UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	Civil Action No.: 05 Civ. 12237 WGY
v.	)	
	)	
F. HOFFMANN-LAROCHE LTD., ROCHE DIAGNOSTICS GMBH, and HOFFMANN LAROCHE INC.,	)	
	)	
Defendants.	)	

AMGEN INC.'S OPPOSITION TO DEFENDANTS' MOTION *IN LIMINE* TO PRECLUDE PLAINTIFF FROM OFFERING INTO EVIDENCE OR REFERENCING TO THE JURY THE JUNE 2001 SETTLEMENT AGREEMENT

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I. INTRODUCTION

Defendants F. Hoffmann-La Roche Ltd., Roche Diagnostics GmbH, and Hoffman-La Roche Inc.'s (collectively, "Roche") motion *in limine* to preclude Amgen from relying upon or referring to a 2001 settlement agreement (the "Agreement") between, *inter alia,* F. Hoffmann-La Roche, Ltd. and Kirin Amgen, Inc. ("Kirin Amgen") at the upcoming trial rests on a flawed and overly expansive reading of Federal Rule of Evidence 408. *See* Exhibit A to Roche's Mem.

Amgen seeks to admit the Agreement as part of establishing its defense of equitable estoppel to Roche's claims that Dr. Lin's patents are invalid. In the Agreement, Roche plainly acknowledged the validity of Dr. Lin's patents – not some different patents as Roche's motion suggests, but any patents that contain the specification common with the identified European patent application, which includes the patents-in-suit with the exact same disclosures and very similar types of claims. The fact that Roche acknowledged the validity of the patents is highly relevant to its validity attacks in this action. Courts around the country routinely admit evidence relevant to admissions or an estoppel arising out of a settlement agreement over a Rule 408 objection. *See, e.g., Carolina Indus. Products, Inc. v. Learjet, Inc*, 168 F. Supp. 2d 1225, 1229-30 (D. Kan. 2001) ("Courts have held that statements made during settlement negotiations or in the compromise of a claim are admissible in a suit asserting a claim for breach of the settlement, fraudulent inducement, or equitable estoppel.")

This is particularly true under Rule 408 where, as here, the Agreement and its terms are relevant to a claim that is different than was litigated and settled in the Agreement. *Id.* The Agreement and option that Roche exercised settled Amgen's infringement claim in Australia. By contrast, here, the issue is whether Roche's affirmative defense of invalidity of the U.S. Lin Patents is estopped by Roche's global acknowledgment of the validity of Dr. Lin's Patents in that Agreement. As such, no Rule 408 issue is raised. At the very least, the jury should hear that in a different setting Roche took a different view of the validity of Dr. Lin's patents.

Recognizing the infirmity in its Rule 408 argument, Roche attempts to argue that the acknowledgment of validity on the Lin Kirin-Amgen Patents does not reach Dr. Lin's U.S. Patents or that Amgen could not have relied on the Agreement. However, the Agreement expressly extends to all patents in the world that share a common specification with Lin's European Application, which includes the Lin U.S. patents-in-suit. The Agreement lacks any specific restriction of the validity acknowledgment to patents in Australia. Amgen is a party to the Agreement under the definition of "Affiliates," as evidenced by Roche sending notice to exercise the option to settle the Australian litigation to Amgen, Inc. And Amgen has stated that it relied on the representations when it dismissed the Australian litigation, to its detriment. Amgen agreed to the settlement and the Australian option because of the acknowledgement of validity. After years of attempting to invalidate Dr. Lin's patents, Roche finally gave up its challenges.

Finally, Amgen's reliance or reference to the Agreement will not unfairly prejudice Roche or mislead the jury as the acknowledgment relates to invalidity. Amgen requests that the motion in limine be denied.

II. ARGUMENT

A. COURTS ROUTINELY ADMIT INTO EVIDENCE SETTLEMENT AGREEMENTS WHEN RELEVANT TO THE ISSUE OF EQUITABLE ESTOPPEL

Although Rule 408 of the Federal Rules of Evidence provides that evidence of compromise and offers of compromise are not admissible "to prove liability for, invalidity of, or amount of a claim," it does ***not*** require exclusion when the evidence is offered for another purpose than proving the liability of the original claim that was settled. Fed. R. Evid. 408; *see Towerridge, Inc. v. T.A.O., Inc.*, 111 F.3d 758, 770 (10th Cir. 1997) (FRE 408 "does not require the exclusion of evidence regarding the settlement of a claim different from the one litigated.")

It is well settled that Rule 408 does not exclude settlement statements or the agreement themselves "when such statements are being offered to prove estoppel." *Savoy IBP v. Nucentrix*, 333 B.R. 114 (N.D. Tex. 2005). Numerous courts around the country are in agreement that

statements arising in the settlement context giving rise to breach or equitable estoppel claims are admissible. *See, e.g., Starter Corp. v. Converse*, 170 F.3d 286, 292 (2nd Cir. 1999); *Bankcard America v. Universal Bancard Systems,* 203 F.3d 477, 484 (7th Cir. 2000); *Carolina Indus. Products, Inc. v. Learjet, Inc,* 168 F. Supp. 2d at 1229-30 ("Courts have held that statements made during settlement negotiations or in the compromise of a claim are admissible in a suit asserting a claim for breach of the settlement, fraudulent inducement, or equitable estoppel."); *see also*, Wright & Graham, Federal Practice and Procedure: Evidence § 5314 ("Another category of permissible uses [(outside FRE 408)] involves cases in which the compromise activities result in a waiver of or an estoppel to assert some procedural or substantive right.")

Here, the equitable estoppel goes to a different claim than that litigated in the 2001 Agreement, and rests squarely on the equitable notion that a party who makes representations in a settlement agreement that are reasonably relied upon by the beneficiary of the representations is estopped from asserting to the contrary elsewhere. The provisions at issue in the 2001 Agreement arise out of the grant of an option from Kirin-Amgen to Roche to dismiss with prejudice the pending litigation in Australia if Roche acknowledged the "validity of the K-A Patents." *See* Agreement § 2.11(ii). The Agreement defined the "K-A Patents" as any patent that shares the common specification with EP 0148605, which is the European counterpart patent application to the patent application that gave rise to Dr. Lin's U.S. Patents. *See* Agreement § 1.2. Roche exercised the option within the allotted time and Amgen in reliance thereon dismissed with prejudice the existing Australian litigation. *See* Agreement § 2.11. (S*ee* Declaration of William G. Gaede, III, in Support of Amgen Inc.'s Opposition to Defendants' Motion *In Limine* to Preclude Plaintiff From Offering Into Evidence or Referencing to the Jury the June 2001 Settlement Agreement ("Gaede Decl."), Ex. 1.) Now, in this action in the United States involving a different infringement claim from the Australian one based on the U.S. Lin patents, Roche seeks to litigate the validity of the U.S. Lin patents despite having agreed that the Lin patents are valid. The claims differ, and no Rule 408 issue is raised.

Moreover, the estoppel serves to advance Amgen's showing of the secondary factor of non-obviousness, and thus validity, of the patents-in-suit. "Evidence of secondary considerations may often be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983) (citations omitted). Roche's acknowledgement of validity builds on earlier acknowledgements by Genetics Institute and Chugai, which are Roche business partners, and further support the nonobviousness of Dr. Lin's inventions. *See* Amgen's Motion *in Limine* No. 17. [Docket No. 876].

Roche cites two cases to support its position, but neither addressed equitable estoppel. Roche Memo at 4. In *Pioneer Hi-Bred*, the court granted Pioneer's motion to exclude settlement agreements with other defendants because the evidence could not properly be considered as evidence of a reasonable royalty. *Pioneer Hi-Bred Int'l, Inc. v. Ottawa Plant Food, Inc.*, 219 F.R.D. 135, 144-145 (N.D. Iowa 2003). Likewise, in *PharmaStem Therapeutics*, the court excluded the use of license agreements to establish a reasonable royalty. *PharmaStem Therapeutics, Inc. v. Viacell Inc.*, 2003 WL 22387038, at *3 (D. Del. 2003). This is not the case here, where Amgen seeks to use the Agreement as evidence of an equitable estoppel to confirm the validity of its U.S. Lin patents. Roche's cited cases do not support exclusion of the Agreement for the equitable estoppel issue that Amgen raises.

In sum, Roche's argument is fundamentally flawed because it effectively stands for the proposition that a breach or equitable estoppel claim arising from settlement conduct is *per se* inadmissible under Rule 408. This inequitable and self-serving position is squarely belied by the foregoing law, which establishes that Rule 408 does not reach the distinct claim of equitable estoppel arising out of settlement agreements.

B. THE 2001 SETTLEMENT AGREEMENT IS RELEVANT TO THE QUESTION OF VALIDITY OF THE PATENTS-IN-SUIT

Roche's factual arguments as to the irrelevance of the 2001 Agreement do not withstand scrutiny. Throughout the 1990's, Amgen and Roche's predecessors-in-interest to its

recombinant human erythropoietin products were engaged in several disputes before the United States Patent and Trademark Office, the Federal Courts, as well as multiple jurisdictions abroad. *See Fritsch v. Lin*, 21 U.S.P.Q. 2d 1731 (1991); *Fritsch v. Lin*, 21 U.S.P.Q. 2d 1737 (1991); *Fritsch v. Lin*, 21 U.S.P.Q. 2d 1739 (1991); *Fritsch v. Lin*, 14 U.S.P.Q. 2d 1795 (1989); *see also Amgen Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200 (Fed. Cir. 1991). They settled in 2001 the actions abroad, and granted Roche immunity from all past and then-ongoing actions for patent infringement under a defined set of patents, the K-A Patents, related to a defined set of products in all countries except the United States, Canada, Australia, China, and Japan. Although the issue of infringement of the U.S. patents by a pegylated EPO product was expressly exempted from settlement, the issue of the validity of Amgen's patents, including its U.S. patents, was not. Amgen was willing to litigate the infringement of its patents by any Roche product in the U.S., but with the exercise of the Australian option, the validity challenges brought for more than a decade in every major patent country around the world came to an end.

Roche contends that its acknowledgment of validity was limited to just the K-A Patents in Australia. However, the Agreement contains no such express limitation. The term "K-A Patents" is defined in Article I of the agreement as meaning "EP 0148605 and its counterpart patents including, but not limited to, ***any patent that has the same disclosure***, and any extensions or the like thereof." Agreement § 1.2 (emphasis added). Roche does not dispute that the disclosures of EP 0148605 and the Lin patents-at-issue are identical, and thus the Agreement by its express terms reaches the validity of the U.S. Lin Patents. If the parties had intended a different and narrow meaning restricted to Australia, they could have expressly so stated it. Instead, they invoked the Agreement's broader K-A Patents definition. Roche should not now be permitted to re-define the meaning of the "K-A Patents" because it has become problematic for Roche's patent invalidity defense.

Roche's argues that Amgen was not a party to the Agreement and thus the Agreement does not reach the Lin U.S. Patents assigned to Amgen. This argument lacks merit. First, the Agreement is binding not only on each party, but also on each party's "Affiliates." Section 1.1

defines "Affiliates" as "any … corporation … which … controls, is controlled by, or is under common control with . . . ROCHE, . . . AMGEN or KIRIN as the case may be . . . ."). *See* Agreement § 1.1. Second, and tellingly, Roche's own conduct is contrary to its rhetoric: It exercised the option to settle the Australian suit by sending notice directly to "Amgen Inc." "Attn: Mr. Stuart L. Watt," not to Kirin-Amgen. (Gaede Decl., Ex. 1.) Roche's conduct shows that it full well understood that Amgen was a party. Third, and most importantly, Roche's argument that Kirin-Amgen did not own the patents in question because they had been assigned to Amgen misreads the Agreement. The definition of "K-A Patents" does not define the patents at issue by specific ownership of Kirin-Amgen; rather, the definition is broader and extends to all patents that share the common specification. There is no reason to exclude Amgen from the acknowledgment of validity where the Agreement's "Affiliate" language specifically identifies Amgen and Roche exercised the option by sending notice to Amgen. Roche is effectively attempting to enjoy the fruits of the Agreement from Amgen but not bear its burdens.

Roche argues that Amgen could not have reasonably relied on Roche's representations or that Amgen was harmed. That is not true. Amgen stated in its July interrogatory response that it relied on the Agreement and caused certain proceedings to be withdrawn and new ones not initiated. (*See* Gaede Decl., Ex. 2.) That is evidence of reasonable reliance, and the harm was the withdrawal of the Australian action and the other representations in the Agreement. The jury will weigh that evidence against Roche's arguments that Amgen could not have reasonably relied or delayed in acting.

Finally, Roche is correct that the estoppel does go to validity and even to the secondary factors of nonobviousness. Use of such evidence for these purposes under equitable estoppel is entirely proper. *See In re Mahurakar Double Lumen Hemodialysis Catheter Litig.*, 831 F. Supp. 1354, 1378 (N.D. Ill. 1993); *Amsted Indus., Inc. v. National Castings, Inc.*, No. 88 C 0924, 1990 U.S. Dist. LEXIS 8553, at *53 (N.D. Ill. July 11, 1990). Even Roche acknowledges this in its brief. Roche Mem. at 7.

There is no merit to Roche's argument that since it did not obtain rights to practice the K-A Patents in the United States that its acknowledgment of their validity should not be imposed upon it. Roche knew or should have known what bargain it made when it decided to exercise the option to end the Australian litigation and cannot now try to change the terms of the Agreement because they no longer suit Roche's purposes.

C. ROCHE WILL NOT SUFFER ANY UNDUE PREJUDICE AND JURY CONFUSION WILL NOT RESULT FROM ANY REFERENCE TO THE 2001 SETTLEMENT AGREEMENT

Roche argues that the Agreement will cause Roche undue prejudice or confuse the jury and should be excluded pursuant to Federal Rule of Evidence 403. But Rule 403 does not allow the court to exclude *any* prejudicial evidence, only evidence whose probative value is ***substantially outweighed*** by the danger of ***unfair*** prejudice, confusion of the issues, or misleading the jury. Roche's arguments collapse under this weight. Undoubtedly, Roche's acknowledgement in the Agreement that the K-A Patents are valid is prejudicial to Roche's invalidity defense, but that is not the type of unfair prejudice that is protected under Rule 403 in the face of this highly probative evidence. Moreover, the Court's separation of the presentation of evidence on validity from the issue of infringement in the trial will minimize the possibility that the jury will confuse the issues or be misled.

The cases relied on by Roche concern exclusion of settlement evidence to prove substantive liability. *See, e.g., Equal Employment Opportunity Commission v. Gear Petroleum, Inc*., 948 F.2d 1542, 1546 (10th Cir. 1991). Here, for the reasons discussed above, Amgen is not relying upon or referring to the Agreement to demonstrate substantive liability of the Australian claim that was dismissed with prejudice. Furthermore, Roche cannot demonstrate that the Agreement will mislead the jury or that Amgen's reliance on the Agreement will unfairly prejudice Roche.

III. CONCLUSION

For the reasons, set forth above, the court should deny Roche's motion in limine to preclude Amgen from submitting the June 1, 2001 Settlement Agreement as evidence or referring to the Agreement at trial.

August 28, 2007

Respectfully Submitted,

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By its attorneys,

/s/ Patricia R. Rich

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