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

MEMORANDUM OF LAW IN SUPPORT OF ROCHE'S MOTION *IN LIMINE* TO PRECLUDE AMGEN FROM CONFUSING THE JURY WITH STATEMENTS MADE IN EARLIER FOREIGN PROCEEDINGS

At trial, Roche will introduce clear and convincing evidence that Amgen's patents are obvious and thus invalid under 35 U.S.C. § 103. Roche expects that, in an attempt to confuse the jury, Amgen will seek to introduce statements Roche made in European proceedings regarding, for example, what was "common general knowledge" in the art during the relevant time period. While those statements touch on some of the same evidence relevant to the obviousness inquiry, they were directed to an entirely different concept--namely whether the claims in the European proceedings were supported by the patent specification. Whether a patent is obvious and whether that patent's specification supports or enables its own claims, however, are different inquiries. Because these and others statements from the European proceedings that Roche expects Amgen to offer will necessarily be taken out of context, the likelihood that they will confuse and mislead the jury outweighs any minimal probative value that the statements may have and should therefore be excluded.

For example, in British proceedings involving a European counterpart to Amgen's Lin patents, the Roche parties argued, *inter alia*, that Amgen's patent specification (including cited prior art references such as Farber *et al.*,) provided insufficient support to enable the claims in suit. Those claims were directed to cDNA ("complementary" DNA) and are not at issue in this U.S. litigation. The Roche parties argued that the European patent failed to identify a tissue source from which an EPO cDNA could be constructed. In this regard, the Roche parties noted that "common general knowledge" at the time could not substitute for the deficient support in the patent. Roche expects that Amgen will seek to introduce Roche's statements regarding what was or was not "common general knowledge" and will argue to the jury that such statements are somehow relevant to whether it would have been obvious to obtain the EPO gene through cDNA cloning. That argument is misleading, however, because what was "common general knowledge" for purposes of the enablement analysis under British patent law and what information was in the prior art for purposes of the obviousness analysis under U.S. law are entirely separate inquiries.

FACTS

Various Amgen and Roche parties were previously engaged in proceedings in the United Kingdom regarding European Patent (UK) No. 0 148 605 ("the '605 Patent"). The claims of the '605 Patent were directed to cDNA sequences from which EPO would be produced. The Roche parties involved in this UK proceeding argued that Claim 1 of the '605 Patent was not supported by the patent specification (*i.e.*, similar to an argument in U.S. litigation that claims are not enabled and are thus invalid under 35 U.S.C. § 112, ¶ 1). For example, the Roche parties argued that the availability of a tissue source for human EPO mRNA was not common general knowledge as of the patent's priority date:

> The major problem facing a skilled person who wanted to obtain human EPO DNA was the absence of a suitable tissue source of human EPO mRNA from which a cDNA library could be constructed. The Roche parties submit that it was common general knowledge that no suitable tissue source had been identified.

Exhibit A, *The Roche Parties' Skeleton Argument on the '605 Patent*, submitted in the UK Chancery Division, Patent Court proceedings CH 1993-K-No. 937 and CH 1993 B-No. 5442, at ¶ 19. *See also id.* at ¶¶ 55-58. Roche based its arguments on opinion testimony of its experts, Drs. Brammar and Fritsch. Their expert reports are attached as **Exhibits B** and **C**, respectively.

In opposition, Amgen argued that support for a suitable tissue source could be found in the patent specification, such as in the Farber ***et al***. reference cited in the specification of the '605 Patent (which shares a common specification with the Lin patents in this U.S. litigation). Roche argued that that passage did not support Claim 1 of the '605 Patent.

It is clear that in making this argument, Roche was addressing a specific issue under British patent law relating to the sufficiency of support in the specification for the claims and was not making an obviousness argument: "The Roche parties contend that this does not amount to enablement. On the contrary, it is asking the skilled person to embark on a research project." **Exh. A**, *The Roche Parties' Skeleton Argument* at ¶ 58. Indeed, Roche emphasized that it was basing its argument on the applicable legal standard for "common general knowledge" and not on what might be disclosed in the prior art for purposes of an obviousness inquiry:

> The common general knowledge is that which is generally known and regarded as a good basis for further action by the bulk of those engaged in the art in question. It is not enough that a piece of information is known to a witness or published in a document, even one which has been widely circulated and read. However, it is not necessary that the information be retained in the mind of the skilled person so long as he knows it exists and would refer to it as a matter of course as a reliable foundation for further work. See *Beloit v. Valmet* [1997] RPC 489 at 494-495 and *Raychem's Patents* [1999] RPC 497 at 503-504.

Exh. A, *The Roche Parties' Skeleton Argument* at ¶ 16.

Thus, as argued further below, the Roche parties were working from a different--and much tougher--standard than would apply to an obviousness analysis under U.S. law. Under U.S. law, information can serve as prior art even if it were not commonly known. Because of the likelihood that a jury would confuse (a) what was not "common general knowledge" with (b) whether a claimed invention was "obvious," the Court should preclude the evidence. In addition, there may be other statements that Roche made in the UK proceeding that are likewise not probative of the issues in the U.S. litigation and should be excluded for the same reasons argued below.

ARGUMENT

Amgen's expected use of Roche's arguments in the UK proceedings about enablement under British patent law would conflate different and mutually exclusive legal standards. For example, when Roche argued that a suitable tissue source for harvesting EPO mRNA was not "common general knowledge," it was not arguing that a suitable tissue source was wholly lacking in the prior art. Rather, it was merely arguing that Amgen could not meet the stringent standard for enablement under British patent law, in which the "common general knowledge" standard requires that the information not only be disclosed somewhere in the prior art but also that it be widely known. That is not the standard for whether, under U.S. law, the same information would be obvious to one of ordinary skill.

Second, aside from differences in European and U.S. patent law, statements Roche may have made to address whether certain prior art references would have provided enabling disclosures are likely to confuse the jury as to a proper obviousness inquiry. While a prior art reference must be enabling for purposes of anticipation under § 102, it need not by itself be enabling for purposes of an obviousness attack under § 103. Thus, Amgen should not be allowed

to introduce Roche's European statements to mislead the jury into thinking that Roche's prior art is not enabling and thus somehow does not qualify as prior art for the obviousness analysis (it does).

Because the distinctions in this complex patent law are often arcane, a jury could be confused or mislead. As explained below, to avoid such confusion, this Court should preclude Amgen from introducing the statements from the foreign proceeding as to what was "common general knowledge" in the art and other statements that may tend to confuse the jury.

I. WHAT IS "COMMON GENERAL KNOWLEDGE" FOR PURPOSES OF THE ENABLEMENT INQUIRY UNDER BRITISH LAW IS DIFFERENT FROM WHAT MIGHT BE KNOWN TO THOSE OF SKILL IN THE ART FOR PURPOSES OF THE OBVIOUSNESS ANALYSIS UNDER U.S. LAW

In the UK proceedings, Roche argued 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 applicable "common general knowledge" standard, 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) (attached as Exhibit D). Thus, under this standard, "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 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"); *see also Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 288 F. Supp. 2d 601, 611-12 (D. Del. 2004) (noting that the standards for determining validity under US and British law are different and thus British's court's validity findings would not collaterally estop U.S. litigant) (rev'd on other grounds).

In its statements in the UK proceedings, Roche was not saying that a tissue source did not exist, or even that it was unknown, but instead that use of a particular tissue source for the purpose of cloning the EPO gene was not "common general knowledge." Given the different standards and legal concepts they embody, and given the potential that a jury will confuse "common general knowledge" with "obviousness," the Court should exclude these statements.

II. A § 103 PRIOR ART REFERENCE NEED NOT BE ENABLING

A further danger of Amgen's expected use of Roche's statements is that Amgen will improperly contend to the jury that Roche's prior art references are not enabling (because Roche argued that prior art cited in the European patent did not enable the claims in the UK proceedings) and thus do not qualify as prior art for the obviousness analysis. That contention, however, would improperly conflate the obviousness inquiry under § 103 with the anticipation inquiry under § 102. A reference need not be enabling to serve as prior art for obviousness. *Amgen Inc. v Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1357 (Fed. Cir. 2003) ("Under § 103, however, a reference need not be enabled; it qualifies as a prior art, regardless, for whatever is disclosed therein"). The distinction between prior art under § 102 and prior art under

§ 103 is perhaps an arcane distinction in patent law that is likely to confuse a jury, especially when the distinction itself is unnecessary for any issues the jury will be considering. Thus, Roche's prior statements regarding whether certain prior art is enabling should be excluded.

III. COURTS SHOULD EXCLUDE EVIDENCE THAT WILL CONFUSE OR MISLEAD A JURY

Under Federal Rule of Evidence 403, trial courts have broad discretion to exclude evidence when the probative value of the proffered evidence is outweighed by its tendency to mislead the jury or confuse the issues. *Shepard v. United States*, 290 U.S. 96, 104 ("When the risk of confusion is so great as to upset the balance of advantage, the evidence goes out"); *U.S. v. Kepreos*, 759 F.2d 961, 964 (1st Cir. 1985) (misleading evidence of marginal relevance properly excluded); *Adams v. Providence and Worcester Co.*, 721 F.2d 870, 872 (1st Cir. 1983) (reversing judgment based on erroneous admission of evidence that resulted in juror confusion).

Litigants frequently seek to introduce documents from earlier proceedings. But even when issues in the two cases overlap, the relevance of material from the earlier proceeding is often outweighed by the likelihood that jurors will be confused by subtle but critical differences between the two cases. Indeed, the First Circuit has held that, in such situations, trial courts "have the right--indeed, the obligation--to guard against juror confusion"). *Torres-Arroyo v. Rullan*, 436 F.3d 1, 8 (1st Cir. 2006) (upholding exclusion of documents from earlier proceedings); *see also Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1276 (Fed. Cir. 1999) (upholding on ground of potential juror confusion the exclusion of evidence that party had relied upon a particular invalidity defense in an earlier trial).

In this case, Roche's statements in the UK proceedings concerning "common general knowledge" is particularly apt to cause confusion. Indeed, as argued above, information that is not "common general knowledge" may still qualify as prior art for the obviousness inquiry. The

"common general knowledge" standard reflects a very specific analysis under British patent law. "Common general knowledge is a legal term of art with a highly evolved definition. The problem, however, it that the term's colloquial, plain English meaning is misleadingly similar to "obvious." Accordingly, the substantial likelihood that the US jury will be confused into thinking that Roche was making an obviousness argument (that is, that a tissue source was not obvious) when, in fact, it was making a different argument under British law outweighs the probative value of that evidence. Thus, these and similar statements from the UK proceedings should be excluded.

CONCLUSION

For all of the reasons stated above, Roche respectfully requests that this Court preclude Amgen from introducing the statements made by Roche and its experts in the U.K. proceedings regarding what was "common general knowledge."

Dated: August 16, 2007

Respectfully submitted,

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

By their Attorneys

/s/ Kregg T. Brooks
Lee Carl Bromberg (BBO# 058480)
Robert L. Kann (BBO# 258025)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
Nicole A. Rizzo (BBO# 663853)
Kregg T. Brooks (BBO# 667348)
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110
Tel. (617) 443-9292
kbrooks@bromsun.com

Leora Ben-Ami (*pro hac vice*)
Mark S. Popofsky *(pro hac vice)*
Patricia A. Carson (*pro hac vice*)
Thomas F. Fleming (*pro hac vice*)
Howard S. Suh (*pro hac vice*)
Peter Fratangelo (BBO# 639775)
Vladimir Drozdoff (*pro hac vice*)
David L. Cousineau (*pro hac vice*)
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022
Tel. (212) 836-8000

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/s/ Kregg T. Brooks
Kregg T. Brooks

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