UNITED STATES DISTRICT COURT
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.: 05-12237 WGY

AMGEN'S BENCH MEMORANDUM TO PRECLUDE ROCHE FROM INTRODUCING TESTIMONY OF DR. LONGMORE THAT IS CONTRARY TO THE COURT'S PRIOR ORDERS REGARDING SAFETY, DOSING, UNDISCLOSED FDA COMMUNICATIONS, AND WHETHER MIRCERA CONTAINS HUMAN EPO

In accordance with this Court's prior Orders regarding the admissibility and relevance of certain categories of information, Roche's expert witness, Dr. Longmore, should be precluded from introducing the following evidence or testimony regarding:

1) Safety, efficacy or dosing of peg-EPO, and clinical comparisons with other ESAs,[1]

2) FDA communications or post-filing submissions to the FDA not produced to Amgen, [2]

3) Claims that MIRCERA does not comprise human EPO. [3]

[1] *See* Amgen Inc.'s Motion Preclude Roche from Introducing Evidence or Testimony Regarding the Safety or Efficacy of PEG-EPO Because Roche has Asserted that these Topics are Irrelevant and on that Basis Denied Amgen Fulsome Discovery, Docket No. 1265, Granted 10/4/07.
[2] *See* Amgen's Motion *in Limine* No. 13: Exclude Evidence and Argument Regarding Roche's FDA Filings and Communications Withheld Throughout Fact Discovery, Docket No. 856, Granted 9/24/07.
[3] *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

ARGUMENT

Dr. Longmore should be precluded from testifying about the clinical benefits of peg-EPO, including its dosing regimen. This Court previously granted Amgen's motion to preclude testimony regarding:

> "[A]rgument or evidence related to the safety and efficacy of its accused product—including dosing regimens, perceived clinical benefits, and clinical improvements over established ESAs."[4]

Dr. Longmore discusses these issues in the following paragraphs of his May 11, 2007 expert report: ¶¶168-186 (clinical benefits); ¶¶80-81 (injection frequency); ¶126 (CERA immunogenicity); ¶142 (dosing and quality of life); ¶143 (medical benefits); ¶147 (dosing); ¶¶213-214 (dosing). Roche also disclosed to Amgen in its evidentiary disclosures for Dr. Longmore's direct examination numerous demonstratives describing injection frequency (GL-4, GL-5, GL-6, GL-7, GL-31, GL32, GL-34) – further proof that Roche intends to elicit this prohibited testimony.

Dr. Longmore should also be precluded from testifying about FDA communications not produced to Amgen. This Court previously granted Amgen's motion to preclude testimony regarding:

> "The potential FDA approved label and uses of peg-EPO," including "supplemental BLA submissions," post-filing evidence relating to the safety of peg-EPO, and expert testimony relying on such post-filing submissions.[5]

Dr. Longmore discusses FDA "certification" in ¶86 of his May 11, 2007 expert report, but never explains or provides a basis for this testimony. This testimony should be excluded as unsupported by any FDA-related document produced by Roche in this litigation. [6]

10/2/07.
[4] *Supra* note 1.
[5] *Supra* note 2.
[6] *See also* Plaintiff Amgen Inc.'s Motion to Preclude Roche's Experts from Claiming Unproven

Finally, Dr. Longmore should be precluded from testifying that MIRCERA does not contain "human EPO." This Court previously granted Amgen's motion to preclude testimony regarding:

> "(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."[7]

Dr. Longmore opines on this topic in the following paragraphs of his May 11, 2007 expert report: ¶¶ 25-26 and 206-211, and any such testimony should be excluded.

CONCLUSION

For the foregoing reasons, Dr. Longmore should be precluded from testifying contrary to this Court's prior Orders on the topics noted above.

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and Undisclosed FDA Certification, filed 10/14/07.

[7] *Supra* note 3.

October 15, 2007

Respectfully Submitted,

AMGEN INC.,
By its attorneys,

/s/ Michael R. Gottfried

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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. By agreement of the parties, paper copies will not be sent to those indicated as non-registered participants.

/s/ Michael R. Gottfried
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