this opinion are twofold. First, he claims that Amgen’s patents cover only “human erythropoietin” with a 166 amino acid sequence, and peg-EPO contains a 165 amino acid EPO. Second, he claims that the “human erythropoietin” covered by

Amgen's patents pertains only to "obligate glycoproteins" and CERA is not comprised of EPO with an obligate glycoprotein. In light of the Court's order of summary judgment on claim 1 of the '422 patent, Dr. Flavell should be precluded from any testimony that (1) "human erythropoietin" is limited to a 166 amino acid sequence; or (2) that "human erythropoietin" includes only EPO with an obligate glycoprotein.

In addition, Dr. Flavell also contradicts this Court's order of summary judgment by claiming that peg-EPO is not comprised of human erythropoietin purified from mammalian cells grown in culture. Dr. Flavell asserts this opinion by referencing only the end product of Roche's pegylation of EPO. He ignores, entirely, the epoetin beta component that Roche incorporates into its peg-EPO. It is the law of this case, however, that this epoetin beta component is purified from mammalian cells grown in culture. Dr. Flavell should be precluded from offering any contrary opinion.

Pursuant to Rule 56(d) and the law of the case doctrine,<sup>1</sup> as well as this Court grant of Amgen's motion to preclude testimony that:

"(1) [MIRCERA Does Not Comprise Human EPO, In Contradiction of This Courts Finding of Infringement on Claim 1 of the 422 Patent] only insofar as the claim may relate to claim 1 of the '422 patent"<sup>2</sup>

Roche should be precluded from contradicting the Court's factual determination as a matter of law. Specifically, Dr. Flavell should not be allowed to present testimony or evidence that

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<sup>1</sup> See *United States v. Medina*, 219 Fed. Appx. 20, 21-22 (1st Cir. 2007) (Under the relevant branch of the law of the case doctrine, "a legal decision made at one stage of a civil or criminal proceeding ... remain[s] the law of that case throughout the litigation, unless and until the decision is modified or overruled by a higher court" citing *United States v. Moran*, 393 F1, 7 (1st Cir. 2004).

<sup>2</sup> See Amgen's Motion *in Limine* To Preclude Roche From Claiming During The Infringement Case That (1) MIRCERA Does Not Comprise Human EPO, In Contradiction Of This Courts Finding Of Infringement On Claim 1 Of The 422 Patent And (2) That European Regulatory Approval Has Any Relevance to the Claims In This Lawsuit, Docket No. 1251, Granted 10/2/07, Note 3.

contradicts this Court's holding that peg-EPO contains human erythropoietin that is purified from mammalian cells grown in culture.

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Of Counsel:  
Stuart L. Watt  
Wendy A. Whiteford  
Monique L. Cordray  
Darrell G. Dotson  
Kimberlin L. Morley  
Erica S. Olson  
AMGEN INC.  
One Amgen Center Drive  
Thousand Oaks, CA 91320-1789  
(805) 447-5000

Respectfully Submitted,

AMGEN INC.,  
by its attorneys

/s/ Michael R. Gottfried

D. Dennis Allegretti (BBO# 545511)  
Michael R. Gottfried (BBO# 542156)  
Patricia R. Rich (BBO# 640578)  
DUANE MORRIS LLP  
470 Atlantic Avenue, Suite 500  
Boston, MA 02210  
Telephone: (857) 488-4200  
Facsimile: (857) 488-4201

Lloyd R. Day, Jr. (pro hac vice)  
DAY CASEBEER MADRID & BATCHELDER LLP  
20300 Stevens Creek Boulevard, Suite 400  
Cupertino, CA 95014  
Telephone: (408) 873-0110  
Facsimile: (408) 873-0220

William G. Gaede III (pro hac vice)  
McDERMOTT WILL & EMERY  
3150 Porter Drive  
Palo Alto, CA 94304  
Telephone: (650) 813-5000  
Facsimile: (650) 813-5100

Kevin M. Flowers (pro hac vice)  
MARSHALL, GERSTEIN & BORUN LLP  
233 South Wacker Drive  
6300 Sears Tower  
Chicago, IL 60606  
Telephone: (312) 474-6300  
Facsimile: (312) 474-0448

