IN THE UNITED STATES DISTRICT COURT
FOR THE 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-12237 WGY

ROCHE'S OPPOSITION TO AMGEN'S MOTION TO ADMIT EXHIBIT BWZa (IN REDACTED FORM) INTO EVIDENCE

Roche submits this memorandum in opposition to Amgen's motion to admit exhibit BWZa into evidence in redacted form.

Exhibit BWZa consists of selected unredacted paragraphs from a Skeleton Argument -- that is, a legal brief -- submitted by Roche in the course of patent proceedings in the United Kingdom concerning Amgen's European Patents (UK) Nos. 148,605 and 411,678. Amgen argues that these paragraphs from Roche's U.K. brief are relevant here because they state facts about cDNA cloning and whether it was "common general knowledge" that no suitable source of EPO mRNA was known by 1983/84. The statements that Amgen seeks to admit, however, are not statements of fact, but rather

arguments made by Roche in a foreign litigation under legal standards that do not apply here. An understanding of the arguments advanced in Roche's U.K. brief requires an appreciation of the differences between the patents and claims at issue in that case and in this case and an understanding of the differences between the U.S. patent laws and U.K. patent law. Plainly, the jury has no basis for conducting the necessary analysis.

As the court has noted, statements made during foreign proceedings are particularly prone to confusion of the issues because, as this Court observed on the first day of trial, "foreign proceedings are under a different legal framework."(Tr. 6). The Federal Circuit has noted this risk, indicating "the varying legal and procedural requirements for obtaining patent protection in foreign countries might render consideration of certain types of representations inappropriate." *TI Group Auto Sys.(N. Am.), Inc. v. VDO N. Am., L.L.C.*, 375 F.3d 1126, 1136 (Fed. Cir. 2004).

In the British proceedings at issue, the Roche parties argued, *inter alia*, in what is now exhibit BWZa, that Amgen's patent specification provided insufficient support to enable the claims in suit which, unlike the claims asserted in the instant case, were directed to cDNA ("complementary" DNA). Roche maintained that a tissue source for constructing an EPO cDNA was not "common general knowledge" and thus the patent specification did not enable the claim.

Under the "common general knowledge" standard applicable there, the skilled artisan is presumed to know only "what is generally known and accepted without question by the bulk of those who are engaged in that particular art." *See Beloit Tech. Inc. v. Valmet Paper Mach. Inc.* [1997] RPC 489, 494-495 (UK). Hence, under that law, "it is not sufficient to prove common general knowledge that a particular disclosure is

made in an article, or series of articles, in a scientific journal, no matter how widely the circulation of that journal may be." *Id.*

That is a far different and more stringent standard than whether a reference qualifies as prior art under U.S. law. For purposes of the § 103 obviousness analysis in the United States, the person of ordinary skill in the art is presumed to know all relevant prior art, no matter how obscure. That is, unlike the "common general knowledge" test, the prior art reference need not be widely known to render a patent claim obvious. *See, e.g., Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985) (the hypothetical person of ordinary skill in the art "is presumed to be aware of all the pertinent prior art"); *Hart v. L.A. Baarcke*, 396 F. Supp. 408, 412 (S.D. Fla. 1975) ("One foreign publication, no matter how obscure, may be sufficient to invalidate a patent claim . . ."). Donald S. Chisum, 2 *Chisum on Patents* § 5.04[1][b] (one of ordinary skill "is presumed to have perfect knowledge of all the pertinent prior art--however obscure the source"). Thus, in the U.K. the Roche parties were working under a different--and much tougher--standard than would apply to an obviousness analysis under U.S. law

In sum, Amgen's reliance on Roche's arguments in the UK proceedings about enablement under British patent law would conflate different and mutually exclusive legal standards. Exhibit BWZa--an argument made entirely under UK law--is therefore not relevant here. Moreover, even if the Roche brief had some probative value, that value would be decidedly outweighed by the risk of prejudice to Roche and jury confusion.

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 that no agreement could be reached.

DATED: October 4, 2007
Boston, Massachusetts

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,
ROCHE DIAGNOSTICS GMBH,
and
HOFFMANN-LA ROCHE INC.

By its attorneys,

/s/ Thomas F. Fleming
Leora Ben-Ami (*pro hac vice*)
Patricia A. Carson (*pro hac vice*)
Thomas F. Fleming (*pro hac vice*)
Howard S. Suh (*pro hac vice*)
Christopher T. Jagoe (*pro hac vice*)
Vladimir Drozdoff (*pro hac vice*)
Peter Fratangelo (BBO# 639775)
Krista M. Rycroft (*pro hac vice*)
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022
Tel. (212) 836-8000

and

Lee Carl Bromberg (BBO# 058480)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
Nicole A. Rizzo (BBO# 663853)
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110
Tel. (617) 443-9292

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
Thomas F. Fleming