

**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 SUPPLEMENTAL DIRECTED VERDICT OPPOSITION IN  
RESPONSE TO AMGEN'S SEPTEMBER 24 ARGUMENT REGARDING  
THE ESTOPPEL EFFECT OF THE CHUGAI LITIGATION**

**I. INTRODUCTION**

During the September 24 hearing, Amgen argued, yet again, that Roche is estopped by the findings, and later settlement between the parties, in *Amgen v. Chugai*. This Court has consistently rejected Amgen's position. Indeed, after full briefing, this Court just yesterday denied Amgen's motion that sought to estop Roche from making an obviousness challenge based on the Chugai litigation. (Electronic Order, dated September 24, 2007, "denying [876] Motion in Limine #17"). In addition, the Court earlier granted Roche's motion *in limine* precluding Amgen from arguing that Roche is estopped by the findings in the Chugai litigation, and from using the settlement of that litigation to contend that Roche acknowledged the validity of any claims of the patents-in-suit. (Electronic Order, dated September 5, 2007, "granting [837] motion in limine"; Trial Tr. 6-7). Notwithstanding the Court's repeated rulings, Amgen persists in

contending that Roche is somehow bound by the Chugai litigation in challenging the validity of the patents at issue. Amgen's argument is without merit.

Conceding -- as it must -- that Roche was not a party to the Chugai litigation, Amgen contends that Roche is estopped based on the doctrine of "virtual representation," -- that the parties in the Chugai litigation were at the time of that litigation Roche's *de facto* representatives -- a doctrine that the First Circuit has described as one that should be kept "on a short tether" and be narrowly and strictly confined. *Gonzalez v. Banco Central Corp.*, 27 F.3d 751, 760 (1st Cir. 1994). However, Amgen does not and cannot demonstrate that that this limited and narrow doctrine applies here. Roche was a stranger to the Chugai litigation and, indeed, was not even involved in working on recombinant erythropoietin while that litigation was pending (1987-93). Roche is not bound by the Chugai litigation simply because, years later, in 2002, a affiliate acquired 50.1% of Chugai's stock, or because in 1997 it acquire Boehringer Mannheim GmbH ("Boehringer"), which Amgen wrongly claims was a joint venturer with GI.

Moreover, Roche is not estopped because the issues raised in the Chugai litigation regarding obviousness differ markedly from the issues in this case -- and Amgen fails to show otherwise. Apart from the fact that the Chugai litigation concerned the obviousness of Amgen's '008 patent, not the patents-in-suit here, Roche's obviousness challenges are not the same as those raised in the Chugai case and are raised against patents having a different priority date. Importantly, in light of the Supreme Court's decision in *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007), the obviousness challenges here must be evaluated under a different legal standard than that applicable at the time of the Chugai litigation -- which, by itself, precludes estoppel.

## II. ARGUMENT

### A. Roche Is Not Estopped Because It Was Not A Party To the Chugai Litigation

As the United States Supreme Court has held, a judgment among parties to a lawsuit “does not conclude the rights of strangers to those proceedings.” *Richards v. Jefferson County*, 517 U.S. 793, 798 (1996). In very limited circumstances, a judgment can bind nonparties, which the First Circuit has counseled is “a murky corner of the law” in which the district courts should “tread gingerly in applying.” *Gonzalez*, 27 F.3d at 757. Thus, in *Gonzalez*, the First Circuit held that nonparty preclusion would only obtain “if a nonparty either substantially controlled a party’s involvement in the initial litigation or, conversely, permitted a party to the initial litigation to function as his *de facto* representative”, the latter which it termed virtual representation. *Id.* at 758.

Here, Amgen still makes no claim that Roche substantially controlled the litigation by Chugai and GI -- nor could it as Roche was not involved in the litigation, nor was it related to the litigants. Nor is there any evidence that Amgen can adduce showing that Roche permitted either Chugai or GI to function as its representative in the case, which dooms Amgen’s attempt to tether Roche to the outcome of the Chugai litigation.

Confirming that Roche was not virtually represented by Chugai and GI, Amgen completely fails to show that Roche meets the demanding test for virtual representation set forth in *Gonzalez* and subsequent cases.<sup>1</sup> While the Chugai litigation was pending

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<sup>1</sup> This test requires that *at the time of the prior litigation* there must have been: 1) a clear identity of interests between the nonparty and the litigants in the first case with respect to relevant issues; 2) actual or constructive notice to the nonparty, “and an opportunity to participate in, the earlier suit,” *and* 3) that “the balance of equities tips in favor of preclusion.” *Gonzalez*, 27 F.3d at 761; *Perez v. Volvo Car Corp.*, 247 F.3d 303, 312 (1st Cir. 2001); *see also Boston Scientific Corp. v. Schneider AG*, 983 F. Supp. 245 (D. Mass 1997).

from 1987-1993, Roche had no ownership interest in Chugai. Nor did Roche have notice with an opportunity to participate in the Chugai litigation. More importantly, Roche had no “identity of interest” with Chugai and GI because Roche was not involved with recombinant erythropoietin at the time.<sup>2</sup>

Finally, Amgen is utterly is unable to demonstrate that any of the factors necessary to tip the equities for preclusion apply here. Roche did not consent to representation by Chugai or GI; neither Chugai nor GI were accountable to Roche; and there is absolutely no evidence of tactical maneuvering by Roche to exploit a “technical nonparty status in order to obtain multiple bites of the litigatory apple.” *See Gonzalez*, 27 F.3d at 761.

Thus, this case differs markedly from *Boston Scientific* on which Amgen heavily relies. There, Boston Scientific acquired SciMed which had been a party to prior litigation with the patentee. However, during the litigation, Boston Scientific and SciMed were both competitors of the patentee. Here, by contrast, there was no such identity of interest between Roche and Chugai at the time of the previous litigation. Moreover, Roche acquired its interest in Chugai many years after the litigation, not while the earlier litigation was on appeal as in *Boston Scientific* case. *See Boston Scientific Corp.*, 983 F. Supp. at 258.

Nor is Roche bound by the Chugai litigation under a successor-in-interest theory. Chugai is an independent corporation in which a Roche affiliate that is not a defendant here -- Roche Pharmholding B.V. – owns 50.1% of the stock. Chugai has other shareholders and its own board of directors. Therefore, Roche is not a successor-in-

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<sup>2</sup> Roche was not involved in work on or marketing of Neorecormon or Recormon until after its acquisition of Boehringer in 1997.

interest to Chugai nor is there any showing by Amgen that the corporate formalities should be disregarded as between any Roche entity and Chugai. Amgen cites no authority for the notion that a corporation is estopped by litigation to which a later acquired subsidiary was a party. Indeed, if the law were as Amgen suggests, there would be no need for the virtual representation theory of estoppel. the lawearlier

Finally, Amgen's successor-in-interest theory based on its 1997 acquisition of Boehringer is even more far-fetched. Boehringer was not bound by the Chugai litigation. Amgen's claim of a joint venture between GI and Boehring is not supported by the evidence. The very agreement between Boehringer and GI that Amgen relies upon expressly states that it is not a joint venture. Nor does Amgen's reliance on Massachusetts joint venture law shed light on whether Boehringer and GI had a joint venture pursuant to their agreement which, by its terms, was governed by Swiss law.

**B. Roche Is Not Estopped Because the Asserted Issues Differ**

Another reason that Roche is not estopped based on the Chugai litigation is that the issues differ markedly. First, the Chugai litigation concerned the validity of the '008 patent -- which is not at issue here. Notably, Amgen has consistently taken the position that the '008 patent differs from the subject matter of the asserted claims in this case. Second, the obviousness challenges that Roche raises as to the patents-in-suit are not identical to those in Chugai -- as they must be for collateral estoppel to apply. Roche's claims of obviousness are not limited to the use of cDNA probes or a genomic library as in Chugai, but also are based on the use of microsequencing and synthesizer technology. In addition, Roche claims obviousness based on the quantity of human EPO that Dr. Goldwasser provided Amgen (that Amgen derived its claims from Goldwasser, and the

rest was obvious) -- another issue not raised in the Chugai case. In addition, the issues concerning invalidity based on prior art are substantively different here than they were in Chugai because the priority date for determining prior art is different. In the present case, there has been no evidence for a priority date prior to November 30, 1984, while in the Chugai case, a much earlier priority date of September-October 1983 was applied.

Also importantly, the legal framework by which obviousness must be judged has changed significantly from the time of the Chugai litigation because of the Supreme Court decision in *KSR*. As the Federal Circuit has held, collateral estoppel should not be applied where there is a change in the “legal atmosphere” with respect to the issue.<sup>3</sup>

**C. Roche Is Not Estopped By the Chugai Settlement**

Finally, Amgen claims that Roche should be estopped because of the terms of the settlement of the Chugai litigation in 1993 in which Chugai and GI recognized the validity of the '008 patent. Beside the fact that Roche had no control or relationship with the parties to the settlement at that time, and that the settlement concerned a different patent, Roche cannot be barred because of well established case law that precludes estoppel based on a statement as to patent validity in a settlement. *See Ecolab, Inc. v. Paraclipse, Inc.*, 285 F.3d 1362, 1377 (Fed. Cir. 2002) (statement in consent judgment that “the [patent-in suit] is a valid patent.” was not sufficient to preclude future challenge

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<sup>3</sup> *Bingamen v. Dep't of Treasury*, 127 F.3d 1431, 1438 (Fed. Cir. 1997).

to validity in a subsequent action).<sup>4</sup> Amgen's claim that the *Ecolab* case concerns issues of *res judicata* rather than collateral estoppel is a distinction without a difference.

### III. CONCLUSION

The Court should deny Amgen's motion for a directed verdict based on the Chugai-GI litigation.

DATED: September 25, 2007

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

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<sup>4</sup> See also *Advanced Cardiovascular Sys. v. Scimed*, 989 F. Supp. 1237, 1246 (N.D. Cal. 1997) (no preclusion based upon consent judgment which "simply state[d] that the patents-in-suit are valid and enforceable").

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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) on the above date.

/s/ Thomas F. Fleming \_\_\_\_\_  
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