

**IN THE UNITED STATES DISTRICT COURT  
IN AND FOR THE DISTRICT OF MASSACHUSETTS**

AMGEN INC.,

Plaintiff,

v.

F. HOFFMANN-LA ROCHE LTD, a  
Swiss Company, ROCHE DIAGNOSTICS  
GMBH, a German Company, and  
HOFFMANN LA ROCHE INC., a New  
Jersey Corporation,

Defendants.

Civil Action No.: 1:05-CV-12237 WGY

**AMGEN’S BENCH MEMORANDUM TO PRECLUDE ROCHE FROM EXAMINING  
DR. TORCHILIN ON EVIDENCE REGARDING PATIENT CHOICE  
AND THE SAFETY AND DOSING BENEFITS OF MIRCERA  
IN CONTRAVENTION WITH THE COURT’S PREVIOUS RULINGS**

Roche should be precluded from contravening several of the Court’s previous orders when it cross-examines Amgen’s expert Dr. Torchilin. Based on Roche’s opening statement and its prior deposition designations of Dr. Torchilin, it is highly probable that Roche intends to question him on topics that the Court has previously precluded from this case. The Court has previously precluded the following: (1) argument or evidence related to the safety and efficacy of Roche’s accused product, including dosing regimens and perceived clinical benefits and improvements;<sup>1</sup> (2) the potential FDA approved label and uses of peg-EPO;<sup>2</sup> (3) supplemental BLA submissions, including post-filing evidence relating to the safety of peg-EPO;<sup>3</sup> (4) argument or evidence that Amgen’s patent enforcement will limit or negatively affect consumer choice;<sup>4</sup> and (5) any reference to Amgen’s patents-in-suit as “monopolies” or that Amgen’s

<sup>1</sup> D.I. 1265 (Granted on October 4, 2007); *see also* D.I. 970 (Granted on September 24, 2007) (The Court precluded Amgen from “offering any evidence concerning the safety of Roche’s MIRCERA product,” “without prejudice to Amgen’s renewal should Roche – in the infringement phase of the case – bring up supposed improvements in its products.”)

<sup>2</sup> D.I. 856 (Granted on September 24, 2007).

<sup>3</sup> *Id.* The Court should also preclude expert testimony relying on such post-filing submissions.

<sup>4</sup> D.I. 847 (Granted on September 4, 2007).

patent enforcement constitutes anticompetitive or monopolistic behavior.<sup>5</sup> The Court should enforce these prior orders and prevent Roche from unfairly prejudicing Amgen during its non-infringement defense.

Roche disregarded the Court's prior rulings during its Infringement opening argument and looks poised to continue its disregard for the Court's orders. In her opening argument, counsel for Roche asserted that: (1) Amgen is attempting to prevent patient choice;<sup>6</sup> and (2) MIRCERA has improved dosing over EPO.<sup>7</sup> Furthermore, Roche designated significant portions of deposition testimony from Amgen's expert Dr. Torchilin, including questions regarding MIRCERA dosing and the perceived benefits of MIRCERA being available on the market. It is feasible that Roche intends to again question Dr. Torchilin regarding these topics during cross-examination, and to offer its own testimony and evidence regarding patient choice, dosing, and the safety and efficacy of MIRCERA during its rebuttal case. Such actions would be in direct contravention of the Court's previous orders, and should be precluded.

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Respectfully Submitted,

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<sup>5</sup> *Id.*

<sup>6</sup> Trial Tr. at 2375:21-25 ("The only choice for patients in this country right now is Amgen. Patients have no choice. Roche has developed a new and different drug, which, if approved by the FDA, and allowed by you and this court, will give patients choice for new treatments.")

<sup>7</sup> Trial Tr. at 2375:10-15 ("The evidence will show that the drug that Roche is making allows the patient to receive 12 shots a year instead of 156 shots a year. The evidence will show that this drug, which is a different drug than EPO, provides patients, who are suffering with a different treatment, once a month versus 156 a year.")

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**CERTIFICATE OF SERVICE**

I hereby certify that this document filed through the Electronic Case Filing (ECF) system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on the above date.

*/s/ Michael R. Gottfried*

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Michael R. Gottfried