

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,)
)
 Plaintiff,)
)
 vs.)
)
 F. HOFFMANN-LA ROCHE LTD,)
 ROCHE DIAGNOSTICS GMBH,)
 AND HOFFMANN-LA ROCHE INC.,)
)
 Defendants)

CIVIL ACTION No.: 05-CV-12237WGY

Leave to file granted on October 1, 2007

**ROCHE’S SUR-REPLY IN RESPONSE TO PLAINTIFF AMGEN INC.’S PROPOSED
REPLY IN FURTHER SUPPORT OF ITS MOTION *IN LIMINE* NO. 17: TO EXCLUDE
ROCHE FROM PRESENTING EVIDENCE TO CHALLENGE THE NON-
OBVIOUSNESS OF THE DNA SEQUENCE ENCODING FOR HUMAN
ERYTHROPOIETIN IN 1983**

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Dated: Boston, Massachusetts
October 1, 2007

I. INTRODUCTION

Amgen has claimed at this trial that Roche is estopped from challenging the obviousness of Amgen's patents based on the outcome, and later settlement, of litigation between Amgen and Chugai Pharmaceutical co., Ltd. ("Chugai") and Genetics Institute ("GI") regarding Amgen's '008 patent. Finding the Chugai litigation to be irrelevant, the Court 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). Nevertheless, Amgen persists in contending that Roche is somehow bound by the Chugai litigation in challenging the validity of the patents at issue.

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). Amgen's proposed reply simply fails to demonstrate that that this limited and narrow doctrine applies here as Roche was a stranger to the Chugai litigation, and indeed was not involved in recombinant erythropoietin while that litigation was pending. Nor is Roche bound by the Chugai litigation simply because an affiliate acquired Chugai stock in 2002, or because of its acquisition in 1997 of Boehringer Mannheim GmbH ("Boehringer"), a non-Roche entity that 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. Importantly, the obviousness challenges here must, in light of the Supreme Court’s decision in *KSR Int’l Vo. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007), be evaluated under a different legal standard than that applicable at the time of the Chugai litigation -- which by itself precludes estoppel. Accordingly, Amgen’s motion should be denied.

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, Alabama*, 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.¹ While the Chugai litigation was pending from 1987-1991, Roche had no ownership interest in Chugai, and did not even have a clear identity of interest regarding recombinant erythropoietin with Chugai and GI because Roche had no commercial products at that time related to recombinant erythropoietin.² Nor did Roche have notice with an opportunity to participate in the Chugai litigation.

Finally, Amgen is utterly unable to demonstrate that any of the factors necessary to tip the equities for preclusion apply -- Roche did not consent to representation by Chugai or GI, neither Chugai nor GI were accountable to Roche, nor is there is evidence of tactical maneuvering 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 because there is no evidence of an identity of interest "at the time of the previous litigation" and Roche acquired interests in Chugai many years later,

¹ 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).

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

not while the litigation was pending as in the *Boston Scientific* case. See *Boston Scientific Corp.*, 983 F.Supp. at 258.³

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 -- an issue not in the present case. 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 Dr. Goldwasser provided Amgen (that Amgen derived its claims from Goldwasser, and the rest was obvious)-- another issue not raised in the Chugai case. With respect to invalidity based on prior art, the issues in the Chugai case are substantively different than the invalidity questions based related to prior art in the present case 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.

³ 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-interest to Chugai nor is there any showing by Amgen that any corporate formalities should be disregarded as between any Roche entity and Chugai. Nor is Roche a successor-in-interest to GI, with which it has no relationship. Finally, Amgen's successor in interest theory based on Boehringer, which Roche did acquire, is even more attenuated because there is no showing that Boehringer is bound by the Chugai litigation.

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.⁴

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. In addition to the fact that Roche had no control or relationship with the parties to the settlement at that time, and that the statement concerns a different patent, Roche cannot be barred because of well established caselaw 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 to validity in a subsequent action).⁵ Amgen’s claim that the *Ecolab* case concerns issues of res judicata rather than collateral estoppel is a distinction without a difference.

III. CONCLUSION

For the foregoing reasons, as well as the reasons in Roche’s opposition brief, Amgen’s Motion *in Limine* No. 17 should be denied in its entirety.

⁴ *Bingamen v. Dep’t of Treasury*, 127 F.3d 1431, 1438 (Fed. Cir. 1997).

⁵ *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”).

Dated: October 1, 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). 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

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