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

ROCHE'S RESPONSE TO AMGEN'S BENCH MEMORANDUM THAT DOCUMENTS SHOWING THAT AMGEN'S COMPETITORS IN 1984 ACKNOWLEDGED THAT AMGEN WAS THE FIRST TO CLONE THE EPO GENE, THAT AMGEN'S CLONING WAS PATENTABLE AND THAT THEY SOUGHT TO COPY AMGEN ARE RELEVANT TO SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS

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Dated: Boston, Massachusetts
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I. INTRODUCTION

Amgen's bench memorandum, in which it requests that the Court admit into evidence trial exhibits BAH and FJX, should be denied, as these documents are not only irrelevant to secondary considerations, but also inadmissible because they do not fall within one of the hearsay exceptions and have not been properly authenticated.

II. ARGUMENT

A. Amgen's Competitors' Statements Regarding Its Cloning of the EPO Gene Are Irrelevant to Secondary Considerations In This Case

Statements made by Amgen's competitors, namely Chugai and Genetics Institute ("GI"), with respect to Amgen's public announcement that it cloned the EPO gene are not relevant to secondary considerations in this case because the claimed inventions in the patents-in-suit do not encompass cloning the EPO gene. The patent that claims the cloning of the EPO gene is the now-expired '008 patent. Thus, at best, Chugai and GI's statements bear on secondary considerations with respect to the obviousness of the claims of the '008 patent, which is not one of the patents at issue in this case and therefore is not relevant.

Amgen makes broad and sweeping statements that the Chugai and GI documents discussing their reaction to Amgen's cloning of the EPO gene show that "Amgen's patents are not obvious." *See* Amgen's Bench Memorandum, D.I. 1241 at 4. This is not only an improper conclusion, it is also an incorrect statement of the law. In evaluating secondary considerations in an obviousness determination, the Federal Circuit has held that the evaluation is between the *claimed* invention and the objective evidence. *See In re Paulson*, 30 F.3d 1475, 1482 (Fed. Cir. 1994) ("[T]here must be a sufficient relationship between . . . evidence and the patented invention"). Thus, Amgen's broad and sweeping statements about the evidence as supporting the nonobviousness of "the patents," Amgen's Bench Memorandum, D.I. 1241 at 2, 4, cannot

satisfy Amgen's burden of proving a nexus exists between the claimed inventions and the statements. *See, e.g., In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995); *In re Vamco Machine & Tool, Inc.*, 752 F.2d 1564, 1577 (Fed. Cir. 1985); *In re Paulson*, 30 F.3d 1475, 1482 (Fed. Cir. 1994).

Here, the specific subject matter asserted to be non-obvious is the subject matter claimed in the '868, '698, '933, '422, and '349 patents. None of these patents claim the cloning of the EPO gene. Thus, Chugai and GI's statements about the cloned EPO gene are unrelated to the claimed inventions at issue in this case. *See Ormco Corp. V. Align Technology, Inc.*, 463 F.3d 1299, 1311-1312 (Fed. Cir. 2006 ("Evidence of . . . secondary considerations, is only significant if there is a nexus between the *claimed* invention and the [secondary consideration]. . . . Thus, if the [secondary consideration] is due to an unclaimed feature of the device, the [secondary consideration] is irrelevant.") (emphasis added); *Amazon.com, Inc. v Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1366 (Fed. Cir. 2001) (vacating order for preliminary injunction where patentee failed to demonstrate that the secondary considerations in support of its nonobviousness argument were related to the claimed invention).

In fact, when Chugai and GI made these statements, the relevant patent application Amgen was prosecuting (TRX 2014) did not even claim pharmaceutical compositions ('933 and '422 patents), methods of use ('933 patent) or vertebrate cells capable of producing a specific amount of EPO as measured by RIA ('349 patent). *See* TRX 2014 at R 008891370-75 (claims 1-28). Thus, there can be no nexus between BAH and FJX and the asserted claims. Likewise, Amgen's contention that there is nexus with respect to the asserted process claims of the '868, '698 and '349 and the product-by-process claims of the '933 patent is belied by (1) Amgen had

not announced the expression of human EPO at the relevant time[1] and (2) Amgen claims here (incorrectly) that there was no reasonable expectation of success until the process for making EPO was confirmed. As Amgen has stated time and again, a party should not be allowed to "have its cake and eat it too". Accordingly, because the statements of Chugai and GI were limited to the cloning of the EPO gene, which is the subject matter of the expired '008 patent, the statements in trial exhibits BAH and FJX are wholly irrelevant to the asserted claims and are therefore inadmissible. Fed. R. Evid. 402, 403.

B. Amgen Has Failed to Demonstrate Authenticity of the Proposed Trial Exhibits and Failed to Provide Valid Exceptions to the Hearsay Rule

Contrary to Amgen's assertions, trial exhibits BAH and FJX do not fall within one of the exceptions to the hearsay rule, nor are they authentic. Further, Amgen should properly present these exhibits to the jury through its witnesses at trial and not through a motion *in limine* masked as a "bench memorandum."

In order for trial exhibits BAH and FJX to fall under the ancient document exception to the hearsay rule, as Amgen contends they do, they must be authentic.[2] *See* Fed. R. Civ. P. 803(6). Federal Rule of Evidence 901(b)(8) provides a multi-pronged test to establish the authenticity of an ancient document. Under that test, it is Amgen's burden to "prove[] that the item is 20 years old, is in a condition that does not raise suspicions as to authenticity, and was found in a place of natural custody for such an item." 31 Wright & Miller § 7113 at 131 (2000).

Amgen fails to provide evidence to authenticate the proposed exhibits that it seeks to admit, as it relies on the testimony of Ian Crawford, who is unable to properly authenticate these

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[1] Both BAH and FJX are dated January 1984.

[2] Amgen also incorrectly contends that "documents attributed to Fritsch are admissions as to Genetics Institute." See Amgen's Bench Memorandum, D.I. 1241 at 1. Documents attributed to Fritsch clearly do not fall under Rule 801(2), as Fritsch is not a party-opponent.

documents for several reasons. In fact, Amgen cannot authenticate these documents. As this Court has already granted Roche's motion to preclude the testimony of Attorney Crawford. (D.I. 1205; October 1, 2007 Order). Thus, trial exhibits BAH and FJX do not fall within the ancient document exception to the hearsay rule because they cannot be authenticated.

Moreover, trial exhibits BAH and FJX contain hearsay within hearsay. It is well-established that the ancient documents exception, which Amgen has claimed as its basis for admitting the documents, "does not justify the admission of double hearsay merely because of its presence in an ancient document." *Hicks v. Charles Pfizer & Co.*, 466 F.Supp.2d 799, 806 (E.D.Tex. 2005). As the *Hicks* court stated "the danger of faulty perception persists unabated because a narrator, such as a reporter, may not properly record the remarks of the speaker." *Id.* Numerous other courts, including sister courts within the First Circuit, have similarly held that hearsay within ancient documents cannot be admitted, as Rule 805 plainly requires. *See, e.g.*, *United States v. Hajda*, 135 F.3d 439, 444 (7th Cir. 1998) ("if the [ancient] document contains more than one level of hearsay, an appropriate exception must be found for each level"); *Elmhart Indus. v. Home Ins. Co.*, __ F. Supp. 2d __, 2007 WL 2782989 (D.R.I. Sept. 26, 2007) (excluding documents under the ancient documents exceptions that were "littered with admissibility issues" some of which contained "more than one level of hearsay"). Thus, Amgen must provide proper exceptions to account for the double hearsay in the documents.

III. CONCLUSION

For the reasons set forth above, trial exhibits BAH and FJX should not be admitted into evidence.

Dated: October 3, 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.

/s/ Thomas F. Fleming