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

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| AMGEN, INC.,<br><br>Plaintiff,<br><br>v.<br><br>F. HOFFMANN-LA ROCHE, Ltd, ROCHE DIAGNOSTICS GmbH, and HOFFMANN-LA ROCHE INC.,<br><br>Defendants. | Civil Action No. 05-12237 WGY<br><br>U.S. District Judge Young |

**ROCHE'S *MOTION IN LIMINE* TO PRECLUDE AMGEN FROM PROFFERING TESTIMONIAL OR DOCUMENTARY EVIDENCE CONCERNING INFRINGEMENT TESTING UNDER FEDERAL RULES OF EVIDENCE 602, 901 AND 702/703**

According to its expert reports and pretrial filings, Amgen intends to introduce test data purporting to show that the DN2-3α3 cell line is capable of producing "in excess of 100 U of erythropoietin per $10^6$ cells in 48 hours as determined by radioimmunoassay" according to the claims of the '349 patent. This Court should exclude this evidence and any expert testimony on this subject matter because:

- Dr. Ronald W. McLawhon, Amgen's expert witness purporting to generate the data in question, lacked personal knowledge of the subject matter of the testing experiments as required by Fed. R. Evid. 602, and these results have not been authenticated as required by Fed. R. Evid. 901; and
- Dr. McLawhon's testing experiments were not the product of reliable principles and methods as required by Fed. R. Evid. 702.

Roche respectfully requests that the Court preclude Amgen from proffering any evidence relating to its purported cell line "testing." Moreover, any expert testimony based on this unconfirmed and unobserved data masquerading as proof of infringement should not be

presented to the jury because, without additional confirmation of its veracity. This information cannot possibly assist the jury in evaluating Amgen's experts' opinions and will only prejudice Roche. Therefore the Court should exclude testimony on this subject matter according to the provisions of Fed. R. Evid. 703.[1]

## I. The Testing Data Reported in the McLawhon Expert Report Is Inadmissible Under Fed. R. Evid. 602 and 901

The Rules of Evidence provide that a witness may not testify to a matter unless there is "evidence to support a finding that the witness has personal knowledge of the matter." *FDIC v. House,* 90 F.3d 600, 606 (1st Cir. 1996) (striking testimony of witness who lacked personal knowledge of events to which he testified); Fed. R. Evid. 602. Amgen asks this Court to accept the "testimony" of its expert witness Dr. Ronald W. McLawhon in the form of an expert report containing results of infringement tests. These tests, radioimmunoassays ("RIA"), were performed in the hopes of proving that elements of the '349 patent claims were met. However Dr. McLawhon did not personally observe the tests, verify their accuracy, or confirm the results obtained -- in fact, he testified that he was in San Diego while the tests were run by others in Chicago:

> Q. These assays were performed in Chicago?
> A. They were performed in Chicago.
> Q. And at the time, on 4 -- they were performed on 4/20/07?
> A. Hmm-hmm.
> Q. And at that time, were you in Chicago?
> A. No, I was not. I was already in San Diego, at that point. We had hoped to have these done before I left Chicago, but there was a delay in getting the materials.

(McLawhon 5/17/07 Depo. Tr., 95:1-11). This testimony, which has no basis in personal observation, cannot meet the standard required by Fed. R. Evid. 602 for witness testimony. This

[1] Indeed, no matter what, the results are irrelevant to infringement and prejudicial because the test did not even use the growing conditions that Roche uses. Fed. R. Evid. 402, 403 (*see* D.I. 540).

information is inadmissible hearsay testimony despite being couched in an expert report, and should be excluded from evidence.

Moreover, a witness cannot rely on a study he simply ordered unless he himself personally participated gathering the data. *See Cuyahoga Metropolitan Housing Authority v. U.S.*, 60 Fed. Cl. 481 (Fed. Cl. 2004). In *Cuyahoga*, because the witness himself did not collect the data, the court held that he did not have the requisite personal knowledge on which to base his opinion during his testimony at trial. *Id.* at 482. Similarly, Dr. McLawhon cannot simply look at the results of a study he commissioned and stand in the shoes of those who conducted the tests.

The only people with the personal knowledge of the tests and results are the University of Chicago Hospital technicians who personally observed them: Angela Baldwin, Julie Burris, and Marsha Hazinger. (McLawhon 5/17/07 Depo. Tr., 89:12-21; 95:4-9). None of these individuals provided a declaration or affidavit that the tests were run on a particular sample, used a particular protocol, and generated certain results. None of these individuals appear on Amgen's witness list or Rule 26 disclosures. Amgen should not be allowed to do end-run around the rules of this Court and Federal Civil Procedure.

Lack of personal knowledge is enough to preclude admissibility, however several other facts also reveal the utter lack of verifiability and reliability of the tests and bring the results into question. Ironically, and not surprisingly, the last time Dr. McLawhon even executed an RIA himself was for litigation purposes on behalf of Amgen in the TKT litigation more than seven years ago. (*Id.*, 85:14-86:5, 88:17-23). For this litigation, however, Dr. McLawhon relied on others to perform the tests. In the absence of his observation and guidance, at least one RIA was performed improperly by technicians, who apparently had limited experience with the procedure.

(*Id.*, 93:14-19). Dr. McLawhon simply assumed that all other RIAs were run properly without any basis. (*See id.*, 94:19-95:11). In fact, the laboratory had long since ceased to use RIAs, when, in 1994, it switched to an ELISA procedure. (*Id.*, 88:5-7). Under these circumstances, it is impossible for Dr. McLawhon to provide any guarantee of accuracy or authenticity to the tests. The Rules of Evidence thankfully prevent such unreliable information from being considered by a trier of fact, and in this case, the testing information should be excluded.

For the same reasons, all materials appended to the McLawhon Expert Report lack reliability and authenticity under Fed. R. Evid. 901. *See Goguen v. Textron, Inc.*, 234 F.R.D. 13, 19 (D. Mass. 2006). There was no laboratory notebook produced from this effort, only pages containing data which this Court must assume -- improperly -- accurately represent what the technicians observed. Without independent guarantors of reliability and authenticity, the entire corpus of information from this effort should remain inadmissible.

## II. Fed. R. Evid. 702 Requires That An Expert Rely On Information That Is The Product of Reliable Principles and Methods

Not only does Dr. McLawhon lack the requisite personal knowledge under FRE 602 to testify, either as a witness or through his expert reports, as to the veracity of the RIAs performed, but this evidence should also be precluded on the grounds that it does not satisfy the requirements of Fed. R. Evid. 702. For largely the same reasons as enumerated above, the information presented in Dr. McLawhon's expert report relied upon in his report are not the product of reliable principles and methods.

Scientists reach conclusions and form opinions largely by direct observation the results of experiments or tests. Therefore, a simple cursory review of resulting data therefore, is not the type of information that is relied upon by a scientist when forming an opinion. Instead the relevant standard under Rule 702 is what an expert would normally rely on as a professional.

*See Kuhmo Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999) (*Daubert* requires the trial court to assure itself that the expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field."); *Sheehan v. Daily Racing Form, Inc.*, 104 F.3d 940, 942 (7th Cir. 1997) (requiring consideration of whether the expert "is being as careful as he would be in his regular professional work outside his paid litigation consulting."). Dr. McLawhon did not perform the testing or his subsequent "analysis" according to the norms and practices of scientists.

According to Dr. McLawhon's own testimony, not only did he not perform the tests himself, but he also failed (1) to supervise the technicians who actually conducted the tests or (2) to even inquire about how the tests were performed. (McLawhon Dep. Trans. 94:19 – 95:11) There is no indication that Dr. McLawhon reviewed the procedures or methods employed by the technicians. By his own admission, Dr. McLawhon was not even in the same state as the technicians while they were performing the tests. (McLawhon Dep. Trans. 95:1-11) It is highly unlikely that such a practice is widely employed by other professionals in the field -- especially when they plan to rely on such testing as proof in a litigation. Even if a scientist could not supervise a test, at a minimum, a review of the methods and procedures used to reach the results would be employed in order to ensure that the test was sufficiently controlled for error and the results are in fact reliable. Dr. McLawhon did not do this; instead he merely reviewed the raw data and made no inquiry as to how the tests were undertaken and performed.

Because Dr. McLawhon was not being as careful as a typical scientist would be outside of litigation in forming his opinion, this data is not reliable and therefore does not satisfy rule 702's requirement that the "testimony is the product of reliable principles and methods."

## III. Amgen's Expert Witnesses Should be Precluded from Disclosing this Highly Prejudicial Evidence to the Jury Under Fed. R. Evid. 703

Because McLawhon lacks personal knowledge that the tests relied upon in his expert report was actually conducted appropriately, Amgen should be precluded from introducing them into evidence and even mentioning them to the jury. This information of questionable origin will serve no other purpose than to prejudice Roche and confuse the Jury. Fed. R. Evid. 403, 703 requires this Court to exclude such prejudicial information when little probative value inures to the proponent. The Court should preclude Amgen from presenting the existence of any of Dr. McLawhon's testing evidence to the Jury.

**CONCLUSION**

For the foregoing reasons, Roche respectfully requests that this Court exclude any proffered information concerning Amgen's RIA testing of the DN2-3α3 cell line, and preclude any Amgen expert witness from providing opinion testimony concerning these tests at trial.

**CERTIFICATE PURSUANT TO LOCAL RULE 7.1**

I certify that counsel for the parties have conferred in an attempt to resolve or narrow the issues presented by this motion and that no agreement was reached.

DATED: October 4, 2007
Boston, Massachusetts

Respectfully submitted,

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

By its attorneys,

*/s/ Thomas F. Fleming*

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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). Pursuant to agreement of counsel dated September 9, 2007, paper copies will not be sent to those indicated as non registered participants.

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