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

ROCHE'S OPPOSITION TO AMGEN'S MOTION TO PRECLUDE ROCHE FROM OFFERING ADDITIONAL EVIDENCE AND ARGUMENT REGARDING THE GENETICS INSTITUTE (D.N. 1333)

Amgen's motion to preclude Roche from offering relevant evidence regarding Dr. Fritsch's invention of the subject matter of the patents-in-suit should be rejected for the following reasons:

- Amgen is wrong in claiming that Dr. Fritsch's invention occurred after the invention date of the patents-in-suit. As Roche has explained in other submissions, (*See* Bench Memorandum, D.N. 1332), Amgen has failed to establish an invention date earlier than the November 30, 1984 filing date of the patents-in-suit. Amgen acknowledges that Dr. Fritsch made his cloning invention in July or August of 1984. Because Dr. Fritsch's invention ***precedes*** the invention date of the patents it is relevant to Roche's anticipation and obviousness defenses.

- Amgen's claim that Dr. Fritsch's invention is not relevant to obviousness because he had some special access to the work of Dr. Lin is entirely baseless. Amgen's only support for this allegation are two documents exchanged between Chugai and Genetics Institute -- Exhs. BAH and FJX -- filled with multiple layers of hearsay that do not even begin to support Amgen's claim that Dr. Fritsch had access to Dr. Lin's work, let alone used it to further his own invention.

- At bottom, this motion is yet another Amgen effort to relitigate the Court's decisions firmly rejecting the admissibility of the Chugai and Genetics Institute documents,

including a clear ruling on October 11, 2007 that the Chugai/GI documents "are not admitted." The Court has ruled against Amgen on its multiple attempts to seek admission of these documents. There is no reason to revisit those rulings now.

A. Dr. Fritsch's Inventive Work Precedes the Invention Date of the Amgen Patents and Is Relevant to Anticipation and Obviousness

Amgen's entire motion is premised on its claim that Dr. Fritsch's invention occurred after the invention date of the patents-in-suit. Amgen's premise is false. As Roche has explained in detail in other submissions[1], Amgen has failed to establish any invention date earlier than the November 30, 1984 filing date of the patents, which is presumed the invention date absent evidence of an earlier invention date. *See Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1577 (Fed. Cir. 1996). Even in this motion, Amgen fails to provide any evidence of an invention date earlier than November 30, 1984.

It is Amgen's burden to demonstrate an earlier invention date by presenting evidence of an earlier reduction to practice or an earlier conception followed by a diligent reduction to practice. *Purdue Pharma Co. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1365 (Fed. Cir. 2001). Moreover, if relying solely on the testimony of the inventor to establish an earlier date, Amgen must provide corroborative evidence supporting that earlier date. *Mahurkar*, 79 F.3d at 1577.

Here, the record is devoid of evidence that, prior to the filing of the patent applications, Dr. Lin actually reduced his invention to practice by demonstrating that the invention worked for its intended purpose. Nor is there evidence that prior to the filing of the applications Dr. Lin "had a definite and permanent idea of the complete and operative invention" that would constitute conception. In addition, to the extent that Dr. Lin may have testified that he cloned the EPO gene

[1] *See* Roche's Bench Memorandum Regarding Amgen's (And Dr. Lin's) Failure To Establish an Invention Date Prior To the Effective Date of the Patents-in-Suit, dated October 10, 2007 (D.N. 1332).

and developed an *in vivo* biologically active EPO protein prior to November 30, 1984, Amgen has failed to produce any corroborating testimony whatsoever.

As Amgen acknowledges, the evidence in this case establishes that Dr. Fritsch's inventions occurred at least as early as July or August 1984 (see Amgen Motion at 2) -- prior to the invention date of the patents-in -suit. As such, Dr. Fritsch's work constitutes prior art, which Roche relies on to anticipate or render obvious the asserted patent claims. (see D.N. 1340) Specifically, Dr. Fritsch's invention is relevant under 35 U.S.C. §102(g) as an invention made prior to that in the patents-in-suit that was not abandoned, suppressed or concealed.

At the very minimum, Dr. Fritsch's work is relevant to the obviousness inquiry as a contemporaneous invention that the jury should consider in determining whether the claims of the asserted patents are obvious. It is well-established that simultaneous or near simultaneous invention by others of the patented subject matter is a secondary consideration favoring obviousness. *See Ecolochem, Inc. v. Southern California Edison Co.*, 227 F.3d 1361, 1379 (Fed. Cir. 2000) ("the fact of near simultaneous invention, though not determinative of statutory obviousness, is strong evidence of what constitutes the level of skill in the art"); *Monarch Knitting Machinery Corp. v. Sulzer Morat GMBH*, 139 F.3d 877, 883-84 (Fed. Cir. 1998); *Ortho-McNeil Pharm., Inc. v. Mylan Labs, Inc.*, 348 F. Supp. 2d 713, 757-58 (N.D. W. Va. 2004). Indeed, the contemporaneous invention is even relevant to obviousness where it is made as much as six or more months after the invention date of the patent. *See Ortho-McNeil*, 348 F.Supp.2d at 757-58 (finding other invention made in late 1985 or early 1986 to be relevant evidence of obviousness as to a patent with a priority date of June 1985). Therefore, Dr. Fritsch's invention is relevant to obviousness even if Amgen can somehow establish some unspecified earlier invention date.

B. Amgen's Claim that Dr. Lin Had Special Access to Dr. Lin's Activities Is Entirely Baseless

Amgen argues that Dr. Fritsch's inventions are somehow irrelevant to the obviousness inquiry because "Dr. Fritsch and GI obtained access to and knowledge of the means by which Dr. Lin successfully isolated the DNA encoding human EPO from a genomic library." (Amgen Motion (D.N. 1333) at 2. Amgen's claim is without support.

The only support Amgen offers for the notion that Dr. Fritsch had some special access are the two Chugai/GI documents that this Court has ruled are inadmissible and are unauthenticated, riddled with hearsay, and highly misleading. But even if admissible -- which they are not, *see* Section C below -- these hearsay documents fail to provide any evidence that Dr. Fritsch or anyone else at GI had access to Dr. Lin's work. Amgen only points to triple hearsay statements attributed to Dr. Fritsch about what Dr. Fritsch had "heard" about Dr. Lin's work -- evidence amounting to no more than gossip. (See Exh. FJX at 3 "we are uncertain as to whether they obtained a baboon cDNA or a human genomic DNA clone first -- ***we have heard conflicting reports***"). Indeed, the memorandum itself attaches only an Amgen press release and a news article as support for its assertions. Furthermore, confirming that Dr. Fritsch and GI had no special access or knowledge, the memorandum is replete with statements showing that the author, GI and Dr. Fritsch were uncertain about how Dr. Lin had done his work. *See* Exh. FJX at 2 ("it will be several months to a year before we see the technical publication of Amgen's work"), and at 3 ("we are uncertain as to whether they obtained a baboon cDNA or a human genomic DNA clone first"). There is simply no evidence in either document that tends even remotely to show that Dr. Fritsch or GI had inside knowledge or Dr. Lin's work that Amgen contends would somehow make Dr. Fritsch's invention less pertinent to the obviousness inquiry.

C. Amgen's Attempt to Relitigate This Court's Ruling That the Chugai and Genetics Institute Documents Are Inadmissible Should Be Rejected

At bottom, Amgen's motion is a thinly-veiled attempt to relitigate the admissibility of the Chugai/GI documents. The Court should reject this latest Amgen effort to relitigate decided issues. If the Court's rulings on these documents were not clear enough, the Court declared in its October 11, 2007 electronic order that the exhibits at issue "are not admitted." (Electronic Order, October 11, 2007). This ends the matter. The Court could not be clearer that Exhibits BAH and FJX are inadmissible.

Yet Amgen ignores the Court's prior rulings, including those the Court made prior to Amgen's current motion. Astonishingly, Amgen fails even to mention this Court's ruling on October 2, 2007, that "the Chugai and GI documents are not admissible for the reasons advanced by Roche notwithstanding their antiquity." (D.N. 1269). Instead, Amgen invokes the Court's statements at trial on October 1, 2007, about whether Amgen could establish the admissibility of these documents. What Amgen fails to mention is that after the October 1 trial day, Roche submitted a bench memorandum detailing the reasons that the Chugai/GI documents were not admissible. (*See* D.N. 1231). In that bench memo, Roche explained that the documents were not admissible because Amgen had failed to authenticate them, because the documents are riddled with multiple levels of hearsay not subject to any exception, and because the documents were highly misleading in that they contain assertions by persons unknown to Roche about the patentability of Amgen's cloning efforts, which include activities not covered by the patents-in-suit. In making its October 2, 2007 ruling the Court ruled the Chugai/GI documents were inadmissible "for the reasons advanced by Roche." And to make that ruling even clearer, the Court issued the October 11 electronic order declaring that "Exhibits BAH and FJX are not admitted."

Those reasons that the documents are inadmissible are equally valid today, and Amgen fails to provide any legitimate basis for the Court to reconsider its ruling. As explained above, these documents are irrelevant -- and certainly do not show that Dr. Fritsch had any special access to, or knowledge of Dr. Lin's work. Nor has Amgen introduced evidence authenticating the documents as ancient as required under Federal Rule of Evidence 901(b)(8), which requires Amgen 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) -- a burden that Amgen has failed to meet.

Nor does Amgen explain how the multiple hearsay statements within the documents are admissible. Exhibit FJX is based on the author's report of "discussion among the management and scientific staff" and a conversation with Dr. Fritsch -- who is not the document's author. Dr. Fritsch's statements are, in turn, based on what he "heard" from unknown sources -- amounting to no more than gossip. Both Exhibit FJX and BAH recount unspecified news reports as sources for many of the assertions that Amgen claims are relevant. Finally, Amgen does not address any of Roche's arguments as to why the documents are highly misleading under Rule 403. Amgen offers no explanation for why statements in the documents as to the legal significance of Amgen's cloning work will not mislead the jury. Nor does Amgen explain how the statements about Amgen's cloning work will not confuse and mislead the jury since they relate to aspects of Amgen's work not claimed in by the patents asserted in this case. In short, as the Court has now held multiple times, the documents are not admissible and Amgen has not and can not provide any reason for reconsideration of those rulings.

CONCLUSION

For the foregoing reasons, the Court should deny Amgen's motion to preclude Roche from offering additional evidence and argument regarding the Genetics Institute in its entirety.

Dated: October 11, 2007
Boston, Massachusetts

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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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