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 **PUBLIC VERSION - REDACTED**

MEMORANDUM IN SUPPORT OF 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 (collectively "Roche") respectfully requests that the Court preclude plaintiff Amgen Inc. ("Amgen") from relying upon, or referring to, a 2001 Settlement Agreement between, *inter alia*, F. Hoffmann-La Roche, Ltd. and Kirin Amgen, Inc. (Kirin Amgen), at the upcoming trial. The Federal Rules of Evidence make inadmissible evidence of prior settlement agreements, as well as evidence of conduct or statements made in settlement negotiations, where this evidence is "offered to prove liability for, invalidity of, or amount of a claim." Fed. R. Evid. 408. Notwithstanding the Rules, Amgen seeks to introduce into evidence and argue before the jury a June 1, 2001 Settlement Agreement (the "Agreement") between F. Hoffmann-La Roche, Ltd. and Kirin Amgen, along with other third parties, which settled claims of infringement outside of the United States on different foreign patents involving different inventions. *See* Exhibit A. As it identified in interrogatory responses, Amgen's sole basis for admission is that the terms of the Agreement should equitably estop Roche from challenging the validity of the patents-in-suit in this action.

Amgen does not come close to stating a claim for equitable estoppel, which requires, among other things, a showing of detrimental reliance. Amgen claims that Roche represented in the Agreement that it would not challenge the validity of the patents-in-suit in the United States. However, the Agreement by its own terms applies only to claims of infringement outside of the United States, and nowhere in the Agreement did Roche acknowledge the validity of any patents in the United States. Furthermore, the Agreement applies only to patents owned by Kirin Amgen that are not the subject of this action. Amgen therefore could not reasonably believe based upon this Agreement that Roche would not challenge the validity of the patents-in-suit in the

United States. Amgen's equitable estoppel argument fails for this reason alone. Thus, Amgen has no legitimate purpose for introducing the Agreement as evidence at trial. In reality, the only reason Amgen wishes to introduce this evidence is to confuse and unfairly prejudice the jury by incorrectly implying that Roche has recognized the validity of the patents-in-suit. However, the Federal Rules of Evidence explicitly prohibit the introduction of prior settlement agreements for this purpose.

Moreover, for these same reasons, the 2001 Settlement Agreement is not relevant to issues of Amgen's alleged secondary considerations of non-obviousness of the patents-in-suit. Amgen may allege that the Agreement is evidence of competitors' acquiescence or copying. But as stated above, the Agreement deals with different foreign patents not owned by Amgen involving infringement actions outside of the United States. As a result, it cannot demonstrate the alleged non-obviousness of the patents-in-suit, since the Agreement does not pertain to Amgen or its patents.

Finally, even the mere mention of this Agreement before the jury would be unfairly prejudicial to Roche, since it would mislead the jury into thinking that the parties had previously settled this matter. To the extent that the Agreement has any probative value (it has none), it would be drastically outweighed by its unfairly prejudicial impact. Defendants therefore respectfully request that the Court preclude Amgen from referencing the June 1, 2001 Settlement Agreement to the jury or introducing it into evidence at trial.[1]

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[1] In addition to the fact that nothing in the Agreement supports equitable estoppel, Amgen failed to properly identify the Agreement as the basis for its equitable estoppel defense until well after the close of discovery. In Roche's Fourth Set of Interrogatories, Amgen was asked to identify the factual and legal bases for all of Amgen's affirmative defenses. In its original responses, Amgen claimed generally that the Agreement supported estoppel, but never identified the terms in the agreement resolving disputes in Australia as the basis for its estoppel defense or explained how these terms supported estoppel. It was not until July 20, more than two months after the close of fact discovery and on the eve of trial, that Amgen filed supplemental responses and claimed for the first time that estoppel was based upon the terms of the

II. ARGUMENT

A. FRE 408 Bars Amgen From Referencing the 2001 Settlement Agreement Before the Jury

Rule 408 of the Federal Rules of Evidence provides:

> Evidence of (1) furnishing or offering or promising to furnish, or (2) accepting or offering or promising to accept, a valuable consideration in compromising or attempting to compromise a claim which was disputed as to either validity or amount, is not admissible to prove liability for or invalidity of the claim or its amount. Evidence of conduct or statements made in compromise negotiations is likewise not admissible.

Fed. R. Evid. 408. Exclusion of evidence of prior agreements and the parties' underlying negotiations reflects Congress' policy of encouraging settlement of disputes, as well as its recognition that " . . . such evidence is of questionable relevance on the issue of liability or the value of a claim, since settlement may well reflect a desire for peaceful dispute resolution, rather than the litigants' perceptions of the strength or weakness of their relative positions." *McInnis v. A.M.F., Inc.*, 765 F.2d 240, 247 (1st Cir. 1985); *see also Advanced Cardiovascular Sys. v. Medtronic, Inc.*, 265 F.3d 1294, 1308 (Fed Cir. 2001) (Rule 408 promotes a "policy in favor of protecting settlement negotiations from being admitted as evidence, thus serving to encourage settlements"). The rule applies equally whether the settlement is between the litigants themselves or between the litigants and a third party. *See McInnis*, 765 F.2d at 247, *see also Crigger v. Fahnestock and Co., Inc.*, 2005 WL 857368, at *2 (S.D.N.Y. Apr. 14, 2005). Accordingly, courts in patent

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agreement related to Australia. *See* Excerpts to *Amgen's Supplemental Responses and Objections to Roche's Fourth Set of Interrogatories*, attached hereto as Exhibit B. Amgen has provided no excuse for its failure to timely identify the basis for its equitable estoppel defense, and accordingly Amgen should be barred from relying upon the Agreement as support for equitable estoppel. *See, e.g., Gem Realty Trust v. First Nat. Bank of Boston*, 1995 WL 136874, at *2 (D.N.H. 1995) (barring plaintiff's expert from testifying to matters not identified in initial disclosures after plaintiff failed to supplement responses to identify new expert opinions prior to close of discovery).

infringement actions have routinely excluded evidence of prior settlement agreements when offered to establish the defendant's liability for infringement or the amount of the patentee's claim. *See Pioneer Hi-Bred Intern., Inc. v. Ottawa Plant Food, Inc.*, 219 F.R.D. 135, 144-45 (N.D. Iowa 2003) (excluding evidence of prior settlement agreement between patentee and third party offered as evidence of reasonable royalty rate owed to patentee by defendant); *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 2003 WL 22387038 (D. Del. 2003) (granting motions to exclude executed settlement agreements as well as underlying negotiations pursuant to Rule 408 where negotiation of agreements was done under the threat of litigation).

Amgen plainly wishes to introduce the Agreement at trial to mislead the jury into believing that Roche recognized the validity of the patents-in-suit, a purpose explicitly prohibited under Rule 408. The terms of the Agreement reflect no such recognition by Roche, reflecting nothing more than the "desire for peaceful dispute resolution," *McInnis, supra,* that is protected from use at trial under FRE 408.

B. The 2001 Settlement Agreement Is Not At All Relevant to the Question of the Validity of the Patents-in-Suit

Apart from the fact that Rule 408 bars its admission, the Agreement is not even relevant to the question of the validity. [redacted]

[redacted]

(Agreement §§. 2.2., 2.7).

More specifically, the term in the Settlement Agreement which Amgen points to as evidence that Roche [redacted] is one of the terms of an option in the Agreement to settle disputes between the parties ***in Australia***. (Agreement § 2.11) Pursuant to the terms of this option, Roche [redacted] (*Id.*) (emphasis added). [redacted]

Even if the Settlement Agreement could be read to apply to infringement claims in the United States, which it cannot, the Agreement would still be irrelevant, as its terms do not apply to any of the patents-in-suit. None of the patents-in suit are referenced in the Agreement. Amgen nevertheless tries to argue that the Agreement incorporates the patents-in-suit because they share the same disclosure as the Kirin Amgen patents referenced in the Agreement. This argument is a red herring, as Kirin Amgen did not even own any the patents-in-suit at the time that the Agreement was signed, having assigned title to these patents to Amgen in 1997 and 1999.[2] *See Black Clawson Co., Inc.*

[2] *See* U.S. PTO website, http://assignments.uspto.gov/assignments/q?db=pat, attached hereto as Exhibit C.

v. Kroenert Corp., 245 F.3d 759, 765 ("Title to a patent is assignable, and an assignee holds the same rights that the original patentee had.") (*citing Prima Tek II, L.L.C. v. A-Roo Co.*, 222 F.3d 1372, 1377 (Fed Cir. 2000)). Amgen was not a party to the 2001 Settlement Agreement, and Kirin Amgen did not have the right to release Roche or any other party from current or future claims of infringement of patents assigned to Amgen. *Cf. Black Clawson*, 245 F.3d at 765 (third party who assigned rights in intellectual property to plaintiff and later settled claims involving this property with defendants could not release defendants from plaintiff's claims, because third party "could not have released the defendants from claims or causes of action to which it was not entitled.")[3] Accordingly, the Agreement cannot be read to encompass the patents-in-suit. *See Kearns v. Gen. Motors Corp.*, 94 F.3d 1553, 1555 (Fed. Cir. 1996) ("By statutory and common law, each patent establishes an independent and distinct property right.")

Amgen tries to manufacture a legitimate reason for admitting the Settlement Agreement by claiming that the Agreement should equitably estop Roche from challenging the validity of the Kirin Amgen patents. *See* Ex. B. However, to successfully assert a claim of equitable estoppel Amgen would have to establish, among other things, that it was ignorant of the true facts and that it *reasonably* relied upon the other party's conduct to its detriment. *See Plumley v. Southern Container, Inc.*, 303 F.3d 364, 374 (1st Cir. 2002) (equitable estoppel requires, *inter alia*, a showing that the party

[3] Assuming, *arguendo*, that Kirin-Amgen did not assign all rights to the patents-in-suit to Amgen, Kirin-Amgen is an indispensable party in this action, and Amgen's failure to join Kirin-Amgen mandates dismissal. Fed. R. Civ. P. 19; *see Intellectual Property Development, Inc. v. TCI Cablevision of California, Inc.*, 248 F.3d 1333, 1348 (Fed Cir. 2001) (" a patent owner should be joined, either voluntarily or involuntarily, in any patent infringement suit brought by an exclusive licensee having fewer than all substantial patent rights."); *Independent Wireless Tel. Co. v. Radio Corp. of Am.*, 269 U.S. 459, 468 (1926) ("the presence of the owner of a patent as a party is indispensable . . . to give jurisdiction under the patent laws . . . ."); *accord Propat Intern. Corp. v. Rpost, Inc.*, 473 F.3d 1187, 1193-94 (Fed Cir. 2007) (plaintiff exclusive licensee lacked standing to sue for infringement on behalf of patentee where license agreement did not convey all substantial rights to licensee).

claiming estoppel relied on estopping conduct to its detriment); *Clauson v. Smith*, 823 F.2d 660, 662 (1st Cir. 1987) (one may be "estopped from denying the consequences of his conduct where that conduct has been such as to induce another to change his position in good faith or such that a reasonable man would rely upon the representations made."); *see also Vistamar, Inc. v. Fagundo-Fagundo*, 430 F.3d 66, 73 (1st Cir. 2005) ("The critical inquiry [in deciding an equitable estoppel claim] is whether plaintiff's reliance was reasonable.")

For the reasons discussed, *supra*, Amgen could not reasonably have believed based upon the terms of the Agreement that Roche would not challenge the validity of the patents-in-suit in the United States. In any event, Amgen cannot claim that it was harmed in any way as a result of its supposed reliance on Roche's representations in the Agreement. [redacted] Nor can Amgen claim that it chose to sit on its rights in reliance upon the Agreement. The record shows that at least as far back as 2003 Amgen began plotting countermeasures, which included litigation strategies, to respond to the future threat it perceived from Mircera. *See* Amgen Conference Call at 6, attached hereto as Exhibit D. As Amgen cannot establish either that it reasonably relied upon Roche's conduct or that it was harmed as a result, Amgen's equitable estoppel claim is baseless.

Moreover, to the extent that Amgen seeks to rely upon the Agreement as evidence of alleged secondary considerations of non-obviousness, this too would be unavailing. While Courts have recognized that licensing of patents-in-suit may indicate commercial acquiescence and industry respect for the invention (*see In re Rouffet*, 149 F.3d 1350,

1355 (Fed. Cir. 1998)), here the Agreement involves rights pertaining to a different entity, Kirin-Amgen (not Amgen) on different patents not even owned by Amgen. Likewise, copying may infer non-obviousness where the accused infringer appropriates the claimed invention in an unauthorized manner separate and distinct from licensing the patent rights. *See e.g., John Charles Designs, Inc. v. Queen Int'l Design, Inc.*, 940 F. Supp. 1516, 1521 (C.D. Cal. 1996). Here however, any argument by Amgen of unauthorized copying is even more attenuated, since the Agreement does provide Roche and others certain legal rights to the Kirin-Amgen patents outside the United States. Thus, patent rights under a binding settlement agreement cannot be evidence of illicit copying. *See In re Rouffet*, 149 F.3d at 1355. Nothing is being copied, especially since Amgen was not a party to that Agreement and the patent rights negotiated in that Agreement are not those of the patents-in-suit.

C. Undue Prejudice and Jury Confusion Will Result From Any Reference to the 2001 Settlement Agreement

Finally, even if Amgen had a legitimate reason for offering the Settlement Agreement into evidence, the risk of jury confusion and prejudice to Roche would mandate its exclusion pursuant to Federal Rule of Evidence 403. *See Southwest Nurseries, LLC v. Florists Mut. Ins., Inc.*, 266 F.Supp.2d 1253, 1259 (D. Colo. 2003) ("[e]ven where evidence is not barred under Rule 408, the trial court must still perform a balancing analysis under Rule 403 of the Federal Rules of Evidence, weighing the probative value of the proffered evidence against its potential for unfair prejudice to the objecting party."). There is a significant risk that the jury will confuse the purpose for which Amgen purports to offer the Agreement at trial and will construe the Agreement as some sort of concession by Roche that the patents-in-suit in this action are valid, a result which would be unfairly prejudicial to Roche. Accordingly, Rule 403 bars admission of

the Agreement. *See id.* at 1258-59 (excluding evidence of settlement negotiations proffered to show defendant's bad faith refusal to settle claim because the risk of unfair prejudice and jury confusion outweighed any probative value); *Equal Employment Opportunity Commission v. Gear Petroleum, Inc.*, 948 F.2d 1542, 1546 (10th Cir. 1991) ("[T]he risks of prejudice and confusion entailed in receiving settlement evidence are such that often ... the underlying policy of Rule 408 require[s] exclusion even when a permissible purpose can be discerned"); *see also* 2 Weinstein's Federal Evidence § 408.08 ("The almost unavoidable impact of the disclosure of [settlement evidence] is that the jury will consider the offer or agreement as evidence of a concession of liability.").

III. CONCLUSION

For the reasons set forth above, the Court should preclude Amgen from submitting the June 1, 2001 Settlement Agreement as evidence or referencing the Agreement at trial.

Dated: August 14, 2007
Boston, Massachusetts

Respectfully submitted,

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