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 [PROPOSED] REPLY IN FURTHER SUPPORT OF THEIR MOTION *IN LIMINE* TO PRECLUDE AMGEN FROM CONFUSING THE JURY WITH STATEMENTS MADE IN EARLIER FOREIGN PROCEEDINGS

Amgen's opposition proves the point of Roche's motion *in limine*: *i.e.*, that Amgen will seek to conflate and thus confuse two distinct issues: the "common general knowledge" standard for enablement inquiries under British patent law and the obviousness inquiry under American patent law. Amgen argues, without supporting authority, that the "common general knowledge" standard is somehow subsumed in the obvious inquiry. In truth, they are distinct, and Roche's statements in the U.K. can be easily reconciled with the opinions of its experts in the U.S. litigation. As such, Roche's statements in the U.K. proceedings are not inconsistent with Roche's evidence supporting it obviousness arguments here. Thus, F.R.E. 801 does not apply.

As argued in Roche's opening brief, under British patent law, what is known in the art and what is "common general knowledge" are distinct matters but are hard to differentiate. Thus, a scientific paper can be published and widely read (and would thus qualify as prior art under 35 USC § 103) but would not necessarily be "common general knowledge." *See Beloit*

Technologies Inc. v. Valmet Paper Machinery Inc., [1997] R.P.C. 489 at 494-495. Accordingly, Amgen's attempt to equate the obviousness and common general knowledge inquiries is unfounded and would only confuse a jury.[1]

In the U.K. proceedings, the Roche parties argued that that a tissue source for human EPO mRNA was not "common general knowledge" (even though such tissue sources were available at the time) and that, therefore, Table VI of the Lin patent could not enable a claim broadly drawn to making a cDNA encoding human EPO.

Those statements are not inconsistent with the evidence Roche will offer at trial here. Both here and in the U.K., Roche has argued that it would have been known in the prior art to synthesize human EPO (even if such prior art references were obscure). The main difference (which is not inconsistent) is whether, under British patent law, doing so using the technique claimed in the U.K patent would have been "common general knowledge."

Consistent with this argument, Roche presented evidence that human EPO could be synthesized without relying on Table VI:

> The key to obtaining human EPO cDNA was not the Table VI sequence, but the 20 week old fetal liver and the library made from it. Human EPO cDNA could have been isolated from that library which mixed oligo probes without any need for the Table VI sequence. . . ..

The Roche Parties' Skeleton Argument [Exh. A to Roche's opening brief, Document 823-2 *et seq.*] at ¶ 61. In other words, Roche was not arguing in the U.K. that synthesizing human EPO

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[1] It is precisely for this reason (*i.e.*, that the standards of patentability differ between the U.S. and U.K.) that courts typically exercise caution before relying on evidence from foreign tribunals. *See, e.g., Merck & Co. v. Teva Pharma. USA, Inc.*, 288 F. Supp. 2d 601, 611-12 (D. Del. 2003) (rev'd on other grounds); *see also, e.g., Heidelberger Druckmaschinen AG v. Hantscho Commercial Products, Inc.*, 21 F.3d 1068, 1072 at n. 2 (Fed. Cir. 1994) ("We take notices of the fact that the theories and laws of patentability vary from country to country . . . caution is [thus] required when applying the action of a foreign patent examiner to deciding whether the requirements of 35 U.S.C. § 103 are met under United States law").

was novel and nonobvious. Indeed, it was obvious. Rather, Roche was arguing only that, under the strict standards of British law, and even if the method were obvious, the specification of the Lin patent (and Table VI of the patent in particular) did not enable a claim that was broad enough to cover Roche's accused process.

Amgen now focuses on a purported inconsistency between Dr. Fromm's opinion that "the Alton reference teaches all the steps necessary to synthesize large fragments of the EPO gene which could then be assembled using the known techniques in the art . . ." with Roche statements in the U.K. proceeding. But Dr. Fromm was not opining on the obviousness of making an exact copy of a cDNA but rather on the smaller (and obvious) project of synthesizing fragments of the EPO gene to create a synthetic gene by assembling those fragments. Indeed, in the UK, Roche pointed out that the two processes are distinct:

> First, the 605 patent [*i.e.*, the UK Lin patent] distinguishes between cDNA and synthetic DNA . . . This is an entirely proper distinction, not only having regard to the different processes by which the two are made but also to the fact that the two are different products with different sequences. There is no suggestion in the patent that this route could be used to make a human EPO cDNA.

The Roche Parties' Skeleton Argument at ¶ 68.

As such, Amgen cannot seriously contend that Roche's UK statements are inconsistent with the opinions of its experts in this case. The experts here are opining on different issues. This is a matter of "apples and dump trucks," of arguments made under mutually exclusive legal standards regarding different claimed inventions, not of inconsistencies.[2]

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[2] Indeed, if Roche's statements are inconsistent, then too are Amgen's statements from the UK proceedings. Here, Amgen argues that its Lin patents are not obvious. But in the UK, Amgen relied on various references, such as papers by a Professor Wall, to argue that the use of certain cells to synthesize a human EPO cDNA was a well known technique. *See, e.g., Roche Parties' Skeleton Argument* at ¶¶ 63-66.

Furthermore, even if Roche's statements qualify as party admissions under Rule 801(d)(2), as Amgen contends, that qualification merely resolves a hearsay problem. Roche, however, does not argue that the statements should be excluded based on hearsay. Rather, as argued previously, the statements should be excluded because their probative value, if any, is outweighed by the potential for confusion and prejudice. Merely because a statement is not hearsay does not mean that it is automatically admissible. A party admission under Rule 801(d)(2) may still be excluded under Rule 403. *See, e.g., Williams v. Drake*, 146 F.3d 44, 48 (1st Cir. 1998) (on appeal of a § 1983 action brought by a former prisoner asserting that a prison guard used excessive force during a prison scuffle, affirming exclusion of that prisoner's guilty plea in an earlier prison disciplinary board hearing on charges that the prisoner injured the guard and observing that a party admission was still excludable under Rule 403).

CONCLUSION

For all of the reasons stated above and in Roche's opening brief, 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: September 3, 2007

Respectfully submitted,

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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) and will be delivered to Amgen's trial counsel by electronic mail in the manner requested in the August 29, 2007, letter of Renee DuBord Brown to Thomas F. Fleming. Paper copies will be sent to those indicated as non registered participants on September 4, 2007.

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