UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GMBH, and HOFFMANN-LA ROCHE INC., Defendants.	CIVIL ACTION No.: 05-CV-12237WGY

ROCHE'S OPPOSITION TO AMGEN'S 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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I. INTRODUCTION

In this motion Amgen seeks to prevent Roche from demonstrating to the jury that Amgen's claimed inventions were obvious based on litigation about a different patent than those at issue in this case that took place years ago involving different companies that at the time were not related to Roche in any way. Specifically, Amgen seeks to tether Roche to adjudications in proceedings between Amgen and Chugai Pharmaceutical co., Ltd. ("Chugai") and Genetics Institute ("GI") regarding Amgen's '008 patent. But Roche was neither a party to the Chugai litigation nor the Fritsch interference, nor was it involved in those cases in any way, and thus cannot be bound by those adjudications.[1]

Amgen argues that Roche is collaterally estopped by the Chugai litigations based on the doctrine of "virtual representation," --that is, that the parties in the Chugai litigation were at the time of the 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). The virtual representation doctrine plainly does not apply here because Roche had no relationship with the parties ***at the time of the Chugai litigations,*** and Amgen has adduced no evidence that Chugai or GI were acting as Roche's *de facto* representatives during that litigation. Roche's purchase of interests in the litigants many years later does not permit a finding of virtual representation because the relevant inquiry for virtual representation collateral estoppel is the relationship at the time of the first suit. Moreover, the issues in the Chugai litigation concerned the validity of certain claims of the now expired '008 patent, and hence, is not at issue in this case. Thus, applying collateral estoppel to Roche based on the Chugai litigations would trample on Roche's due process rights.

[1] Roche has already filed a motion in limine to preclude Amgen from offering evidence or argument that Roche is bound or estopped in any way by prior adjudications and transactions involving GI and Chugai. (D.I. 837). Roche incorporates the arguments set forth therein by reference.

Amgen's other arguments as to why Roche should not be allowed to present an obviousness challenge to the validity of its patents are also without merit. Roche is not a joint venturer of any parties to the Chugai case, certainly not as a matter of law. Nor does the 1993 settlement of the Chugai litigations provide any basis to preclude Roche from contending before the jury that the patents-in-suit are obvious.

Not only is Roche not bound by the terms of the Chugai Settlement, the Federal Circuit has held - regarding a settlement stunningly similar to this case - that a statement in a consent judgment that a patent is valid does not in itself preclude a future challenge to validity, even by the parties to that agreement. ***Ecolab, Inc. v. Paraclipse***, 285 F.3d 1362 (Fed Cir. 2002).

Even assuming that Roche was bound by the prior decisions (it is not), Roche would still be able to argue ***different*** theories of obviousness that were not presented in those cases. For example, the inventions at issue in the Chugai litigation and Fritsch Interference dealt specifically with an isolated and purified DNA sequence encoding a 166 amino acid protein of human erythropoietin. Roche's theories of obviousness are much broader than this, and include the use of synthetic DNA to show obviousness of the asserted claims of the patents-in-suit, as well as the use of a DNA sequence encoding a 165 amino acid protein. These obviousness issues were not at issue in the prior cases, and thus Roche cannot be precluded from arguing these positions.

Finally, the issues of obviousness in the prior decision were decided under an outdated and completely different legal standard from that of today. Under the new obviousness standard set forth in the Supreme Court's ***KSR*** decision, the '008 claims at issue in the prior litigations very well could have been held invalid.

II. ARGUMENT

A. Roche Is Not Collaterally Estopped By the Chugai Litigations Because It Was Not a Party and Those Litigations Concerned Different Issues

The Chugai litigation commenced in 1987 when Amgen sued Chugai and GI alleging that their production of recombinant erythropoietin infringed certain claims of Amgen's '008 patent. As the Court is well aware, MIRCERA® was not at issue in the Chugai case. In 1991, the Federal Circuit decided the appeal of this Court's determinations of the Amgen-Chugai case, and the parties entered into a settlement of the case in 1993. *See Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200 (Fed. Cir. 1991); Gaede Decl. Ex. 1[2]. Among the issues determined in the Chugai litigations were the validity of certain claims of the '008 patent based on the law applicable at the time. The issue of the validity of the six patents-in-suit in this case was not at issue in the Chugai cases.

Significantly, Roche had no interest whatsoever in either Chugai, GI, or Boehringer Mannheim GmBH ("Boehringer"), another non-Roche entity that Amgen wrongly claims was a joint venturer with GI. In its voluminous papers in support of its motion in limine, Amgen has not a shred of evidence that Roche had any involvement in the Chugai litigation, nor any other close relationships with any of the entities involved in that litigation.

In 2002, nearly a decade after the conclusion of the Chugai litigations, Roche Pharmholding B.V., which is not a party in this case, acquired slightly over 50% of the shares in Chugai. Chugai remains an independent company based in Japan, with its own corporate structure and board of directors. In 1997, four years after the conclusion of the Chugai litigation, Roche acquired Boehringer.

[2] All Exhibits henceforth shall refer to Exhibits from the Gaede Declaration attached to Amgen's brief.

Amgen's argument that Roche is collaterally estopped by the Chugai litigation over the '008 patent -- a litigation to which Roche was a stranger for the entire duration of the case -- is fundamentally flawed because, as explained below, Roche was not a party, nor was in privity with parties, and the Chugai litigation concerned different issues from those in this litigation. So too, Roche cannot be estopped by any finding in the Fritsch interference when it has had no relation virtual or otherwise to Genetics Institute.

1. Roche Is Not Collaterally Estopped Because It Was Not a Party, Nor in Necessary Privity With a Party, to the Chugai Litigation

a. The Law Governing Collateral Estoppel Against a Non-Party

As the United States Supreme Court has stated, it is "part of our deep-rooted historic tradition that everyone should have his day in court," and that consequently 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). Here, Roche was a stranger to the Chugai litigations, and Amgen presents no evidence to the contrary.

In very limited circumstances -- that, as will be shown below are not applicable here -- a judgment can bind "persons who, technically, were not parties to the initial action." *Gonzalez*, 27 F.3d at 757. As the First Circuit has counseled, finding a nonparty to be precluded is "a murky corner of the law and caution the district courts to tread gingerly in applying [the doctrine] to nonparties." *Id.* Indeed, the First Circuit cautioned that the "perils of nonparty preclusion are real", and that "an overly expansive arrangement of the concept, and too free of it, may endanger constitutional rights." *Id.* at 757, n.4.

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."

Id. at 758. The court termed the *de facto* representation theory as "virtual representation" or "representation by proxy." *Id.*

Here, Amgen 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.[3] Nor, despite Amgen's claim that virtual representation applies here, is there any evidence that Amgen adduces showing Roche to have permitted either Chugai or GI to function as its representative in the case. None whatsoever. And the absence of any such evidence of a relationship between Roche, on the one hand, and Chugai, GI, or even Boehringer, on the other, ***while the litigation was ongoing***, dooms Amgen's motion.

Amgen attempts to skirt First Circuit precedent by invoking and relying upon sweeping statements in a case from the Fifth Circuit --*Aerojet-General Corp. v. Askew*, 511 F.2d 710 (5th Cir. 1975) -- that has been roundly criticized not only by the First Circuit in *Gonzalez*, but also by the Fifth Circuit itself in later decisions. *See* Amgen Br. at 14 (quoting *Aerojet*). In *Gonzalez*, the First Circuit stated that the *Aerojet* decision contained "sweeping generalities" -- quoting the very language in that opinion that Amgen relies upon here -- that if deployed "to justify nonparty preclusion in a broad spectrum of cases, would threaten the core principles underpinning the due process equation." 27 F.3d at 760. The *Gonzalez* court also noted that the Fifth Circuit itself has subsequently limited the scope of the *Aerojet* case. *Id.*[4] Thus, the First Circuit held that the current state of the law "placed the theory of virtual representation on a short tether significantly

[3] As the First Circuit held in *Gonzalez*, "[s]ubstantial control means what the phrase implies; it connotes the availability of a significant degree of effective control in the prosecution or defense of the case - what one might term, in the vernacular, the power - whether exercised or not - to call the shots." 27 F.3d at 758.

[4] *See also Pollard v. Cockrell*, 578 F.2d 1002, 1008-09 (5th Cir. 1978) ("virtual representation demands the existence of an express or implied legal relationship in which parties to the first suit are accountable to non-parties who file a subsequent suit raising identical issues")

restricting its range," and approvingly cited cases from other circuits that virtual representation "must be kept within strict confines" and have a "narrow role." 27 F.3d at 760.

i. The First Circuit Test for De Facto Representation

Consistent with narrow role for virtual representation, the First Circuit in *Gonzalez* and subsequent cases has set forth a strict test for determining whether a nonparty was virtually represented in a prior suit. Under this test there must be, ***at the time of the prior litigation***:

> 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).

With respect to factor 3) above -- whether the balance of the equities tip in favor of precluding a nonparty-- the *Gonzalez* court made clear that at least one of the following had to be found in order to tip the balance in favor of preclusion:

> -- "actual or implied consent to be bound by the results of the prior action";
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> -- "an express or implied legal relationship in which parties to the first suit are accountable to non-parties who file a subsequent suit raising identical issues";
>
> -- "certain types of familial relationships linking parties and nonparties", such as wife-husband, or father-son; or
>
> -- "tactical maneuvering designed unfairly to exploit technical nonparty status in order to obtain multiple bites of the litigatory apple."

Gonzalez, 27 F.3d at 761.[5]

The burden of showing virtual representation -- which the First Circuit has characterized as a "demanding" one -- rests with the party asserting it. *See Tapalian v. Tusino*, 377 F.3d 1, 7, n. 1 (1st Cir. 2004). Amgen doesn't come close to meeting its demanding burden here.

b. The Balance of Equities Do Not Tip In Favor of Precluding Roche

Amgen's failure to demonstrate that any of the *Gonzalez* balance of equity factors apply to Roche regarding the Chugai litigation is dispositive of Amgen's virtual representation claim. Indeed, in its motion, Amgen completely fails even to articulate how any of the factors apply to Roche and the Chugai litigation. Amgen offers no evidence -- nor could it -- that Roche consented to be bound by the results of the Chugai litigation or the Fritsch interference as to any challenge that it would later make to Amgen patents. Amgen has adduced zero evidence of any relationship whereby Chugai, GI, or even Boehringer were accountable to Roche during the pendency of the Chugai litigation or the Fritsch interference. Again, given that Roche was not affiliated with those entities at that time, no such evidence of accountability exists. Nor has Amgen put forth any evidence that there was any tactical maneuvering during the pendency of the Chugai litigation or the interference designed to give Roche an unfair chance of litigating anew the validity issues raised there.

Instead of addressing the *Gonzalez* balance of equities factors, Amgen claims only that the "equities" require Roche preclusion because Amgen would have to incur additional expenses relitigating the same issues as in the Chugai and GI cases. (Amgen Br. at 16). Putting aside the

[5] Other courts in this circuit have framed the issue the same way. *See North Atlantic Distribution Inc. v Teamsters Local Union No. 430*, __F.Supp.2d __ , 2007 WL 2110951 at *5 (D.R.I. July 24, 2007) (noting that First Circuit rule is that balance of equities exist where actual or implied consent, express or implied legal relationship, familial relationships or tactical maneuvering to exploit nonparty status); *Doral Pharmademedics, Inc.*, 148 F.Supp. 2d 127, 133 n. 4 (D.P.R. 2001) ("[t]he First Circuit has limited the application of the theory of virtual representation to those cases where there has been 'tactical maneuvering designed to exploit technical non-party status in order to obtain multiple bites or the same litigatory apple' or in cases where 'a non party has consented to be bound by the result of a prior action.'") (*quoting Gonzalez*).

fact that the issues are not the same (*see* infra at 13-18), the cost to a party of having to litigate an issue with a new party is not a factor that is relevant to this prong of the virtual representation test.

The lack of any close relationship between Roche and the Chugai parties during the pendency of the Chugai litigation, and the absence of any tactical maneuvering distinguish this case from the *Boston Scientific* case on which Amgen heavily relies. In *Boston Scientific*, a company (Scimed) which had challenged the validity of the plaintiff's patent in a prior litigation merged with a second company (BSC) *while this litigation was still ongoing*. When BSC sought to challenge the validity of the plaintiff's patent in a subsequent action, the court held that BSC was estopped from doing so. *See* 983 F. Supp. at 257-60. Thus, in *Boston Scientific* the relationship between the parties giving rise to estoppel existed *at the time when the first litigation was still activ*e. By contrast, Roche did not have any interest in Chugai until fourteen years after the Amgen-Chugai litigation had ended. Furthermore, the court in *Boston Scientific* found a close nonlitigating relationship between the parties which tipped the equities in favor of preclusion. *Id.* at 260. Specifically, the court found that BSC had transferred all sales of its allegedly infringing product to Scimed, even though BSC continued to manufacture the product. *Id.* Thus, the party to the first suit sought to avoid the judgment in the first suit notwithstanding the fact that it was the sole distributor of the allegedly infringing product that was the subject of the second suit. The court therefore found "that the effective identity of the relevant nonlitigating relationship between BSC and Scimed weighs heavily in favor of applying collateral estoppel." *Id.* at 259. Amgen in this case does not even argue that Chugai is attempting to avoid the judgment in the prior Amgen-GI litigation.

c. Roche Did Not Receive Notice of the Chugai Litigation With an Opportunity to Participate in That Litigation

In addition, Amgen has adduced no evidence that Roche received notice of the Chugai litigation that would have afforded it an opportunity to participate in that litigation-- an independent ground for why virtual representation does not exist here. As evidence of notice, Amgen offers only surmise that Roche must generally have known about the litigation and attaches a copy of Amgen's own annual report broadly describing the litigation. None of this shows that Roche received notice that would have given it an opportunity to intervene.

Indeed, any attempt by Roche to intervene during the pendency of the Chugai litigation would certainly have been rejected. Roche would not have been able to intervene in the Chugai cases as of right under Federal Rule of Civil Procedure 24(a) as it had no interest in the time in any property or transaction at issue in the Chugai case. Roche had no interest in the recombinant product Amgen accused of infringement in the Chugai cases. Nor would Roche have been granted permissive intervention under FRCP 24(b) because Roche in 1987 had no claim to assert against Amgen, nor did it have any defense at issue as it had not been sued itself by Amgen for infringement. *See* FRCP 24(b) (permissive intervention can be granted only "when an applicant's claim or defense and the main action have a question of law or fact in common"). General knowledge that a litigation is happening -- which is all Amgen can show -- cannot be enough; otherwise every patent litigation would be inundated with intervention motions by every conceivable current and potentially future competitor regarding the product covered by the patent. Certainly with respect to the Fritsch interference, an *inter partes* contest between two competing patent application holders, Roche had no opportunity to participate.

d. Amgen Fails To Show That Roche and the Chugai Litigants Had A Clear Identity of Interests At the Time of the Chugai Litigation

Amgen contends that the common interest prong of the virtual representation test is met simply because Amgen was a common competitor of Roche, Chugai and GI during the Chugai litigation. Amgen is wrong. Amgen relies on *Boston Scientific*, in which Judge Woodlock concluded that a nonparty and a party shared a common interest at the time of the first litigation because at issue was "the validity and enforceability of a patent held by a common competitor, which was potentially infringed by both companies." 983 F.Supp. at 258. Again, Amgen fails to recognize that during the time of the Chugai litigation (1987-1991), Roche neither potentially nor actually infringed any Amgen patent. Indeed, Amgen did not sue Roche until November 2005, more than 14 years after the Chugai litigation concluded. Moreover, the Chugai litigation concerned the '008 patent, which Amgen has not accused Roche of infringing even 14 years later and indeed cannot as the patent expired in 2004. Amgen fails to articulate any specific common interest between Roche and the Chugai parties as to the '008 patent ***at the time of the pendency of the Chugai litigation***. The short answer is that there was no common interest at that time, and therefore virtual representation should be rejected.

e. There Is No Other Basis For Privity Between Roche and the Chugai Litigants

i. Privity Cannot Be Based On A Parent-Subsidiary Relationship

Amgen tries to claim that Roche should be estopped from challenging the validity of the patents-in-suit merely because Roche acquired an interest in Chugai years after the prior litigation between Amgen and Chugai had ended. However, none of the cases cited by Amgen support the application of estoppel solely based upon a corporate relationship that did not exist at the time of the prior litigation. Furthermore, a relationship between Chugai and Roche that did

not exist at the time of the prior litigation is not relevant to a determination under the *Gonzalez* test of whether estoppel should apply.

Consistent with this logic, in all of Amgen's cases the corporate relationship between the party against whom collateral estoppel was applied and the party to the prior suit existed at the time of the prior suit.[6] In fact, *Nordhorn v. Ladish Co.*, 9 F.3d 1402, 1405 (9th Cir. 1993), cited by Amgen, flatly contradicts Amgen's assertion that the relationship between Roche and Chugai should give rise to estoppel in this case. In *Nordhorn*, the defendant Ladish Corporation argued that plaintiff's suit was barred by claim preclusion because the plaintiff had filed a previous action asserting the same claims against a company (HITCO) which at one time had been owned by the same corporate parent as Ladish. The Ninth Circuit, however, refused to apply claim preclusion, because the relationship between Ladish, HITCO and the parent corporation had dissolved before the litigation commenced:

> Although the interests of Ladish and HITCO were aligned in the 1980s when they were marketing their related products to airline manufacturers, by the time of the HITCO litigation there was no relationship whatsoever. Ladish had no participation in or control over the HITCO lawsuit, and there is no indication that HITCO had any interest in Ladish's affairs or well-being during or after the lawsuit against HITCO. Thus, it cannot be said that HITCO was Ladish's "virtual representative," or that fairness requires that Ladish not be sued at this time.

Id. at 1405-06.[7]

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[6] *See Mars, Inc. v. Nippon Conlux*, 58 F.3d 616 (plaintiff who obtained final judgment against wholly owned U.S. subsidiary precluded from subsequently bringining same claim against Japanese parent corporation); *G & T Terminal Packaging Co. v. Consolidated Rail Corp.*, 719 F. Supp. 153, 159 (SDNY 1989) (plaintiff who had previously filed separate suits against parent corporation and wholly owned subsidiary asserting the same causes of action was barred by res judicata from filing a new action against either of them) Another case cited by Amgen, *Tyus v. Schoemehl*, 93 F.3d 449 (8th Cir. 1996) does not even involve a corporate relationship. *See id.* at 445-46 (state representatives precluded from filing suit challenging voter redistricting plan because of prior suit brought by voters in these districts).

[7] Amgen's cases are further distinguishable because Chugai is not and has never been a subsidiary of any of the Roche Defendants. Rather, Roche Pharmholding B.V., which is not a party in this case, acquired slightly over 50% of the shares in Chugai. Chugai is an independent company based in Japan with its own board of directors. *See* http://www.chugai-pharm.co.jp/english/corporate/index.html

ii. Privity Cannot Be Based On Any Alleged Joint Venture

Amgen also claims that Roche should be estopped from asserting its invalidity defenses based upon a supposed "joint venture" agreement between GI and Boehringer Manheim ("Boehringer") to develop and commercialize EPO in Europe. (Amgen Br. at 17-19) Even though Boehringer was not a party to the GI/Chugai litigation, Amgen claims that as a result of this Agreement, Boehringer was bound by GI's actions related to the settlement of the litigation. Amgen further argues that Roche is now bound by GI's actions as a result of Roche's subsequent acquisition of Boehringer.

As a preliminary matter, the agreement Amgen relies upon was between GI and Boehringer, not GI and Roche. Furthermore, Roche did not acquire Boehringer until 1997, four years after the Amgen-GI litigation was settled, and Amgen fails to cite any evidence of a relationship between Roche and Boehringer before the date of the acquisition. As discussed, *supra*, there is no basis for applying collateral estoppel against Roche based solely upon its acquisition of a company that may have been involved in a prior litigation where the purchase was made years after the prior litigation ended.

Even assuming, *arguendo*, that Roche could be bound by the actions of Boehringer in connection with the Chugai litigation or the Fritsch interference, Amgen's argument would still be unavailing, as Amgen cannot show that Boehringer and GI ever entered into a joint venture agreement. To begin, Amgen asserts that the parties' agreement qualifies as a joint venture under Massachusetts law, notwithstanding that the terms of the Agreement state explicitly that the Agreement is to be governed and interpreted in accordance with Swiss law. (Ex. 8, Agreement Sec. 10.4, AM-ITC 00119917). Amgen fails even to address the question of whether the parties' agreement could constitute a "joint venture" relationship under Swiss law. In any

event, Amgen's claim would have no merit even if Massachusetts law did apply, because nothing in the terms of the Agreement suggests that the parties intended to enter into a joint venture relationship.[8] In fact, the terms of the GI-Boehringer agreement clearly state that the parties did *not* intend to enter into a joint venture, and further provide that neither party had the authority to obligate the other party without its consent. Specifically, the Agreement provides in Section 10.8:

> No Agency: Nothing herein shall be deemed to constitute either Party as the agent or representative of the other Party, or both Parties as joint ventures or partners for any purpose. GI shall be an independent contractor, not an employee or partner of [Boehrenger], and the manner in which GI renders its services shall be within GI's sole discretion. Neither party shall be responsible for the acts or omissions of the other Party, and neither Party will have authority to speak for, represent or obligate the other Party in any way without prior written authority from the other Party.

(Ex. 8, Sec. 10.8, AM-ITC 00119919) This unequivocal contractual language is the best evidence that the parties did not intend to enter into a joint venture agreement.[9]

Other sections of the Agreement further confirm that Boehringer and GI did not enter into a joint venture. Specifically, the Agreement does not provide that the parties will share in all profits and losses resulting from the venture.[10] Rather, under the Agreement, "[i]n return for certain rights under the patents and Know-how developed by GI, [Boehringer] will financially

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[8] *See Cardullo v. Landau*, 105 N.E.2d 843, 845 (Mass. 1952) ("As between the parties, as in the case of a partnership, the relationship of joint adventurers is a matter of intent and arises only when they intend to associate themselves as such."); *see also Itel Containers v. Atlantafrak*, 909 F.2d 698, 701-02 (2d Cir. 1990) (defendant not liable based on joint venture theory where plaintiff presented no evidence that defendant intended to enter into a joint venture relationship).

[9] *See Ringier America v. Land O'Lakes*, 106 F.3d 825, 829 (8th Cir. 1997) (holding that plaintiff could not rely upon existence of joint venture relationship because, *inter alia*, there was language in the contract in which the parties disclaimed their intent to enter into such a relationship, which was " . . . strong evidence that the parties did not intend that their cooperative undertaking create a partnership or joint venture.")

[10] *See Petricca v. Pioneer Develop. Corp.*, 40 F. Supp. 2d 49, 53 ("a right to share in the profit" and "an express or implied duty to share in the losses" are relevant factors under Massachusetts law in determining the existence of a joint venture relationship); *Itel Containers*, (no joint venture because, while plaintiff "plainly hoped to share in whatever profits" the business relationship produced, "there was no indication that it expected to share in the losses except as a lender to [the other party]").

support the research and development activities of GI and will pay GI the royalties provided for herein." (Ex. 8, Intro ¶2) Furthermore, the Agreement provides that each party retains all rights to patents and inventions conceived solely by its own employees. (*Id.*, Article 5, AM-ITC 00119905. The parties only share title and interest in patents developed jointly by both parties. (*Id.*, Article 5, AM-ITC 00119905). Thus, the terms of the Agreement neither support the existence of a joint venture between Boehringer and GI nor otherwise support Amgen's claim that Boehringer can be bound by the actions taken by GI in the course of litigating and settling the Amgen-GI dispute or by the result of the Fritsch interference.

Significantly, the question of whether Boehringer was a joint venturer of GI is not one that can be resolved as a matter of law. *See 46 Am. Jur. 2d Joint Ventures § 73*("The existence or nonexistence of a joint venture is a question of fact for the trier of fact"). Thus the Court cannot preclude Roche from arguing non-obviousness to the jury based upon Amgen's allegations of a GI-Boeringer joint venture.

2. <u>Collateral Estoppel Cannot Apply Because the Asserted Issues are Different</u>

All of the actions upon which Amgen relies for collateral estoppel and preclusion deal with the expired '008 patent, not at issue in this litigation. In asserting the Chugai litigation and Fritsch interference, Amgen glosses over the clear lack of identity of the very subject matter upon which it claims preclusion, concluding without explanation: "the fact that Roche does not state that it is expressly challenging the validity of Claim 2 of the '008 Patent directed to the DNA sequence is irrelevant." Independent claim 2 of the '008 Patent is directed exclusively to a DNA sequence, specifically reading:

> A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin.

Amgen has not asserted any DNA claims in this case. Rather, Amgen's product claims in the '422 patent and '933 patent are directed to pharmaceutical compositions or glycoproteins. As an initial matter, the obviousness of these claims and the claims of the '008 patent are not coextensive. Further, Amgen has long contended in this litigation in response to Roche's double patenting arguments that the subject matter claimed in the '008 patent is different from the subject matter of the asserted claims in this case.

Amgen asserts that Roche is precluded from offering evidence that the cloning of the EPO DNA sequence was obvious in 1983. This argument is unfounded. Identity of legal and factual issues is required for preclusion; there are numerous differences between the obviousness issues in this case and in the Chugai litigation and the Fritsch interference. Roche's § 103 contentions in this case with respect to the use of an EPO DNA sequence in the subject matter of Amgen's claims are not limited to the use of cDNA probes or the use of a genomic library. For example, Roche also contends that the use of synthetic DNA techniques as referenced in the patents-in-suit, including the use of microsequencing and synthesizer technology available as of 1983 renders Amgen's claimed inventions obvious. This particular theory was not advanced in either the Chugai litigation or the Fritsch interference. Roche further argues that the existence of a finite number of predictable strategies known in the art and the strong motivation in the art to implement any one of them, taken together renders the cloning of the EPO gene obvious.

Moreover, the inventions at issue in the '008 patent were directed to DNA sequences encoding a 166 amino acid protein, based on what was known by the written description at the time of the filing. *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1308 (Fed. Cir. 2006). Here, Roche may show that a DNA sequence encoding a 165 amino acid protein can invalidate the asserted claims of the patents-in-suit.

Another fundamental difference between the § 103 analysis in this case and the Chugai litigation and the Fritsch interference. A recent change in law has altered the legal framework for determining obviousness. In *KSR Int'l Co v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007), the Supreme Court held that

> [w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103. *KSR*, 127 S.Ct. at 1742 (2007).

As Amgen notes, during the Fritsch interference, the Board of Patent Appeals and Interferences stated that it was bound by the District Court and the Federal Circuit's conclusion that "a person of ordinary skill in the field of gene cloning, armed with knowledge available in the prior art, would have found it 'obvious to try' to isolate the EPO gene using the probing technique employed by Lin". (Amgen Br. at 7). Under prevailing law at that time, "obvious to try" was a disfavored basis for obviousness. Now, as *KSR* dictates, "obvious to try" may show obviousness under § 103 where, as here, "there are a finite number of identified, predictable solutions." The Supreme Court also held in *KSR* that the formulaic teaching, suggestion and motivation analysis upon which the Federal Circuit had relied was a rigid rule unduly limiting the obviousness inquiry. The court held that "in determining whether the subject matter of a patent is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim." *Id.* at 1741-42.

Courts have since adjusted their obviousness analysis, taking into account the direction of *KSR*.[11] Accordingly, even if the Court found that issues concerning the '008 patent and the

[11] *See, e.g., Omegaflex Inc. v. Parker-Hannifin Corp.*, 2007 WL 1733228 (Fed. Cir. 2007) (unreported) (holding that the district court erred in finding validity and in light of *KSR*, there remained material issues as to obviousness);

patents-in-suit could be conflated, the significant change in the legal analysis for obviousness dictates that collateral estoppel could not apply. *See Bingamen v. Dep't of Treasury*, 127 F.3d 1431, 1438 (Fed. Cir. 1997) (holding where there was a change in the "legal atmosphere" with respect to the issue at hand, "the bar of collateral estoppel should not be applied").

There is an additional difference in the legal theory Roche advances with respect to the obviousness of the cloning of the EPO DNA sequence from the contentions in the Chugai litigation and the Fritsch interference. As Amgen's citations to Roche's interrogatory responses and expert report make clear, Roche also argues that the EPO cDNA clone would have been obvious to one of skill in the art in possession of a sufficient amount of purified human EPO such as the EPO protein that Dr. Goldwasser provided only to Amgen. (Amgen Br. at 10). Thus, Roche also contends that Amgen's asserted claims are invalid pursuant to §102(f) in combination with § 103 because it derived enough of the subject matter of the claims from Dr. Goldwasser to render the rest obvious. This invalidity theory was not put forward in either the Chugai litigation or the Fritsch interference.

Amgen responds to this argument, cursorily claiming that "such an argument necessarily disturbs the prior adjudication" of non-obviousness. Amgen adduces no evidence that the tryptic fragment was publicly available prior to Lin's invention. Even it the fragments were published (they were not), this still would be of no moment. A prior finding relating to a *public* disclosure can have no bearing on the import of Dr. Goldwasser's secret disclosure of separate subject matter to Amgen only -- the full protein sequence -- which also underlies Roche's 102(f) argument.

Andersen Corp. v. Pella Corp., 2007 WL 2372396 (D. Minn. 2007) (finding summary judgment of invalidity for obviousness in light of *KSR*).

Amgen further misunderstands the requirements for estoppel; a prior finding must be necessary to the judgment. Both the factual issue regarding the particular disclosure by Dr. Goldwasser was different in the prior adjudications and the legal issue was different as § 102(f) was not even asserted in the previous cases. Indeed, the combination of § 102(f) derivation and § 103 obviousness was not even explicitly recognized as a basis for invalidity until the Federal Circuit's decision in the *Oddzon* case in 1997, well after the adjudication of the Chugai litigation and the Fritsch interference.[12] Clearly, Amgen's cited finding regarding disclosure of the Goldwasser tryptic fragment could not be necessary to a judgment where there was no judgment regarding § 102(f).

Finally and again, one of the cases upon which Amgen relies heavily notes that successor-in-interest privity exists only where the product at issue is the same in the prior and current matters. *Boston Scientific Corp. v. Schneider (Europe) AG*, 983 F. Supp. 245, 257 (D. Mass. 1997) ("[T]his case involved a different product, thus BSC may not be estopped as a 'successor-in-interest'").[13] Courts have thus recognized that for a prior decision to preclude a later decision, that prior decision must possess identity of parties, identity of legal theory, identity of applicable law, and identity of relevant subject matter. As the subject matter adjudicated in the Chugai litigation and in the Fritsch interference is indisputably different than

[12] *Oddzon Products, Inc. v. Just Toys, Inc.*, 122 F.3d 1396 (Fed. Cir. 1997) ("The prior art status under § 103 of subject matter derived by an applicant for patent within the meaning of § 102(f) has never expressly been decided by this court. We now take the opportunity to settle the persistent question whether § 102(f) is a prior art provision for purposes of § 103. As will be discussed, although there is a basis to suggest that § 102(f) should not be considered as a prior art provision, we hold that a fair reading of § 103, as amended in 1984, leads to the conclusion that § 102(f) is a prior art provision for purposes of § 103").

[13] Another of Amgen's cited cases, *Pall Corp. v. Fisher Scientific Co.*, 962 F.Supp. 210, 213 (D. Mass. 1997), found no collateral estoppel because the prior validity holding only pertained to two products and not an additional product asserted in the instant matter. The court stated: "To allow Pall to piggy-back on that finding of privity [with respect to the earlier-adjudicated products] so as to bar Fisher from litigating the validity of the Pall Patent with respect to any product would, in the view of this Court, unduly infringe upon Fisher's due process rights." *Id.*

the subject matter adjudicated in this case, Amgen cannot establish the requisite identity of issues between the asserted actions and the current matter.[14]

B. No Contractual Estoppel

Amgen's alternative argument that the 1993 Settlement Agreement entered into by Amgen and GI contractually estopps Roche from challenging the validity of the '008 Patent also fails for numerous reasons. First and foremost, nothing in the 1993 Agreement or the related consent judgment entered by this Court evidences an intent by the parties to waive future challenges to validity. The Federal Circuit has held that "a party does not waive its right to challenge the validity of a patent as to future accused products absent a clear intent do so." *Ecolab, Inc. v. Paraclipse, Inc.*, 285 F.3d 1362, 1376 (Fed. Cir. 2002). Accordingly, "provisions in a consent judgment asserted to preclude litigation of the issue of validity in connection with a new claim must be construed narrowly." *Foster v. Hallco Mfg. Co.*, 947 F.2d 469, 481 (Fed.Cir.1991).

In fact, the 1993 Settlement Agreement clearly indicates that the parties did *not* intend to waive any right to challenge the validity of the '008 Patent with respect to future claims. The Settlement Agreement expressly states that the parties "agree to settle their respective claims against one another . . . without admitting to the validity of any assertion, contention or defense made in said legal proceedings." (Ex. 1, Agreement at Sec. I.(4), AM-ITC 00799256-57). Furthermore, while the Agreement contains a standard mutual release clause (Agreement Sec. II (3)(d)), the Agreement specifically provides that:

[14] Amgen claims that arguments underpinning a validity challenge can be given collateral estoppel effect. This is incorrect. *See Crossroads Sys. (Texas), Inc. v. Dot Hill Sys. Corp.*, 2006 WL 1544621, *5 (W.D. Tex. May 31, 2006) (unreported) ("[T]he overwhelming weight of authority suggests that the 'issue' that is to be given issue-preclusive effect to a judgment in the patent context is the ultimate determination on patent validity itself, not the sub-issues or the individual pieces of evidence and arguments that may have been necessary to support the validity determination."); *Dana v. E.S. Originals, Inc.*, (Fed. Cir. 2003) (characterizing both validity and infringement as single issues in the context of a collateral estoppel inquiry).

> Entry into and consummation of the SETTLEMENT AGREEMENT shall not be construed as an admission of liability or culpability on the part of any party hereto, nor shall the mutual releases contained above in Paragraph II.3.d. be construed to support the validity of any claim or contention made by or threatened against either party hereto.

(Ex. 1, Agreement Sec. 2(10), AM-ITC 00799263).

Amgen relies upon the language in this Court's Consent Judgment, incorporated into the Settlement Agreement as Exhibit A, which states that "[t]he '008 Patent was duly and legally issued, is valid and enforceable in law and equity." (Am. Ex. 2, ¶2, AM44 2024651). However, the Federal Circuit has held that such language is insufficient to bar a party from challenging the validity of a patent in a future action involving a different product. *See Ecolab,* 285 F.3d at 1377 (statement in consent judgment that "the [patent-in suit] is a valid patent" was not sufficient to preclude future challenge to validity); *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").[15]

Furthermore, the only two signatories to the 1993 Settlement Agreement were Amgen and GI. Roche was not a signatory to the Agreement[16] and, as discussed, *supra*, there is no basis to hold Roche responsible for GI's decision to settle its dispute with Amgen. Thus, even if the Agreement could preclude GI from challenging the '008 Patent, there would be such no preclusive effect upon Roche.[17]

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[15] By contrast, in *Flex Foot v. CRP, Inc.*, 238 F.3d 1364 (Fed. Cir. 2001), the only case Amgen cites in support of contractual estoppel, the defendant was estopped from asserting a future validity challenge based upon a prior Settlement Agreement in which the defendant "agree[d] not to challenge or cause to be challenged, directly or indirectly, the validity or enforceability of [the patents] in any court or other tribunal, including the United States Patent and Trademark Office." GI made no such concession in the 1993 Agreement.

[16] Chugai likewise was not a party to the 1993 Settlement Agreement. In any event, as discussed, *supra*, Chugai's involvement in the prior litigation and settlement is irrelevant, as Roche cannot be estopped from challenging the validity of the '008 based upon Chugai's actions.

[17] In addition, for the reasons discussed, *supra*, collateral estoppel cannot apply because the issues in this case are entirely different from those in the Chugai litigation.

III. CONCLUSION

Based on the foregoing, Roche requests that the Court deny Amgen's 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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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.

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