

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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AMGEN INC.,	)
	)
Plaintiff,	)
	)
v.	)
	) CIVIL ACTION No.: 05-CV-12237WGY
F. HOFFMANN-LA ROCHE LTD	)
ROCHE DIAGNOSTICS GmbH	)
and HOFFMANN-LA ROCHE INC.	)
	)
Defendants.	)
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**ROCHE’S MOTION *IN LIMINE* TO PRECLUDE AMGEN FROM INTRODUCING  
EVIDENCE REGARDING THE SAFETY OF MIRCERA®**

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively “Roche”) respectfully move that the Court preclude Amgen from offering any evidence concerning the safety of Roche’s MIRCERA® product. In an obvious attempt to prejudice Roche and its product MIRCERA® in the minds of the jury with what this Court has already ruled to be irrelevant and erroneous evidence, Amgen plans to introduce to the jury alleged evidence concerning the safety of MIRCERA®. The issue of MIRCERA®’s safety profile is of no relevance to any issue at this jury trial — it is not relevant to the question of whether MIRCERA® infringes the claims in Amgen’s patents, nor can be possibly relevant to the questions of the validity of Amgen’s patents or whether Amgen’s conduct before the PTO was inequitable. Thus, Amgen plainly seeks to introduce this evidence for improper purposes — to make the baseless suggestion to the jury that Roche’s product may raise safety issues, which Amgen well knows is untrue.

Moreover, once approved, the FDA will have determined that MIRCERA<sup>®</sup> is safe and efficacious for its approved indication, putting to rest once and for all this spurious attack raised by Amgen.<sup>1</sup> Amgen knows that its own products have been the subject of publicized criticism from both the FDA and Congress raising serious health and safety issues, and apparently to deflect whatever publicity that may have been raised as to these products, Amgen seeks to denigrate Roche's product. This entire subject area is unfair and Amgen should not be permitted to raise this issue. This gambit is precisely what FRE 403 protects against. Therefore, the Court should preclude Amgen from introducing evidence, or referring in any way to questions about the safety of MIRCERA<sup>®</sup>.

For the foregoing reasons, Defendants request that this Court preclude Amgen from introducing evidence, or referring to evidence, regarding the safety profile of MIRCERA<sup>®</sup>.

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<sup>1</sup> MIRCERA<sup>®</sup> has already been approved for use outside the United States and thus the allegation of safety issues is wholly inappropriate.

Dated: September 3, 2007  
Boston, Massachusetts

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,  
ROCHE DIAGNOSTICS GMBH, and  
HOFFMANN-LA ROCHE INC.

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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 (NEF) and will be delivered to Amgen's trial counsel by electronic mail in the manner requested in the August 29, 2007, letter of Renee DuBord Brown to Thomas F. Fleming. Paper copies will be sent to those indicated as non registered participants on September 4, 2007.

/s/ Keith E. Toms  
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