

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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AMGEN INC., )  
 )  
 Plaintiff, )  
 )  
 v. )  
 )  
 F. HOFFMANN-LA ROCHE LTD )  
 ROCHE DIAGNOSTICS GmbH )  
 and HOFFMANN-LA ROCHE INC. )  
 )  
 Defendants. )

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CIVIL ACTION No.: 05-CV-12237WGY

**DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR MOTION *IN LIMINE* TO  
PRECLUDE AMGEN FROM PRESENTING EVIDENCE REGARDING (1) A 1993  
SETTLEMENT AGREEMENT BETWEEN AMGEN AND GENETICS INSTITUTE  
AND (2) A 1989 DECISION THAT GENETICS INSTITUTE USED CELLS THAT  
INFRINGED THE '008 PATENT**

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Dated: Boston, Massachusetts  
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Roche Diagnostics GmbH, and  
Hoffmann-La Roche Inc.*

## **I. INTRODUCTION**

Amgen takes the position that Roche is bound or estopped in this case by certain prior actions or statements of corporations that are not Roche. As demonstrated below, there is no merit to Amgen's arguments. Moreover, allowing Amgen to present evidence in support of its unfounded theories will needlessly prejudice Roche.

## **II. ARGUMENT**

### **A. Roche Is Not Bound By the 1993 Settlement Agreement Involving the '008 Patent**

In its Supplemental Response to Roche's Fourth Set of Interrogatories (No. 41), Amgen asserts that Roche should be estopped from challenging the validity of the '008 patent "and the inventions defined therein" based on a May 12, 1993 Settlement Agreement ("the 1993 Agreement") (AM-ITC 00799255-00799271)<sup>1</sup> in which, according to Amgen, the parties "recognized and acknowledged the validity of the '008 patent." Amgen asserts that the 1993 Agreement was between Amgen and Chugai Pharmaceutical Co., Ltd. ("Chugai"). Amgen describes Chugai as being Roche's "predecessor-in-interest" by virtue of an October 1, 2002 merger through which Roche obtained "a majority ownership of 50.1% of Chugai."

Amgen's theory is flawed for multiple reasons. For one thing, the 1993 Settlement Agreement, by its terms, is between Amgen and Genetics Institute ("GI"), not Chugai. Amgen does not make clear how Roche's acquisition of an interest in Chugai binds Roche to the terms of an agreement between GI and Amgen.

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<sup>1</sup> Roche is not submitting the 1993 Agreement to the Court because it has been designated as confidential by Amgen and because the agreement itself contains a confidentiality provision. If the Court determines it requires the 1993 Agreement to decide Roche's motion, then Roche will submit it to the Court pursuant to the procedures of the Protective Order in this case, with appropriate notice to the parties to the agreement.

Moreover, the 50.1% of the shares of Chugai were acquired by Roche Pharmholding B.V., a Dutch affiliate of Roche Holding Ltd., Switzerland, neither of which is a party to this case. Amgen cannot show that the Roche defendants are bound by the acts of Chugai. *See Hiller Cranberry Prods. Inc. v. Koplowsky*, 165 F.3d 1, 9-10 (1st Cir. 1999), quoting *Amer. Home Assurance Co. v. Sport Maska, Inc.*, 808 F. Supp. 67, 73 (D. Mass. 1992) (“In order for a court to disregard separate corporate entities, a plaintiff must meet a very high standard . . . A court may pierce a corporate veil only when there is evidence of a ‘confused intermingling between corporate entities or when one corporation actively and directly participates in the activities of the second corporation, apparently exercising pervasive control’”); *DeJesus v. Sears, Roebuck & Co.*, 87 F.3d 65, 69 (2d Cir. 1996), quoting *Thomson-CSF, S.A. v. Amer. Arbitration Ass’n*, 64 F.3d 773, 797 (2d Cir. 1995) (“As a general matter . . . a corporate relationship alone is not sufficient to bind a [parent corporation for the actions of its subsidiary]”); *My Bread Baking Co. v. Cumberland Farms, Inc.*, 233 N.E.2d 748, 751 (Mass. 1968) (“corporations are generally to be regarded as separate from each other and from their respective stockholders”); *see also A. Stucki Co. v. Worthington Indus., Inc.*, 849 F.2d 593, 596 (Fed. Cir. 1988).

Furthermore, while this Court did enter judgment in *Amgen Inc. v. Chugai and Genetics Institute, Inc.*, Civil Action 87-2617-Y, that the “‘008 Patent was duly and legally issued” and was “valid and enforceable in law and equity,” the Settlement Agreement expressly stated that the parties “agreed to settle their respective claims against one another” “without admitting the validity of any assertion, contention or defense made in said legal proceedings” (at ¶ 4).

In any event, the 1993 Agreement resolved only “any and all *present* claims either party may have against the other relating to the ‘008 patent or any divisions or continuation thereof.” (*Id.* at ¶ 5; emphasis added). Because the patents-in-suit issued between August 20, 1996 and

September 21, 1999 -- years after the 1993 settlement -- the “present claims” settled by the 1993 Agreement necessarily did not encompass the validity of the later patents at issue in this case. Thus, the 1993 Agreement had no bearing on the patents-in-suit or the claims asserted in this case.

Accordingly, the 1993 Agreement is not relevant to any issue in this case and any suggestion by Amgen that the 1993 Agreement constitutes an admission by Roche as to the validity of any of Amgen’s asserted patents would be highly prejudicial and should be barred by FRE 402 and 403.

**B. Roche is Not Bound or Estopped Based on Any Prior Finding Against GI or Any Relationship With BM**

In its Statement of Contested Issues of Fact (Exhibit A to the Joint Pretrial Memorandum), Amgen recites as relevant facts: (1) that in 1989, in the *Amgen v. Chugai Pharm. Co.* case, the Court held that GI’s DN2-3 $\alpha$ 3 cell line infringed DNA and host cell claims in Amgen’s now expired ‘008 patent, (2) that the DN2-3 $\alpha$ 3 cell line used by Roche to manufacture epoetin beta was originally created and supplied by GI; (3) that GI licensed the DN2-3 $\alpha$ 3 cell line to Boehringer Manneheim (“BM”); and (4) that in 1997 Roche acquired BM. (See Joint Pretrial Memorandum, Ex. A. at pp. 10, 12).

Roche respectfully submits that even accepting the above-cited facts as entirely accurate, for purposes of this motion, they are irrelevant in this case. The holding that GI’s DN2-3 $\alpha$ 3 cells infringed the ‘008 patent has no estoppel effect here because: (1) Roche was not a party to that case and does not have (and never has had) any corporate relationship with GI; (2) the ‘008

patent at issue in that case is not at issue here; and (3) there are no host cell claims asserted in this case against any cell line used by Roche.<sup>2</sup>

Furthermore, Roche's acquisition of BM does not bind Roche with respect to any judgment in the *Chugai* case. BM was not a party to that suit.

For all the foregoing reasons, Amgen should be precluded from arguing that the prior finding in the *Chugai* case with respect to infringement by GI's use of its cell line in the U.S. binds or estops Roche in any way. Pursuant to FRE 402 and 403, Amgen should be precluded from offering evidence or argument relating to this finding at trial.

### **III. CONCLUSION**

Defendants respectfully request the Court to preclude Amgen's estoppel argument based on the 1993 Agreement and to preclude Amgen from arguing to the jury that Roche acknowledged the validity of any of the claims of the patents-in-suit or the '008 patent by virtue of the 1993 Agreement. Defendants further ask that Amgen be precluded from arguing that Roche is bound or estopped by findings against GI in the *Chugai* case and from offering evidence relating to such findings against Roche.

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<sup>2</sup> While Amgen's '349 patent has claims to host cells, the only asserted claim in that patent is claim 7 which recites "a process for producing erythropoietin . . . ."

Dated: August 20, 2007  
Boston, Massachusetts

Respectfully submitted,

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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/ Kimberly J. Seluga  
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