

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

_____	)	
AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	
	)	CIVIL ACTION No.: 05-CV 12237WGY
F. HOFFMANN-LA ROCHE LTD,	)	
ROCHE DIAGNOSTICS GMBH,	)	
AND HOFFMANN-LA ROCHE INC.,	)	
	)	
Defendants	)	
_____	)	

**ROCHE’S MOTION *IN LIMINE* TO EXCLUDE DR. EUGENE GOLDWASSER  
FROM TESTIFYING REGARDING EXHIBIT AYS, DECLARATION OF  
THOMAS HECKLER**

On September 26, 2007 Amgen disclosed to Roche that it intends to use Exhibit AYS, a Declaration by a Dr. Thomas Heckler submitted in an unrelated proceeding regarding experiments performed by others in Dr. Heckler’s laboratory. This document should be barred from evidence and Dr. Goldwasser should be precluded from testifying regarding what is described in this document because it is 1) hearsay not subject to an exception; 2) a document on experiments about which Dr. Goldwasser and even the declarant himself lacks personal knowledge; 3) not properly authenticated; 4) not supported by proper discovery of the experiments it describes (Roche has not been given any of the underlying notebooks or reports); 5) not sufficiently reliable under *Daubert* principles as to Dr. Goldwasser or Dr. Heckler; and 6) inadmissible under FRE 403 because of the risk that the jury may give undue weight to it as a quasi-legal document in another proceeding.

**I. The Heckler Declaration is Hearsay Not Subject to FRE 703**

The Heckler Declaration is inadmissible hearsay. Presumably Amgen intends to use it regarding the truth about certain purification experiments with recombinant EPO described therein. Dr. Goldwasser has been disclosed both as an expert witness and a fact witness<sup>1</sup>. Should Amgen call Dr. Goldwasser as an expert witness (as they should as he has already given fact testimony and should now be limited by his expert report) the Heckler Declaration is not subject to FRE 703 as it is not the type of information “reasonably relied upon by experts in the particular field” to which Dr. Goldwasser’s opinions relate. A declaration in a legal proceeding is certainly not the type of experimental evidence a scientific expert like Dr. Goldwasser relies upon in his work as a biochemist.

**II. Dr. Goldwasser and Even Dr. Heckler Lack Personal Knowledge**

Should Dr. Goldwasser testify as a fact witness, there is no possible way Dr. Goldwasser could have the requisite personal knowledge under FRE 602 to support admission of the document or to otherwise lay the foundation for it. Moreover, the Heckler Declaration would be inadmissible even as to Dr. Heckler (whoever he may be) as it is not clear from the face of the document that Dr. Heckler would have sufficient personal knowledge. The face of the document says that the procedure it purports to describe was in fact performed by Paul Remsen and Somesh C. Nigam rather than himself. Moreover, this would make the reports of Messrs. Remsen and Nigam hearsay within hearsay in the document.

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<sup>1</sup> The impropriety of Dr. Goldwasser’s “dual role” is the subject of a separate motion in *limine Roche* is filing to confine Dr. Goldwasser to expert testimony within the bounds of his report.

### **III. The Document is Not Properly Authenticated**

The document lacks proper authentication under FRE 901. The format and sub-par legibility of the document call into question what proceeding the document was to be submitted in and to what agency and whether it was ever accepted by that agency. The “declaration” portion of the document is actually only one page and the rest of the document that contains the substance of the experiments to which Dr. Heckler was declaring exists as an internal memorandum of the “R.W. Johnson” division of the Ortho company. The document therefore does not present itself as self authenticating under FRE 901(7). Given Dr. Goldwasser’s lack of involvement with any of the experiments described in the declaration or the creation and submission of the declaration himself, it seems highly improbable that Dr. Goldwasser can provide authenticating testimony for the document.

### **IV. Roche Was Not Provided With the Data Underlying the Declaration**

The document should not be admitted under FRCP 37 due to Amgen’s failure to make available the underlying documents generated during the course of the experiments described in the declaration. Without any supporting documentation it is unfair and prejudicial for Dr. Goldwasser to vouch for the credibility of the results and Dr. Heckler’s conclusions.

### **V. The Experiments in the Declaration Do Not Satisfy *Daubert***

Further the tests described in the declaration are not consistent with reliable principles and methods for Dr. Goldwasser to provide expert testimony relating thereto or even Dr. Heckler himself were he to appear. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589 (1993) (“...under the Rules the trial judge must ensure that any

and all scientific testimony or evidence admitted is not only relevant, but reliable.”). *See Polaino v. Bayer Corp.*, 122 F. Supp. 2d 63, 69 (D. Mass. 2000) (Stearns, J.) (expert opinion based on speculation rather than investigation properly excluded). Dr. Goldwasser and even Dr. Heckler’s lack of personal involvement with the experiments of the declaration renders any expert testimony on the experiment unreliable.

**VI. The Document is Inadmissible Under FRE 403**

Finally, the declaration should be barred from evidence and Dr. Goldwasser precluded from giving related testimony because of the risk that the jury will give the document too much weight because it bears the name “declaration” and originated from some kind of judicial or administrative proceeding. Presenting the document as a sworn “declaration” even though the declarant is not Dr. Goldwasser, did not do the work himself and is not appearing in Court may confer some undeserved and prejudicial credibility to the document in the minds of the jurors.

**VII. Conclusion**

In light of the foregoing, Roche respectfully submits that Amgen be precluded from offering AYS into evidence and from eliciting testimony from Dr. Goldwasser that relates to the document and the experiments contained therein.

**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 could be reached.

*/s/ Alfred H. Heckel*

DATED: September 27, 2007

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) and paper copies will be sent to those indicated as non registered participants on the above date.

/s/ Thomas F. Fleming

Thomas F. Fleming