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 OPPOSITION TO ROCHE'S MOTION TO PRECLUDE THE DEPOSITION TESTIMONY OF DR. EDWARD EVERETT HARLOW

Dr. Harlow's deposition admissions go to the heart of Roche's obviousness case and, likewise, pertain to Roche's enablement challenge related to the use of RIA (radioimmunoassay) to measure the amount of EPO produced by vertebrate cells. Given these admissions, perhaps it is not surprising that Roche has decided not to call Dr. Harlow in its case-in-chief, despite telling the Court and Amgen in the Joint Pretrial Memorandum that it would do so. Now, by its present motion, Roche seeks to preclude Amgen from introducing the deposition testimony of ***Roche's own expert***, Dr. Edward Everett Harlow, in Amgen's case in chief.

But Dr. Harlow's deposition testimony is both relevant and admissible evidence. In particular, Dr. Harlow conceded in his deposition that:

- One of skill in the art in 1983 would have understood that a DNA sequence is necessary but not sufficient to obtain protein expression and

that even with the correct DNA sequence, many steps were required to produce a functional, secreted protein like EPO;[1]

- One of skill in the art in 1983 would have understood that post-translational modifications, including glycosylation, could affect *in vivo* biological activity and were not predictable;[2]

- One of skill in the art in 1983 would have understood that changes in glycosylation could ***eliminate*** the *in vivo* biological activity of a recombinant protein;[3] and

- By December 1983, one of skill in the art could have followed the RIA referred to in Dr. Lin's patents-in-suit to quantify the levels of EPO being produced by vertebrate cells.[4]

These deposition admissions pertain to issues of obviousness and enablement placed squarely before the jury by Roche and as such are clearly relevant.

Even after his deposition, Roche has continued to adopt Dr. Harlow's statements as its own, submitting declarations by Dr. Harlow in support of its summary judgment briefing and even identifying Dr. Harlow as one of its testifying experts at trial.

Because Dr. Harlow's testimony is relevant evidence to the defenses alleged by Roche before the jury and is admissible as a non-hearsay admission by a party opponent under Fed. R. Evid. 801(d)(2), it should be admitted.

ARGUMENT

A. Dr. Harlow's Statements Are Admissions of Roche And Are Therefore Admissible At Trial under Fed. R. Evid. 801(d)(2).

Dr. Harlow has played an integral role in this case as an expert for Roche. Dr. Harlow filed an expert report, provided deposition testimony, and filed two declarations on behalf of

[1] 6/25/07 Harlow Dep. Tr. at 168: 19-22; 171:24-174:9.

[2] 6/25/07 Harlow Dep. Tr. at 197:25-198:9.

[3] 6/25/07 Harlow Dep. Tr. at 243:2-14.

[4] 6/25/07 Harlow Dep. Tr. at 252:18-23.

Roche, even after his deposition on this matter. Roche has never withdrawn Dr. Harlow as an expert in this case, and has done nothing to indicate that it no longer relies on the declarations that Dr. Harlow filed with the Court. In fact, Roche listed Dr. Harlow in the Joint Pretrial Memorandum as one of its testifying experts at trial.[5] Dr. Harlow's statements and opinions related to this matter constitute admissions on behalf of Roche.

As this Court has already found, prior statements of an expert, like Dr. Harlow, constitute admissions of the party that retained him: "What your experts have said in prior proceedings are admissions. But that's what they are, admissions. If they're relevant they come in evidence. They're not conclusive."[6] Certainly where the testimony of an expert deposed in the current proceeding is offered in the current proceeding, the argument for admissibility is even more compelling.

Not surprisingly, other courts have also found such statements admissible pursuant to Fed. R. Evid. 801(d)(2).[7] Statements made by an expert during a current litigation are admissible in that litigation as admissions. This is especially true where, as here, the party against whom the admissions are offered has taken actions that manifest an adoption of, reliance

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[5] 8/10/07 Joint Pretrial Mem., Ex. F at 7 (Docket No. 807). Amgen indicated that intended to call Dr. Harlow by deposition designation in the Joint Pretrial Memorandum. *Id*., Ex. E. at 8.

[6] 9/4/07 Trial Tr. at 5:13-20.

[7] *See Collins v. Wayne Corp.*, 621 F.2d 777, 781 (5th Cir. 1980) (finding district court erred in "not allowing the plaintiffs to offer [defendant's expert's] deposition into evidence as an admission of [defendant]"); *In re the Chicago Flood Litigation*, No. 93-1214, 1995 WL 437501, at *11 (N.D. Ill. July 21, 1995) ("A party's pleadings and expert reports often constitute party admissions pursuant to Fed. R. Evid. 801(d)(2)."); *Dean v. Watson*, No. 93-1846, 1996 U.S. Dist. LEXIS 2243, at *16 (N.D. Ill. Feb. 16, 1996) (finding that parts of experts deposition were admissions of party); *Kreppel v. Guttman Breast Diagnostic Inst., Inc*., No. 95-10830, 1999 U.S. Dist. LEXIS 19602 (S.D.N.Y. Dec. 21, 1999).

upon, or belief in the expert's statements.[8] Having relied on Dr. Harlow as an expert throughout this proceeding and having failed to withdraw him as such before trial, Roche should be bound by his statements: "When an expert witness is put forward as a testifying expert at the beginning of trial, the prior deposition testimony of that expert in the same case is an admission against the party that retained him."[9]

Notably, each of the cases cited by Roche in support of its Motion is distinguishable—both factually and legally – from the instant case.

First, in *Sabel v. Mead Johnson & Co.*, 737 F. Supp. 135 (D. Mass 1990), the plaintiff attempted to introduce an audio tape of a meeting held by defendant in which some of defendant's experts made "off the cuff" statements that were not "opinions carefully formulated after a through investigation and analysis." *Id.* at 139. In finding that these statements were not admissible, the court noted that defendants had not adopted the statements nor had they hired the experts to prepare a report on their findings or recommendations. *Id.*

Next, in *Kirk v. Raymark Industries, Inc.*, 61 F.3d 147 (3rd Cir. 1995), the testimony that the plaintiff sought to introduce at trial was from an expert that defendant had used in a prior litigation and was not using in the current litigation.

Finally, in *Koch v. Koch Industries, Inc.*, 37 F. Supp. 1231 (D. Kan. 1998), the district court precluded the plaintiff from offering testimony from defendant's expert during the plaintiff's case because the defendant indicated that it would put the expert on during its case and accordingly plaintiff was free to cross-examine the expert.

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[8] *See Kreppel,* 1999 U.S. Dist. LEXIS 19602, at *3 (finding that statements made by expert were admissible as adoptive admissions of party because party proffered her as its expert witness, produced her report as the summary of opinions to which she would testify, proffered her for deposition and then listed her as a witness).

[9] *Glendale Fed. Bank, FSB v. United States*, 39 Fed. Cl. 422, 425 (Ct. Cl. 1997); *see also Kreppel,* 1999 U.S. Dist. LEXIS 19602, at *3.

Because Dr. Harlow is an expert that Roche hired to perform an analysis and provide expert findings, because Roche has adopted and relied extensively on those analyses and findings, even submitting declarations from Dr. Harlow in support of its summary judgment briefings, and because Roche has indicated it will not call Dr. Harlow in its case-in-chief, each of these cases is distinguishable from the present case. Dr. Harlow's deposition testimony from this case should be admitted as a party admission of Roche under Fed. R. Evid. 801(2)(d).

B. Dr. Harlow's Testimony Is Relevant To Issues of Validity Placed Squarely Before the Jury By Roche.

Roche tries to cast the testimony of Dr. Harlow as relevant only to the issue of obviousness-type double patenting. In truth, however, Dr. Harlow offered opinions in his expert report and his deposition on the obviousness of Dr. Lin's patents-in-suit and, in particular, whether one of skill in the art in possession of the human EPO gene would have had a reasonable expectation of success in producing an *in vivo* biologically active recombinant human EPO. Roche put this issue squarely before the jury in the lengthy testimony of another of its obviousness experts, Dr. Lowe.

In addition, in his deposition, Dr. Harlow offered testimony regarding Claim 7 of Dr. Lin's '349 patent and whether the use of RIA to measure the quantity of EPO produced by the vertebrate host cells was enabled by Dr. Lin's patent filings. Dr. Harlow's admissions are directly relevant to contradict the anticipated testimony of Roche's expert, Dr. Flavell.

The fact is that Dr. Harlow's admissions in deposition undermine the positions taken by other of Roche's experts and that allowing Roche to put on its other experts without also hearing Dr. Harlow's significant admissions risks creating a false impression before the jury. As the Ninth Circuit has commented, "It would be intolerable to allow a party to suppress unfavorable

evidence by deciding not to use a retained expert at trial."[10] Because Dr. Harlow's testimony is relevant to issues put into dispute by Roche, it should be admitted into evidence.

C. Amgen's Use of Dr. Harlow's Testimony Is Not Prejudicial.

As set forth above, Amgen has designated testimony from Dr. Harlow because it is relevant to the issues being decided by the jury, not for any unduly prejudicial purpose. Indeed, Roche had the opportunity to avoid the prejudice it now claims it will suffer.

Amgen provided its affirmative designations to Roche on July 28, 2007 and listed Dr. Harlow in the Joint Pretrial Memorandum, thereby indicating its intent to play those designations in its case-in-chief. Since that time, Amgen has asked Roche to provide its counter-designations but Roche has refused to do so. If Roche were truly concerned about "cherry-picking," it has had the ability to submit other portions of the testimony to provide a full picture. Having refused to do so, Roche should not be allowed to sit back and argue prejudice.

Despite having Amgen's designations of Dr. Harlow's testimony in late July, Roche waited until the eve of Amgen's validity case to move to exclude this testimony – suggesting that Roche's motion is nothing more than obstructionist gamesmanship. Because Dr. Harlow's deposition testimony is relevant and admissible evidence and because Roche had ample opportunity to counter-designate his deposition testimony for context or completeness, Dr. Harlow's deposition testimony should be admitted.

CONCLUSION

For the reasons set forth above, Roche's motion to preclude the designations of Dr. Harlow (Docket No. 1098) should be denied.

[10] *See, e.g.*, *United States v. Meyer*, 398 F.2d 66, 76 (9th Cir. 1968).

Dated: September 23, 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 and paper copies will be sent to those indicated as non-registered participants on September 23, 2007.

/s/ Patricia R. Rich
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