

**IN THE UNITED STATES DISTRICT COURT  
FOR THE 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

U.S. District Judge Young

**ROCHE'S MOTION *IN LIMINE* TO BIND AMGEN INC. TO  
PRIOR ADMISSIONS RELEVANT TO DOUBLE PATENTING**

Leora Ben-Ami (*pro hac vice*)  
Mark S. Popofsky (*pro hac vice*)  
Patricia A. Carson (*pro hac vice*)  
Thomas F. Fleming (*pro hac vice*)  
Howard S. Suh (*pro hac vice*)  
Christopher T. Jagoe (*pro hac vice*)  
Peter Fratangelo (BBO# 639775)  
Krista M. Rycroft (*pro hac vice*)  
Kaye Scholer LLP  
425 Park Avenue  
New York, New York 10022  
Tel. (212) 836-8000

Lee Carl Bromberg (BBO# 058480)  
Timothy M. Murphy (BBO# 551926)  
Julia Huston (BBO# 562160)  
Keith E. Toms (BBO# 663369)  
Nicole A. Rizzo (BBO# 663853)  
Bromberg & Sunstein LLP  
125 Summer Street  
Boston, MA 02110  
Tel. (617) 443-9292

Dated: Boston, Massachusetts  
September 10, 2007

*Counsel for Defendants  
F. Hoffmann-La Roche Ltd,  
Roche Diagnostics GmbH, and  
Hoffmann-La Roche Inc.*

Roche respectfully moves this Court for an order binding Amgen Inc. to prior admissions made during Interference No. 102,097 relating to the obviousness of the '868 and '698 patent claims over the claims of the expired '008 patent.

Amgen's current assertions regarding the non-obviousness of the '868 and '698 patent squarely contradict arguments and representations Amgen made to the Board of Patent Appeals and Interferences in reliance on this Court's decision in *Amgen Inc. v. Chugai Pharm. Co.*, 13 U.S.P.Q.2d 1737 (D. Mass. 1989). For example, Amgen argued to the Board, relying on this Court's decision, that there was "no distinction" between the process claims of the '868 and '698 patents and the '008 patent claims. Moreover, Amgen admitted that "transforming and transfecting a mammalian host cell" with the DNA sequence of the '008 patent and growing under nutrient conditions "necessarily and inherently involves transcription, translation and glycosylation...to provide the *in vivo* biologically active recombinant EPO." Amgen's current position — that the process claims of the '868 and '698 patents are not obvious over the '008 patent claims — directly contradicts Amgen's prior position. Courts, including this Court, have consistently prohibited parties from making such intentionally contradictory assertions through the application of the doctrine of judicial estoppel.

Based on the foregoing, Roche respectfully requests that this Court invoke that doctrine and preclude Amgen from arguing:

- (1) that the Lin process claims of the '868 and '698 patent are not obvious over the expired '008 patent claims;
- (2) that expression of an *in vivo* biologically active recombinant EPO polypeptide confers patentability;
- (3) that isolation of an *in vivo* biologically active recombinant EPO polypeptide confers patentability;
- (4) that transcription confers patentability;

- (5) that translation confers patentability;
- (6) that glycosylation of the EPO polypeptide confers patentability; and
- (7) that the asserted claims are patentable because production of a biologically active protein was an unexpected result.

**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.

Dated: September 10, 2007  
Boston, Massachusetts

Respectfully submitted,

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

*By their Attorneys*

/s/ Keith E. Toms

Leora Ben-Ami (*pro hac vice*)  
Mark S. Popofsky (*pro hac vice*)  
Patricia A. Carson (*pro hac vice*)  
Thomas F. Fleming (*pro hac vice*)  
Howard S. Suh (*pro hac vice*)  
Peter Fratangelo (BBO# 639775)  
Vladimir Drozdoff (*pro hac vice*)  
David L. Cousineau (*pro hac vice*)  
KAYE SCHOLER LLP  
425 Park Avenue  
New York, New York 10022  
Tel. (212) 836-8000

Lee Carl Bromberg (BBO# 058480)  
Robert L. Kann (BBO# 258025)  
Julia Huston (BBO# 562160)  
Keith E. Toms (BBO# 663369)  
Nicole A. Rizzo (BBO# 663853)  
Kregg T. Brooks (BBO# 667348)  
BROMBERG & SUNSTEIN LLP  
125 Summer Street  
Boston, MA 02110  
Tel. (617) 443-9292  
ktoms@bromsun.com

**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/ Keith E. Toms

Keith E. Toms

3099/501 737522.1