

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

AMGEN INC.,)	
)	
)	Plaintiff,
)	
v.)	Civil Action No.: 05 Civ. 12237 WGY
)	
F. HOFFMANN-LA ROCHE LTD, ROCHE)	
DIAGNOSTICS GmbH, and HOFFMANN-)	
LA ROCHE INC.,)	
)	Defendants.
)	
)	

**DEFENDANTS' MOTION FOR CLARIFICATION OF THE COURT'S RULING ON
ROCHE'S MOTION TO ADMIT EXHIBITS INTO EVIDENCE**

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann La Roche Inc. (collectively “Roche”) respectfully submit this motion for clarification of the Court’s ruling on Roche’s Motion to Admit Exhibits into Evidence.

I. INTRODUCTION

On September 25, 2007, the Court ruled on Roche’s motion to Admit Exhibits into Evidence. (*See* Ex. A). Roche seeks clarification of the Court’s order with regard to exhibits NZR and PRX. Amgen’s objections to these exhibits – based on the fact that the exhibits were not disclosed in Roche’s 35 U.S.C. § 282 Notice, and because of lack of foundation – were sustained. However, these exhibits were in fact disclosed by Roche’s § 282 Notice. (*See* D.I. 799, Defendants’ August 2, 2007 § 282 Notice, relevant excerpts of which are attached as Ex. B). Moreover, these two documents have adequate foundation relating to Roche’s claims of invalidity. Therefore Roche respectfully requests that the Court clarify its ruling with regard to these exhibits, and to the extent it was based on Amgen’s incorrect assertion that they were not disclosed in Roche’s § 282 Notice, admit NZR and PRX into evidence.¹

II. ARGUMENT

Exhibit NZR, Urlaub and Chasin, “Isolation of Chinese hamster cell mutants deficient in dihydrofolate reductase activity,” *PNAS* 77:4216-4220 (1980) (“Urlaub”) was identified by Roche in its § 282 Notice (*see* Ex. B at 35) providing Amgen with proper and adequate notice of Roche’s intention to use it as prior art. Furthermore, Urlaub is discussed in the Lin specification, and thus Amgen has admitted it to be relevant prior art. (*See* TRX 0001 at col. 25, line 46)

Exhibit PRX (Bates numbered W00306-W00316), “Erythropoietin Presentation to Chugai Pharmaceutical Company, Genetics Institute, October 17, 1983” was also disclosed by

¹ Exhibit NMY, Lawn et al. (1978), was also objected to by Amgen on the basis of lack of disclosure in Roche’s § 282 Notice, although the exhibit was indeed disclosed. However, subsequent to the Court’s September 25, 2007 Order, exhibit NMY has been admitted as TRX 2101.

Roche's § 282 Notice. (*See* Ex. B at 40 ("Activities from 1981 through 1985 conducted by and/or on behalf of Genetics Institute concerning the cloning, characterization and expression of the human erythropoietin gene"). This exhibit, a presentation dated October 17, 1983, discusses the properties of EPO, as well as EPO cloning, expression and purification, and therefore is relevant prior art. Moreover, the Declaration of Christopher Chung, dated September 6, 2007 (attached as Ex. C), establishes the document's authenticity. Therefore, there should be no barrier to the admission of PRX into evidence.

III. CONCLUSION

For the foregoing reasons, Roche respectfully requests that this Court admit into evidence Exhibits NZR and PRX.

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 1, 2007
Boston, Massachusetts

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

By its attorneys,

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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.

/s/ Thomas F. Fleming
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