

**IN THE UNITED STATES DISTRICT COURT  
IN AND FOR THE DISTRICT OF MASSACHUSETTS**

AMGEN INC., )

)

Plaintiff, )

)

v. )

)

F. HOFFMANN-LA ROCHE LTD, a )

Civil Action No.: 1:05-cv-12237 WGY

Swiss Company, ROCHE DIAGNOSTICS )

GMBH, a German Company, and )

HOFFMANN LA ROCHE INC., a New )

Jersey Corporation, )

)

Defendants. )

)

)

**[PROPOSED] PLAINTIFF AMGEN INC.'S REPLY IN 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**

## I. INTRODUCTION

Roche asks the Court to apply a rigid rule to the flexible equitable doctrine of virtual representation by limiting it only to situations where a party essentially could have intervened in the first judicial proceeding. The doctrine, however, is not so limited, and courts recognize that the doctrine should apply “where there is tactical maneuvering designed unfairly to exploit technical nonparty status in order to obtain multiple bites of the litigatory apple.” *Gonzalez v. Banco Central*, 27 F.3d 751, 761 (1st Cir. 1994).

That is the case here. As Roche told the world, by 2002, it had cornered all rights to Genetics Institute’s (“GI”) EPO around the world from Boehringer Mannheim (“Boehringer”) and Chugai, which includes Chugai’s rights to the licensed US territory. Roche is enjoying the fruits of those rights, but is asking this Court that it not shoulder those burdens of prior adjudications. Worse, Roche is again challenging the non-obviousness of Dr. Lin’s cloning of the EPO gene in the same Court as its predecessor-in-interest, openly cherry-picking deposition testimony as well as quotes and statements from this Court’s 1989 *Amgen v. Chugai* decision to again challenge, but before a different trier-of-fact hoping to get a different result. No notion of equity is served by such gamesmanship, and Roche should be estopped.

## II. ARGUMENT

### A. THE DOCTRINE OF VIRTUAL REPRESENTATION ESTOPS ROCHE FROM CHALLENGING THAT DR. LIN’S EPO DNA SEQUENCE IS NOT OBVIOUS

Roche does not dispute that (1) facts material to its position in this litigation on whether it was obvious to clone the DNA sequence in 1983 was fairly and fully litigated through the District Court and through the Federal Circuit, and (2) that its subsidiary Chugai was a party to the litigation and further stipulated in a final judgment before this Court as to the ‘008 Patent’s validity. Roche attempts to evade the reach of collateral estoppel by arguing that it was not in privity with Chugai or Boehringer, both of whom it now owns, at the time of the *Amgen v. Chugai* litigation.

Roche overstates the rigidity of the virtual representation doctrine when it states that the First Circuit “held” that the virtual representation doctrine is limited to circumstances only “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,” *Gonzalez*, 27 F.3d at 758. While it is true the *Gonzalez* decision does point to the application of the doctrine as typically applying to such situations, the Court stated that there is “no black letter law” and continued: “We would not conclude that a case falls outside the theory’s purview solely because it does not fit snugly into some preconceived niche or mirror some established fact pattern.” *Id.* at 761, 763; *see Shaw v. Hahn*, 56 F.3d 1128, 1131 (9th Cir. 1995) (A stranger having no relationship with the plaintiffs was found to have privity because of “the identity of interests between Shaw and the *Tapia* plaintiffs, and the adequacy of the *Tapia* plaintiffs’ representation of her equal protection interests, were such that they were in privity.”).<sup>1</sup>

Importantly, *Gonzalez* recognized the doctrine clearly applies where courts have detected “tactical maneuvering designed unfairly to exploit technical nonparty status in order to obtain multiple bites of the litigatory apple.” 27 F.3d at 761. That is the case here where GI, Chugai and Boehringer all lost the issue of whether it was obvious to clone the EPO gene, but Roche, the acquirer, is seeking to have another bite of the litigation apple on cloning.

Roche belittles the fact that it acquired Chugai. However, when Roche’s chairman described the merger, he explicitly noted the importance of Chugai’s “Epogin” assets:

Thanks to NeoRecormon (Roche) and Epogin (Chugai) we now control the global marketing rights to epoetin beta, a major anemia treatment, outside the United States. The smooth and seamless integration of Chugai in Japan will be of great importance for the future growth of our pharmaceuticals business.

---

<sup>1</sup> Roche claims that cost is not an appropriate factor when dealing with a party such as Roche. The use of the term “new party” belies the fact that Roche acquired a majority stake in Chugai and that Roche defendant Roche Diagnostics GmbH merged with Boehringer. Roche’s attempt to create the appearance that it is a “stranger” to the action is not convincing.

(Gaede Decl., Ex. 2 at 4; *see also* Gaede Decl., Ex. 1.)<sup>2</sup> Roche wants to have the benefits of controlling the global marketing rights Chugai and Boehringer obtained from GI as set forth in the GI/Chugai/Boehringer Agreements, but does not want to bear the burdens of those predecessors litigating and losing in this Court on the same issue Roche wants to relitigate here.

Roche's non-privity argument further glosses over the glaring fact that its 50.1% stake in Chugai made Roche an "Affiliate" under the terms of the Chugai-GI license agreement.

"Affiliate" means a corporation, company, or partnership, joint venture and/or firm which controls, is controlled by or is under common control with Licensee. For purposes of this Section 1.2 "control" shall mean (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares entitled to vote for the election of directors. . .

(Docket No. 878-3 at AM-ITC 00078878-79; *see also* AM-ITC 00078896 ("Genetics hereby grants Licensee and its Affiliates" licenses to Genetics's patents).) Therefore, when Roche took a 50.1% interest in Chugai, it came into privity with Chugai, having inured to all the benefits of the Chugai-GI license agreement as an "Affiliate."

In point of fact, Roche wants to have its proverbial relitigation cake and eat it too. Not just content to relitigate the issue of the cloning of the gene, Roche in fact seeks to use statements from this Court's decision in *Amgen v. Chugai* against Amgen on the alleged obviousness of the cloning of the gene even though Amgen proved long ago it was not obvious. Consider the following paragraph from the Second Supplemental Expert Report of Dr. Lowe:

In this regard, a number of the findings *made by the district court* further strengthen my conclusion that in view of the evidence cited in my April 6, 2007 report, before October 1983, it would have been obvious to one of skill in the art to achieve this objective through cloning the cDNA for EPO. At the time, a finite number of practical approaches were available to clone the gene, essentially using cDNA libraries or using genomic libraries. *The findings of the district court* are consistent with my conclusion that the approach using cDNA libraries was both well within the routine technical knowledge of one of skill at the time and predictable, and therefore would have been an obvious choice.

---

<sup>2</sup> "Gaede Decl." refers to the Declaration of William G. Gaede, III, in Support of Plaintiff Amgen Inc.'s Reply in 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, filed herewith.

(Gaede Decl., Ex. 3, ¶ 10 (emphasis added).) Roche further intends to play to the Jury deposition testimony from Dr. Miyake in its efforts to argue that cloning the DNA sequence was obvious. (Gaede Decl., Ex. 4.) Roche intends to use the *Amgen v. Chugai* litigation against Amgen, yet Amgen is prohibited from informing the Jury that Amgen in fact prevailed on these very issues that Roche is seeking to relitigate.

Finally, Roche does not dispute Amgen's factual showing that it had actual and constructive notice of the litigation. Roche's arguments that notice requires it to be able to intervene are unconvincing and contrary to the central equitable heart of the doctrine. Roche provides no authority to support reading this additional element into the notice "requirement."<sup>3</sup>

**B. ROCHE IS IN PRIVITY WITH THE PRIOR ADJUDICATIONS BECAUSE BOEHRINGER WAS BOUND BY THE ACTS OF GI, ITS JOINT VENTURE PARTNER**

Roche argues that because it acquired Boehringer after the prior adjudications, it is absolved from being bound by Boehringer's acts, despite Boehringer's involvement in the *Amgen v. Chugai* litigation. Roche does not dispute that named party Roche Diagnostics GMBH is the former Boehringer entity, and thus any distinction on the technicality of the other Roche defendants not technically owning or being affiliated with Boehringer is irrelevant. Moreover, Roche's relationship with Boehringer at the time of the prior adjudications has no bearing on the liabilities it assumes as a successor-in interest. *See, e.g., Hodges v. El Torito Restaurants*, 1998 U.S. Dist. LEXIS 11517, at \*11 (N.D. Cal. 1998) ("companies assume the liabilities of other companies they acquire"); *Okaw Drainage Dist. v. Nat'l Distillers & Chem. Corp.*, 739 F. Supp. 459, 461 (C.D. Ill. 1990). Roche is bound by whatever Boehringer was bound to.

---

<sup>3</sup> Contrary to Roche's assertion, *Nordhorn v. Ladish Co.*, 9 F.3d 1402, 1405 (9th Cir. 1993), does not contradict Amgen's assertion that Roche is estopped in this case. Equity demanded the court not bind the plaintiff in *Nordhorn*. There, the plaintiff filed suit against the defendant, a former subsidiary to HITCO. The former subsidiary moved for claim preclusion against the plaintiff because it had filed suit earlier against the defendant subsidiary's former parent, HITCO. The court refused to estop the plaintiff because HITCO was no longer in privity at the time the estoppel issue was being decided. That is not the case here. At the time the Court is to decide the issue of collateral estoppel, Roche is in privity with Chugai. (*See Amgen Br.* at 16-17.)

Roche urges the Court to ignore the overwhelming evidence of the presence of the eight *Petricca* joint venture factors in favor of § 10.8 of the 1985 agreement containing boiler plate that there is no agency. *Petricca Development Limited Partnership v. Pioneer Development Co.*, 40 F. Supp. 2d 49, 53 (D. Mass. 1999). All eight factors were present in the Boehringer-GI relationship, strongly evidencing the formation of a joint-venture. (See Amgen Br. at 17-19 (addressing the presence of the eight factors in detail).) The boiler plate language only shows that there is no general agency agreement.<sup>4</sup>

Roche tries to rewrite the test for a joint-venture when it argues that the “Agreement does not provide the parties will share in *all profits and losses* resulting from the venture.” (Roche Opp. at 13.) The *Petricca* factors of “a right to share in the profit” and “an express or implied duty to share in the losses” places no requirement that the parties share in *all* the profits and losses.

Roche claims that joint venture is question of fact. (Roche Opp. at 14 (citing to Am. Jr. 2d.)) The question of whether there is a joint venture under Massachusetts law is a matter of law because “[i]n this case, the existence of a joint venture hinges on interpretation of the parties’ agreement. Generally, ‘under Massachusetts law, the interpretation of a contract is ordinarily a question of law for the court.’” *Petricca*, 40 F. Supp. at 53.

### C. COLLATERAL ESTOPPEL APPLIES – THE ISSUES ARE NOT DIFFERENT

Invalidity is an “issue” for the purposes of collateral estoppel. See *Pall Corp., v. Fisher Scientific Co.*, 962 F. Supp. 210, 213 (D. Mass. 1997); *Applied Med. Resources Corp., v. United States Surgical Corp.*, 352 F. Supp. 2d 1119, 1124 (C.D. Cal. 2005). Once an issue is raised and determined, it is the entire issue that is precluded, not just the particular arguments raised in support of the first case. See *Applied*, 352 F. Supp. 2d at 1124 (rejecting a party’s attempt to escape collateral estoppel on the issue of invalidity by raising anticipation and obvious

---

<sup>4</sup> Roche has argued that Boehringer did not enter into a joint venture with GI because the governing law section of the 1985 agreement indicates that Swiss law applies. The governing law section read properly addressed disputes between GI and Boehringer as it relates to the agreement. Moreover, joint venture does not require an explicit agreement. Under Massachusetts law, GI’s activities with Boehringer for the research, development, and commercialization of EPO, strongly evidences the formation of a joint venture.

arguments not previously raised). As explained earlier, Roche has indicated that it will challenge the prior adjudication that Dr. Lin's EPO DNA sequence was non-obvious and the findings essential to that determination.

In arguing that the "issues" are different, Roche commits the cardinal error of equating "argument" with an "issue." The issue of non-obviousness of Dr. Lin's EPO DNA sequence was raised. The entire issue is precluded from relitigation, including arguments that could have been raised. *See Applied*, 352 F. Supp. 2d at 1124 (rejecting a party's attempt to escape collateral estoppel on the issue of invalidity by raising anticipation and obvious arguments not previously raised).

**D. THE CHANGE IN THE LAW EXCEPTION TO COLLATERAL ESTOPPEL IS INAPPLICABLE HERE**

Roche claims that the Supreme Court's recent *KSR v. Teleflex* decision on obviousness is a change in legal atmosphere that warrants not applying collateral estoppel. Roche has failed to show that *KSR* is a "significant change in decisional law." In *KSR*, the U.S. Supreme Court reaffirmed the long standing test for obviousness in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1965). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1734 (2007) ("the [Graham] factors continue to define the inquiry that controls"). And in the instant case, Roche has made no showing that the prior adjudication would likely be resolved differently post-*KSR*.

Roche relies on the Federal Circuit's decision in *Bingaman v. Dept. of Treasury*, 127 F.3d 1431 (Fed. Cir. 1997). The *Bingaman* Court concluded that there was a change in "governing legal principles" with regard to "key legal issue" and opined that there had been a significant change in decisional law that justified not applying equitable estoppel. *Id.* at 1438. No such change occurred here where the Supreme Court affirmed its prior decisions in this area.

**E. CONTRACTUAL ESTOPPEL APPLIES**

The 1993 Settlement Agreement gives rise to contractual estoppel. *See Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362 (Fed. Cir. 2001) (Federal Circuit precluded challenge of the validity of the patent based on contractual estoppel due to terms of the settlement agreement). Pursuant to the 1993 Settlement Agreement, there was an entry of judgment in this Court in which this Court stated that "[t]he '008 Patent was duly and legally issued, is valid and enforceable in law and equity..." (Docket No. 878-36, AM44 2024650-52.) The Federal Circuit has held, like in the

case here, where a party agrees to a dismissal with prejudice with an accompanying settlement agreement, the party is contractually estopped from challenging the patents validity. *Flexfoot*, 238 F.3d at 1367.

Roche's reliance on *Ecolab, Inc. v. Paraclipse, Inc.*, 285 F.3d 1362 (Fed. Cir. 2002) is not relevant to the issue of collateral estoppel.<sup>5</sup> *Ecolab* addressed the issue of whether *res judicata* applied to a party. Moreover, unlike *Ecolab*, the issues have been fully and fairly litigated, with decisions from the Board of Interference, a trial and adjudication with this Court, and Federal Circuit review and affirmance.

Finally, Roche's argument that there is not contractual estoppel because Chugai was not a signatory to the 1993 Settlement Agreement misses the point. GI's settlement agreement, in furtherance of the Boehringer-GI joint venture, bound Boehringer. Roche Diagnostics as the successor-in-interest is bound by the settlement agreement. Thus, contractual estoppel is appropriate.<sup>6</sup>

---

<sup>5</sup> Roche cited to *Ecolab* in its opposition to Amgen's Motion *In Limine* No. 17 as supporting its position that contractual estoppel does not apply.

<sup>6</sup> Moreover, Roche citation to *Pall*, 962 F. Supp. 210 does not support its argument that if different products are involved a "successor-in-interest" is not collaterally estopped from relitigating adjudicated issues. *Pall* was a "successor-in-interest" to products and did not buy a company. Accordingly, the Court held that due process would have been violated if the company was precluded from relitigating. That is different than here where Roche merged with Boehringer.



### III. CONCLUSION

For the foregoing above reasons, the Court should grant Amgen's Motion *In Limine* No. 17 in its entirety.

DATED: September 6, 2007

Respectfully Submitted,

Of Counsel:

AMGEN INC.,

Stuart L. Watt  
Wendy A. Whiteford  
Monique L. Cordray  
Darrell G. Dotson  
Kimberlin L. Morley  
Erica S. Olson  
AMGEN INC.  
One Amgen Center Drive  
Thousand Oaks, CA 91320-1789  
(805) 447-5000

/s/ Michael R. Gottfried  
D. Dennis Allegretti (BBO# 545511)  
Michael R. Gottfried (BBO# 542156)  
Patricia R. Rich (BBO# 640578)  
DUANE MORRIS LLP  
470 Atlantic Avenue, Suite 500  
Boston, MA 02210  
Telephone: (857) 488-4200  
Facsimile: (857) 488-4201

Lloyd R. Day, Jr. (pro hac vice)  
DAY CASEBEER MADRID & BATCHELDER LLP  
20300 Stevens Creek Boulevard, Suite 400  
Cupertino, CA 95014  
Telephone: (408) 873-0110  
Facsimile: (408) 873-0220

William G. Gaede III (pro hac vice)  
McDERMOTT WILL & EMERY  
3150 Porter Drive  
Palo Alto, CA 94304  
Telephone: (650) 813-5000  
Facsimile: (650) 813-5100

Kevin M. Flowers (pro hac vice)  
MARSHALL, GERSTEIN & BORUN LLP  
233 South Wacker Drive  
6300 Sears Tower  
Chicago, IL 60606  
Telephone: (312) 474-6300  
Facsimile: (312) 474-0448

**CERTIFICATE OF SERVICE**

I hereby certify that this document filed through the Electronic Case Filing (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/ Michael R. Gottfried*

Michael R. Gottfried