

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,)
)
 Plaintiff,)
)
 vs.)
)
 F. HOFFMANN-LA ROCHE LTD,)
 ROCHE DIAGNOSTICS GMBH,)
 AND HOFFMANN-LA ROCHE INC.,)
)
 Defendants)

CIVIL ACTION No.: 05-CV-12237WGY

Leave to file granted on September 10, 2007

**REPLY MEMORANDUM OF LAW IN SUPPORT OF ROCHE’S MOTION *IN LIMINE*
TO PRECLUDE AMGEN FROM INTRODUCING INTO EVIDENCE OR
REFERENCING TO THE JURY: 1) THE SEPTEMBER 30, 1985 AMGEN/ORTHO
PRODUCT LICENSE AGREEMENT, AND 2) EVIDENCE CONCERNING LICENSING
OF THE PATENTS-IN-SUIT**

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Dated: Boston, Massachusetts
September 10, 2007

I. INTRODUCTION

In opposing Roche's motion, Amgen fails to explain why judicial estoppel does not preclude it from contending here that its arrangement with Ortho Pharmaceutical Corporation ("Ortho") -- pursuant to which Ortho has the right to sell recombinant human erythropoietin -- is a patent license, after Amgen had represented to this Court that Ortho had only a product license. Nor does Amgen make any attempt to explain why its responses to interrogatories in this case make no mention of licensing as relevant to whether the patents-in-suit are invalid for obviousness. Finally, Amgen provides no explanation for why it should be allowed to offer evidence to the jury about licensing, whether to Ortho or any other third party, when it failed to provide discovery about the Ortho license -- contending it was irrelevant -- and provided no discovery whatsoever about possible licenses to other entities. Thus, Roche's motion to preclude reference to the Ortho PLA, as well as any other evidence concerning licensing, should be granted.

II. ARGUMENT

A. Amgen's License Agreement Is For a Product and Not For the Underlying Patents

Amgen's own opposition brief recognizes that Ortho "was willing to pay Amgen to use the *products* of Amgen's inventions." (Amgen Br. at 2). As Roche pointed out in its original motion, Amgen, in its Opposition to Ortho's Motion to Intervene (D.I. 34, at 8), represented to this Court that the PLA was a mere product license offering no direct, substantial, or legally protectable interest in the patent claims-in-suit. Conceding that it secured a favorable decision based on this representation, Amgen fails to address why it should not be judicially estopped from now claiming that the PLA *did* offer a protectable interest in the *patent claims-in-suit* as opposed to just the *product*.

B. Amgen Fails to Demonstrate the Requisite Nexus Between the PLA and Secondary Considerations of Obviousness

Amgen is correct in its assessment that what “is critical for purposes of evaluating secondary considerations is that members of the industry licensed Amgen’s EPO *patents* and thus, *recognized and respected* Amgen’s inventions.” (Amgen Br. at 3) But Amgen has failed to show how the PLA meets either of these two criteria. First, as expounded on above and by Amgen’s own assertion, the license at issue was for *products*, not *patents*. Second, as explained in Roche’s original motion, the PLA covered a bundle of products, spanning disparate inventors and inventions. To make its case, Amgen must prove a nexus between the patentability of the specific subject matter claimed to be nonobvious and the motivation to enter into the PLA. *See In re GPAC*, 57 F.3d 1573, 1580 (Fed. Cir. 1995); *Automotive Tech. v. TRW Vehicle Safety Sys., Inc.*, 2006 WL 2794338, *33 (holding that “because none of the licenses identified by [the patentee] concern the [patent-in-suit], . . . they are not pertinent to the obviousness determination”).

Moreover, when providing discovery responses asking for the basis of any invalidity defense based on secondary considerations of nonobviousness, Amgen failed to say a word about any license, including the Ortho license, as a basis for that defense. Having failed to disclose licenses as a basis for a secondary considerations defense, Amgen cannot be permitted now to ambush Roche at trial by contending licenses are relevant to such a defense.

C. Amgen Failed to Provide Discovery Regarding the PLA and Any Other Licenses

Finally, Amgen fails to show that it made a full disclosure of documents regarding the Ortho PLA. Its contention that the documents regarding the arbitration between it and Ortho about the PLA, is irrelevant to the PLA is absurd. As stated in Roche’s original brief, the

discovery Roche was denied (at Amgen's insistence) could have revealed a myriad of facts important in construing and interpreting the PLA. Amgen cannot be allowed to choose which relevant documents to produce and which to exclude and then characterize the selective production as "full and fair."

Additionally, Amgen fails to dispute that it produced *no* evidence in discovery related to licensing discussions of the patents-in-suit with any other third parties. Because Amgen admits that it produced no relevant documents on this point, it must be precluded from offering evidence of licensing now. If such evidence in fact exists, it was clearly withheld, and Amgen must not be permitted to present any such evidence to the jury -- as this court has directed repeatedly.¹

III. CONCLUSION

For the reasons set forth above, as well as for the reasons in Roche's opening brief, the Court should grant Roche's motion to preclude Amgen from introducing into evidence, or referring to: 1) the September 30, 1985 PLA with Ortho, and 2) evidence concerning licensing of the patents-in-suit.

¹ May 16, 2007 Electronic Order, "No Witness May Rely On Evidence Withheld From Discovery."

Dated: September 10, 2007
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). Pursuant to agreement of counsel dated September 9, 2007, paper copies will not be sent to those indicated as non registered participants.

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