IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LA ROCHE LTD, a Swiss Company, ROCHE DIAGNOSTICS GMBH, a German Company, and HOFFMANN LA ROCHE INC., a New Jersey Corporation, Defendants.	Civil Action No.: 1:05-cv-12237 WGY

AMGEN'S BENCH MEMORANDUM EXCLUDING EVIDENCE REGARDING AMGEN'S CLINICAL TRIAL AND OTHER EVIDENCE THAT ROCHE INTENDS TO PROFFER DURING THE TESTIMONY OF DR. SPINOWITZ

Amgen objects to the use of Amgen documents from its regulatory filings, other documents dated after Dr. Lin's priority date, and any testimony by Dr. Spinowitz thereto directed to the issue of obviousness. The documents and any testimony thereto are not directed to the prior art.[1] Thus, the documents and testimony are irrelevant under Rule 402 and prejudicial under Rule 403.

The fundamental test for obviousness, set forth in *Graham v. John Deere*, mandates that the inquiry be focused on the prior art, and requires:

[1] Attached as Exhibit A is a chart listing several exhibits that Roche has indicated it will use during its examination of Dr. Spinowitz. Attached as Exhibit B is a demonstrative that Roche intends to use that it made from an Amgen document related to Phase I clinical studies. Amgen objects to the use of these documents and demonstratives as irrelevant to invalidity and obviousness and as prejudicial. These do not contain all of the exhibits that Amgen objects to.

> the scope and the content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt needs, failures of others, etc. might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.[2]

"While the sequence of these questions might be reorganized in any particular case, ***the factors continue to define the inquiry that controls***."[3]

Thus, the focus must be on the prior art. Documents generated after the priority date that are not prior art are rarely properly used for establishing what one of ordinary skill in the art knew and slips into the impermissible use of hindsight.[4]

There are few limited exceptions, that do not apply here. First, the documents in question are not admissions by Amgen about the art as of 1983 as they do not address the art in 1983. Attempting to bring these documents in to define what the art was prior to Lin's invention resorts to impermissible hindsight.

Second, while in some circumstances a later-dated reference may be evidence of the level of skill in the art at the time of an earlier-filed patent application, that is not so here. When a party like Roche fails to show that a later-dated reference, such as the Amgen documents, is probative of the state of the art at the pertinent time, courts generally exclude such references from evidence.[5]

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[2] *Graham v. John Deere*, 838 U.S. 1, 17-18 (1965).

[3] *KSR International v. Teleflex*, 127 S.Ct. 1727, 1736, 167 L.Ed.2d 705, 715 (2007) (emphasis added).

[4] *Marhurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1576 (Fed. Cir. 1996) ("[U]nder Section 102(a), a document is prior art only when published before the invention date.").

[5] Amgen acknowledges it is not precedent, but in *In re Omeprazole Patent Litigation*, 84 Fed. Appx. 76, 81 (Fed. Cir. Dec. 11, 2003) (*reh'g and reh'g en banc denied*), the Federal Circuit held "the district court did not clearly err in declining to consider [a later-dated document] as reflecting the level of skill in the art" when the party seeking to rely on the document failed to offer "additional support in the form of testimony about the state of art at the time of the publication." *See also Graco Children's Products, Inc. v. Century Products Company, Inc.*, 1996 WL 421966 at *15-16 (E.D. Pa. July 23, 1996) (excluding seven exhibits offered as

Third, according to the Federal Circuit, even when there was later arising independent development of an invention identical to that claimed, there needs to be some showing that the later arising invention applies to the time the claimed invention was made.[6] Using events subsequent to the invention date to establish the level of ordinary skill in the art at the time the invention was made is improper and "is magnified in the context of rapidly evolving technology."[7]

At its core, the evidence should be excluded because it wrongfully seeks to bring subsequent art into the prior art analysis. That brings in impermissible hindsight into the analyis, and comparing what Amgen may have done years later in a clinical trial to what may have occurred earlier brings in information that one of ordinary skill in the art could not have known. Therefore, under Rule 402 and Rule 403, the evidence should be excluded.

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Respectfully Submitted,

AMGEN INC.,

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evidence of the level of skill in the art, stating "[t]his evidence is not indicative of the level of technical sophistication in the [pertinent art] at the time of the invention of the [patent-in-suit]").

[6] *Stewart-Warner Corp. v. City of Pontiac, Michigan*, 767 F.2d 1563, 1570 (Fed. Cir. 1985) ("Development by others may also be pertinent to a determination of obviousness of an invention; but the evidence presented was of activities occurring well after the filing date of the '926 patent application, and was not shown to apply to the time the invention was made, as required by 35 U.S.C. § 103." (internal cites omitted)).

[7] *Id.*

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CERTIFICATE OF SERVICE

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/s/ Michael R. Gottfried

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