

EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

DEFENDANTS’ [PROPOSED] REPLY IN SUPPORT OF MOTION *IN LIMINE* TO PRECLUDE PLAINTIFF AMGEN INC. FROM ASSERTING OUTCOMES OF PRIOR LITIGATION CONCERNING THE VALIDITY AND INFRINGEMENT OF CERTAIN CLAIMS OF THE PATENTS-IN-SUIT AS EVIDENCE AND ATTORNEY ARGUMENT

I. INTRODUCTION

Notwithstanding Amgen’s arguments, the Court should grant Roche’s motion *in limine* to preclude Amgen from presenting as evidence and attorney argument, outcomes of the prior litigations concerning the validity and infringement of certain claims of the patents-in-suit. Amgen’s opposition is telling because it confirms Roche’s propensity for exposing extraneous, irrelevant, and highly prejudicial court proceedings in this case. Amgen proposed to introduce no less than five different litigations involving numerous patent claims not at issue in this case and parties absent from this case, including TKT, Hoechst, Kirin-Amgen, and Boehringer Mannheim. In this already complex patent case, the jury should not be burdened with these prior findings which have no probative value. Amgen argues that it should be allowed to present these prior findings so that it can highlight alleged Roche admissions and provide context for evidence

Roche may present. These arguments are ill-masked attempts to improperly use highly prejudicial legal conclusions and factual findings underlying prior litigations to which Roche was never a party.

Amgen provides no support for binding Roche on any issue considered in the prior litigation. Aside from Roche never being a party, all of these prior litigations involved different patents, different products, different law, and unrelated settlement agreements not at issue in this case. Furthermore, even if Amgen has a need to provide “context” for evidence Roche may choose to put on concerning findings and holdings from prior litigation involving Amgen but not Roche (which Amgen has not shown), this does not give Amgen carte blanche to present any evidence it chooses from prior litigation. The outcome of prior litigation only has bearing on legal issues but not fact issues for the jury and its use represents a substantial risk of prejudice to Roche who was not a party to any of these litigations. Therefore, Roche requests that Amgen be precluded from presenting such evidence.

II. ARGUMENT

Amgen gives two explanations for its need to present outcomes of prior litigation as evidence, both without merit. Amgen first suggests that it must be allowed to present as evidence and argument prior litigation outcomes because it has a need to “cite to highly relevant Roche admissions.”¹ However, this is nonsense. Roche was never a party to any of the prior litigations involving the patents-in-suit. Instead, Amgen makes strained arguments to suggest that foreign proceedings, involving different entities, different patents, and settlement agreements somehow bind Roche with respect to issues in this case.

¹ Amgen’s Opposition (“Amgen Opp.”) at p. 1.

First, as to the Canadian and Dutch litigations, it is not uncontested that these involved different products, different patents, and different legal standards. In fact, those decisions involved Kirin-Amgen, the owner of Canadian and Dutch patents at issue. Kirin-Amgen is not even a party to this case and assigned away its rights to the patents-in-suit to Amgen. Under these situations, there can be no issue preclusion against Roche. Issue preclusion would only apply if the matters raised in this suit are *identical in all respects* with those raised in the Canadian and Dutch litigations.² They are not. The Canadian litigation concerned primarily molecular weight differences between recombinant EPO and human urinary EPO, different subject matter than that of the asserted claims of the patents-in-suit. In fact, the patent claim BM was found to infringe, is identical with one of Amgen's European patents invalidated during the UK litigation as described below. Both the Canadian and Dutch litigations concerned different products, Recormon® and Neorecormon® respectively. By definition, separate suits involving different patents and different products are not identical.³

Second, as to the UK litigation, which also involved Kirin-Amgen, Amgen conspicuously fails to inform the Court that the Kirin-Amgen patent claims at issue were actually found to be invalid and non-infringed by Roche and TKT.⁴ Under Amgen's faulty reasoning, that same holding should also apply here to find that CERA does not infringe and that the asserted claims of the patents-in-suit are invalid. As with the Canadian and Dutch litigations, the UK litigation concerned three different European patents, not the patents-in-suit.

² *Faigin v. Kelly*, 184 F.3d 67, 78 (1st Cir. 1999).

³ *Diomed, Inc. v. Total Vein Solutions, LLC*, Civ. Action No. 04CV10686-NMG, 2007 WL 2280451 at *1, *2 (D. Mass. July 13, 2007) (holding that although the same patent was at issue, the contested acts of infringement necessarily differed in part because "the other defendants are different companies, wholly independent of [defendant], who produce different products....").

⁴ *Kirin-Amgen v. Hoechst Marion Roussel Ltd.*, 2004 WL 2330204(HL), [2005], [2004] UKHL 46.

Third, Amgen tries to bootstrap Roche's current interest in Boehringer Mannheim (BM) as a means of binding Roche under an improper application of successor liability. However, Amgen's position is unavailing because the BM decision, which also involved Kirin-Amgen, issued before Roche Diagnostics took a controlling interest in BM. As a result and as acknowledged in the law, Roche could not have contemplated that it would be bound by that decision, let alone on patents and products that are different from those being litigated here.⁵ Therefore, the actions and intentions of BM concerning a different product cannot be imputed to Roche, an entirely different defendant, to establish same identity for purposes of issue preclusion.⁶

Fourth, Amgen is attempting to taint the jury trial by introducing evidence of a 2001 Settlement Agreement involving Australian litigation between Kirin-Amgen and Roche. Roche has already briefed this matter in its own motion *in limine* (Docket No. 815), and for all the reasons set forth there, Amgen's arguments are again disingenuous, especially in view of (1) FRE 408's prohibition against the use settlement agreement as evidence of liability; (2) the fact that the agreement involved different entities (Kirin-Amgen, not Amgen) and different patent rights; (3) the fact that the settlement agreement was specifically limited to litigation in Australia; and (4) undue prejudice against Roche and jury confusion over foreign litigation involving different entities and patents.

⁵ Successor-in-interest privity only exists where the product at issue is the same in the prior and current matters. See *Int'l Nutrition Co. v. Horphag Research, Ltd.*, 220 F.3d 1325, 1329 (Fed. Cir. 2000) (“[W]hen one party is a successor in interest to another with respect to particular property, the parties are in privity only with respect to an adjudication of rights in the property that was transferred; they are not in privity for other purposes, such as an adjudication of rights in other property that was never transferred between the two.”).

⁶ *Diomed, Inc. v. Total Vein Solutions, LLC*, Civ. Action No. 04CV10686-NMG, 2007 WL 2280451 at *1, *2 (D. Mass. July 13, 2007).

In each foreign litigation described above, Amgen ignores the strong policy against precluding issues determined according to different legal standards, especially when applied to foreign-issued patents. It has long been recognized that when there is a prior adjudication “by a foreign nation’s court applying its patent law to its patents, the barriers to reliance on the foreign judgment for collateral estoppel purposes becomes almost insurmountable.”⁷ Different law means different issues of underlying fact, and issue preclusion is therefore not appropriate.

Amgen next attempts to justify the use of prior findings and holdings by arguing that it needs to “give proper context to the many statements about prior litigations Roche intends to make.”⁸ Far in excess of providing “context”, Amgen suggests an all or nothing approach that seeks to use the legal conclusions and factual findings underlying the prior litigations to help prove its case on the law and the facts against Roche. This is clear from Amgen’s blanket statement that “if Roche intends to introduce and refer to evidence of prior litigations at trial, Amgen should be able to do so, including to refer to the outcomes of the prior litigations.”⁹ But such a “tit-for-tat” approach is not sanctioned by the law. For example, it is a basic principle of law that findings of validity have no estoppel value against subsequent challenges to the patent by litigants who were not parties to the prior lawsuits.¹⁰ However, Amgen (not Roche) was a party to those prior lawsuits, so therefore, judicial findings against Amgen do act as issue

⁷ *Heineken Tech. Serv., B.V. v. Darby*, 103 F. Supp. 2d 476, 480 (D. Mass. 2000) (emphasis added) (quoting *Cuno Inc. v. Pall Corp.*, 729 F. Supp. 234, 238 (E.D.N.Y. 1989)).

⁸ Amgen Opp. at p. 1.

⁹ Amgen Opp. at p. 4.

¹⁰ *In re Trans Texas Holdings Corp.*, Nos. 2006-1599, 2006-1600, 2007 WL 2377009 at *1, *5 (Fed. Cir. Aug. 22, 2007) (“We have never applied issue preclusion *against* a non-party to the first action.”); *Wang Labs, Inc. v. Oki Elec. Indus. Co.*, 15 F. Supp. 2d 166, 175 (D. Mass. 1998).

preclusion.¹¹ In short, Amgen has had full and fair opportunity to be heard on those issues, but Roche has not.

In an effort to provide support for its argument, Amgen also claims that Roche intends to “rely heavily” on findings and holdings in the TKT case and some foreign litigation.¹² This argument is baseless. First off, the list Roche provided in the joint pre-trial memorandum represents not so much evidence Roche aims to rely on heavily, as it is a clear statement of findings and holdings to which Amgen is bound as a matter of law. Amgen was a party to the suits listed and the issues are the same as in this case. Therefore, Amgen is precluded from relitigating these issues, *whether or not* Roche presents any evidence of these findings at all. Furthermore, as Roche rightly stated in the joint pre-trial memorandum, Roche is not similarly bound by these findings and holdings because it was not a party.¹³ Importantly, with respect to findings of infringement of Roche products, the issues in those suits were different from this case as the accused product was not CERA.

Furthermore, even if Roche does present such evidence of prior litigations at trial, Amgen’s right to present contextual evidence is not unbounded. The Court may fairly decide what evidence of prior litigations if any, Amgen should be able to present to provide context.¹⁴ This makes sense given that generally, a prior ruling is entitled to *legal* deference, but only that. The idea that Roche should be exposed to a substantial risk of prejudice from jury confusion as to prior litigation outcomes to which it was not a party, just because Roche may present evidence concerning those litigations because Amgen *was a party*, would thwart due process.

¹¹ *Id.*

¹² Amgen Opp. at p. 5

¹³ Joint Pre-Trial Memorandum (Docket No. 807) at p. 40.

¹⁴ *Mendenhall v. Cedarapids, Inc.*, 5 F.3d 1557, 1573 (Fed. Cir. 1993).

Contrary to Amgen's assertion, the rights of the jury are not threatened by excluding Amgen from presenting such evidence. As is well-known, the charge of the jury concerns fact-finding. A prior finding of validity is not fact evidence for the jury.¹⁵ Amgen argues that prior outcomes may be "informative" and cites the *Mendenhall* case for this proposition.¹⁶ But Amgen misunderstands the law as prior opinions are information primarily for the judge in formulating a *legal* conclusion.¹⁷ The jury, which will undoubtedly look to the judge to try and discern his opinion, should not be guided to its factual determinations by legal opinions.

III. CONCLUSION

For the foregoing reasons, Roche respectfully requests that this Court grant Roche's motion to preclude Amgen from presenting evidence or argument of prior litigation outcomes concerning the validity and infringement of the patents-in-suit. As this evidence is of little to no probative value and presents substantial risk of prejudice to Roche, this Court should prevent Amgen from using legal conclusions and factual findings underlying the prior litigations to help prove its case on the law and the facts against Roche.

¹⁵ *Id.* at 1569-70.

¹⁶ Amgen Opp. at p. 6.

¹⁷ *Mendenhall*, 5 F.3d at 1569-70 ("A prior decision that a patent has previously survived an attack on its validity serves only to inform the district court, and the [Federal Circuit], that caution must be taken in reaching a contrary *legal* conclusion.") (emphasis added).

Dated: August 30, 2007
Boston, Massachusetts

Respectfully submitted,

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