UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN, INC., Plaintiff, v. F. HOFFMANN-LAROCHE LTD., a Swiss Company, ROCHE DIAGNOSTICS GMBH, a German Company, and HOFFMANN LAROCHE INC., a New Jersey Corporation, Defendants.	)	Civil Action No. 05 CV 12237 WGY

PLAINTIFF AMGEN INC.'S MOTION TO PRECLUDE ROCHE FROM OFFERING ADDITIONAL EVIDENCE AND ARGUMENT REGARDING THE GENETICS INSTITUTE

Roche should be precluded from presenting further evidence or arguing at closing obviousness based upon the work performed by The Genetics Institute ("GI") to clone the EPO gene because the work was performed by GI after the date that Dr. Lin filed for his patent and was aided by information GI had regarding Dr. Lin's work. As such, it is not proper evidence of obviousness and, therefore, is not relevant to the litigation.

Notwithstanding the irrelevance of the information, Roche has taken steps to make this an issue in this case in the hopes that the jury will consider it. Specifically, Roche introduced the deposition testimony of Dr. Fritsch who was employed at GI and was involved in the work that was performed. This deposition testimony was introduced in the middle of the live testimony of Dr. Lowe. At the time, the Court remarked, "I don't understand what this has to do with this

case."[1] Nonetheless, after introducing the deposition of Dr. Fritsch, Roche went on to question Dr. Lowe about Dr. Fritsch's work. Dr. Lowe testified that "Dr. Fritsch was able to clone the human EPO gene sometime, depending on how you define finished cloning, but roughly July of 1984. July, August of '84" and based on this fact Dr. Lin's work was obvious.[2]

However, this testimony that Roche presented regarding the work performed at GI is not relevant to this matter. As Exhibit BAH and FJX indicate, GI conceded that the work was performed after the date by which Dr. Lin cloned the Epo gene.[3] Moreover as Exhibit FJX indicates, 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.[4] Specifically, FJX states that:

> Regarding to the specific points in your telex, I have reviewed it with Dr. Fritsch and the management staffs of GI. Following are Dr. Fritsch's answers:
>
> 1) 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.

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[1] Trial Tr.,9/7/07, p. 361 ll. 19-21

[2] Trial Tr., 9/7/07, p. 365, ll. 21-23 and p. 369, ll. 10-12.

[3] Copies of Exhibits BAH and FJK are attached hereto as Exhibit A and B respectively.

[4] During a sidebar on 10/1/07 (Trial Tr., p. 2083, l, 21-22) the Court accepted Amgen's position that Exhibits BAH and FJK were ancient documents, but deferred to the end of the case the issue of relevancy. Specifically, the Court stated:

> Here's what we're going to do. Looks to me like they're ancient. I don't know that they're relevant at all. Because I don't know whether we're getting into anything that Genetics Institute did, whenever it did it. But looks to me like they're ancient. So I don't think I need any testimony on this from Crawford or anyone else. It its alive, maybe I'll put them in at the end. Not now.

> We are using nucleic acid technology which has the same sensitivity. We are currently in the process of purifying more protein. We hope to purify enough to get additional N-terminal sequence and potentially some internal sequence.
>
> We are uncertain as to whether they 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.

These statements make clear that Dr. Fritsch had access to information regarding Dr. Lin's work and that his subsequent work was materially aided by his knowledge of Dr. Lin's work. This is particularly evident in light of the evidence of record that GI thereafter contracted with Dr. Miyake to obtain EPO purified from urine, performed trypsin digests of the EPO provided by Dr. Miyake, and used the resulting EPO fragments to design fully degenerate probes that were then used to screen the same genomic library used by Lin. In light of such evidence, Roche cannot be allowed to argue that the evidence regarding Dr. Fritsch and GI demonstrates that Dr. Lin's invention was obvious.

In addition, because Roche has already introduced the deposition transcript of Dr. Fritsch and questioned Dr. Lowe regarding the matter, if the Court determines that the issue is irrelevant, then Amgen respectfully requests that the Court provide an instruction to the jury that it should disregard the deposition testimony of Dr. Fritsch as well as the questioning of Dr. Lowe regarding the matter, that this information is not evidence in the case, and that the information is of no legal significance to this matter.

In the alternative, should the Court determine that the information is relevant to any issue in dispute and the testimony and argument regarding the work allegedly performed by GI and Dr. Fritsch will remain in the case, the Court should admit into evidence and allow Amgen to read to the jury, the relevant portions of Exhibits BAH and FJX to rebut the evidence put on by Roche

because, as the Court found, they are admissible as ancient documents and exceptions to the hearsay rule. When Amgen previously moved to have the documents admitted into evidence, the Court was concerned that they were not relevant.[5] However, the documents are relevant to rebut the evidence put on by Roche and the argument Roche will make in its closing regarding this evidence.

The first document is a Telex dated January 11, 1984 from GI to Chugai Pharmaceutical (Exhibit BAH). This article discusses the fact that Amgen was the first to clone EPO and had done so before GI. It is relevant both as secondary, objective evidence of the contemporaneous recognition of competitors of the non-obviousness of Lin's inventions, but also because it establishes the context in which GI sought out and obtained further non-public information regarding the means by which Lin successfully cloned the EPO gene. The second document, is GI's response to Chugai Pharmaceutical dated January 16, 1984 (Exhibit FJX). In its response, GI states:

> After receiving your telex of January 11, 1984, we had a serious discussion among the management and scientific staff at Genetics Institute. 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, for the following two major reasons . . .

It is evident from the face of these documents that they are relevant to the issue of non-obviousness as well as the work allegedly performed by The Genetics Institute. Accordingly, should the Court determine that this issue is relevant to the litigation, then the Court should allow Amgen to introduce Exhibits BAH and FJX into evidence in this matter so that it may rebut Roche's contentions.

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[5] *See* Supra, fn. 2.

Based on the foregoing, the Court should preclude Roche from introducing additional evidence regarding the alleged work performed by The Genetics Institute and preclude Roche from arguing that this work goes to the issue of obviousness. Moreover, the Court should instruct the jury to disregard the testimony of Dr. Fritsch and Dr. Lowe regarding this matter, that such testimony is not evidence in this case and is of no legal significance in this matter. In the alternative, if the Court determines that the evidence is relevant and will remain in the case, the Court should allow Amgen to introduce Exhibits BAH and FJX into evidence in this matter.

Dated: October 10, 2007

Respectfully Submitted,

AMGEN INC.,
By its attorneys,

/s/ Michael R. Gottfried

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CERTIFICATE PURSUANT TO LOCAL RULE 7.1

I certify that counsel for the parties have conferred in an attempt to resolve or narrow the issues presented by this motion and no agreement was reached.

/s/ Michael R. Gottfried
Michael R. Gottfried

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 10, 2007.

/s/ Michael R. Gottfried
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