

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

**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**

Trial exhibits BAH and FJX are contemporaneous evidence of the reactions of Amgen’s competitors upon learning that Amgen cloned the EPO gene. As this Court has stated regarding these documents, the question surrounding their admissibility is relevance.¹ The documents are not hearsay because they are not being offered for the truth of the matter asserted but rather to show the state of mind of Genetics Institute and Chugai, competitors of Amgen, in 1984. Moreover, even if Amgen submitted them for the truth of the matter in the documents, both fall within the ancient document exception to the hearsay rule and any statements in the documents attributed to Fritsch are admissions as to Genetics Institute.² Moreover, Amgen has established their authenticity through several sworn declarations, including that of Ian Crawford, an attorney

¹ See 10/1/2007 Trial Tr., p. 2083: 21 – 2084: 3.

² Roche has already put into evidence that Fritsch was Genetics Institute’s scientific advisor in 1984.

for Genetics Institute who attests that these documents came out of Genetics Institute's files.³ As set forth, these documents are directly relevant to secondary considerations of non-obviousness because they show that Amgen's competitors, at the time that Dr. Lin invented recombinant EPO, recognized his achievements, and that Amgen beat them to this invention, and that they sought to copy Amgen's work. Accordingly, because these documents are relevant, authentic and not hearsay (or fall within hearsay exceptions), this Court should admit them into evidence.

The law is clear that this Court and the jury must look at the public and commercial response to Amgen's patents when assessing Roche's claim that the patents are obvious.⁴ Indeed, as the Federal Circuit has held, "evidence of secondary considerations may often be the most probative and cogent evidence in the record."⁵ Secondary considerations are even more important in a highly technical case.⁶ This is because although Courts may not always fully understand the technical considerations, economic and motivational factors are more susceptible to judicial treatment.⁷

Trial exhibits BAH and FJX are directly relevant to secondary considerations of non-obviousness. First, they show that Amgen's competitors, in 1984, recognized that Amgen was the first to clone EPO, that they had failed to clone EPO before Amgen, and that Amgen was

³See Docket #s 1048, 1049, 1153, 1154. Mr. Crawford is prepared to testify that he personally retrieved copies of these documents from Genetics Institute's file cabinets in Cambridge.

⁴See *Graham v. John Deere Co.*, 383 U.S. 1, 35-36 (1966) (stating that secondary considerations of non-obviousness serve to "guard against slipping into use of hindsight, and to resist the temptation to read into the prior art the teachings of the invention in issue"); *Amgen v. Hoechst Marion Roussel*, 339 F. Supp. 2d 202, 319 (D. Mass. 2004) (setting forth factors to consider to assess objective indicia of non-obviousness).

⁵*Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 957 (Fed. Cir. 1997) (finding that patentee's licenses showed objective indicia that patent was not obvious).

⁶*Ortho Pharmaceutical Corp v. Smith*, 1990 U.S. Dist. LEXIS 1951 at *22 (E.D. Pa. 1990) (stating that courts "had best appraise the originality involved by the circumstances which preceded, attended and succeeded the appearance of the invention").

⁷*Graham v. John Deere Co.*, 383 U.S. at 35-36.

likely to get a patent for EPO. Thus, in the January 11, 1984 letter from Chugai to Genetics Institute (Tx. BAH), Chugai states:

We assume that Amgen's first cloning of EPO is certainly patentable [sic] and it will seriously damage commercial interest of other EPO projects inclusive of yours ...⁸

Genetics Institute's response (Tx. FJX) is equally relevant, acknowledging:

We came to the conclusion that although we missed the chance to be the first one to clone EPO, we will continue to pursue this project aggressively...⁹

Evidence suggesting that others tried and failed to make an invention before the patentee are squarely within recognized secondary factors of non-obviousness.¹⁰

In addition, the Genetics Institute letter is also significant because it shows that Genetics Institute was actively looking into Amgen's technology to enable its own attempts to clone the EPO gene. Thus, Genetics Institute writes that it is aware that:

To clone EPO Amgen used new sequence information obtained from tryptic fragments of EPO obtained from Dr. Goldwasser. They also claim to use novel hybridization technology which allowed them to use oligos of high degeneracy.¹¹

and

We are uncertain as to whether they [Amgen] obtained a baboon cDNA or a human genomic DNA clone first – we have heard conflicting reports. However, with this information they can certainly predict the human cDNA sequence and synthesize it easily.¹²

and

If Amgen obtained a genomic clone first using synthetic oligonucleotides then our approach could be similar.¹³

⁸ See Tx. BAH, p. 1.

⁹ See Tx. FJX, p. 1.

¹⁰ *Litton Systems, Inc. v. Honeywell, Inc.*, 87 F.3d 1559, 1570 (Fed. Cir. 1996) (recognizing that defendant, and other companies, repeated failure to build products before patentee was relevant to obviousness inquiry).

¹¹ See Tx. FJX, p. 4.

¹² *Id.*

¹³ *Id.*

Genetics Institute's efforts to copy Amgen's technology shows that Amgen's patents are not obvious.¹⁴ Put simply, there would be no need for a competitor to copy something that was obvious to them.

Because trial exhibits BAH and FJX are relevant, authentic and within the scope of a hearsay objection, they should be admitted into evidence.

¹⁴ *Litton Systems, Inc.*, 87 F.3d at 1569 (holding that defendant's effort to copy patentee's invention weighed against claim that patent was obvious).

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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 and paper copies will be sent to those indicated as non-registered participants on October 2, 2007.

/s/ Michael R. Gottfried
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