UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LA ROCHE LTD ROCHE DIAGNOSTICS GmbH and HOFFMANN-LA ROCHE INC. Defendants.	CIVIL ACTION No.: 05-CV-12237WGY

ROCHE'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION *IN LIMINE* TO PRECLUDE AMGEN FROM INTRODUCING EVIDENCE REGARDING THE SAFETY OF MIRCERA®

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Dated: Boston, Massachusetts
September 3, 2007

I. INTRODUCTION

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. 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® is safe and efficacious for its approved indication, putting to rest once and for all this spurious attack raised by Amgen.[1] 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®.

[1] MIRCERA® has already been approved for use outside the United States and thus the allegation of safety issues is wholly inappropriate.

II. ARGUMENT

A. EVIDENCE ABOUT MIRCERA®'S SAFETY PROFILE IS IRRELEVANT

Amgen states that it intends to introduce during the patent trial evidence concerning the safety profile of MIRCERA®. This Court has already repeatedly ruled that this evidence is not relevant to the jury phase of the trial. Indeed, one of the ten experts Amgen states that it plans to call at trial, Dr. Glenn Chertow, opines in his report on the clinical safety data of MIRCERA®, but Amgen fails to explain how Dr. Chertow's assessment of MIRCERA®'s safety profile relates to alleged infringement. Another Amgen expert, Dr. John Lubina, whose opinion Dr. Chertow cites in his report, is a biostatistician who opines on the safety data in MIRCERA® clinical trials. These opinions are also totally irrelevant to any jury issue.[2]

B. EVIDENCE REGARDING MIRCERA®'S SAFETY PROFILE IS UNDULY PREJUDICIAL UNDER THE FEDERAL RULES OF EVIDENCE RULE 403.

While evidence about MIRCERA®'s safety profile has zero probative value at this trial, the use that Amgen wants to make of it is inaccurate, incomplete, and will create the danger of unfair prejudice. Moreover, the potential for confusing the jurors by the introduction of such irrelevant, erroneous and prejudicial evidence is palpable. If Amgen is allowed to argue safety, the jury will be distracted from core validity and infringement issues by these collateral irrelevant issues. Accordingly, the evidence regarding MIRCERA®'s safety profile that Amgen seeks to introduce meets every factor of Rule 403's exclusion test — it encourages the jury to decide the case based on irrelevant, erroneous, and inflammatory allegations of product

[2] Amgen has made a motion *in limine* to preclude Roche from relying on certain clinical safety data that post-dates the filing of its Biologics Licensing Application, Amgen Motion *In Limine* No. 13, Docket No. 856, dated August 22, 2007. As explained in Roche's opposition to that motion, Roche only relies on that information to rebut the baseless and irrelevant contentions that Amgen raises about safety. Should the Court grant this motion, Roche will not have to rely on post-BLA submission clinical safety data at the jury trial.

disparagement, while wasting the parties' and the Court's of time as competing evidence on safety is presented. As such, the evidence should be excluded.

III. CONCLUSION

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

Dated: September 3, 2007
Boston, Massachusetts

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,
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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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