

**IN THE UNITED STATES DISTRICT COURT  
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. 05-12237 WGY

U.S. District Judge Young

**ROCHE'S OPPOSITION TO AMGEN'S MOTION *IN LIMINE* NO. 25: EXCLUDE  
DEPOSITION TESTIMONY FROM A PRIOR LITIGATION OF TAKAJI MIYAKE, A  
NON-PARTY WITNESS WHOM ROCHE DID NOT PREVIOUSLY DISCLOSE**

**I. INTRODUCTION**

Dr. Miyake's prior deposition testimony is highly relevant to the issues in this case. Amgen's Motion *in Limine* ignores the fact that Amgen's own actions, not Roche's, necessitate the introduction of Dr. Miyake's testimony to present the jury with all pertinent facts. Amgen's counsel extensively questioned Roche's expert, Dr. Lowe, regarding Dr. Miyake's prior work. Moreover, Amgen's experts repeatedly referred to Dr. Miyake's work in their expert reports. Yet, curiously, Amgen now seeks to preclude Roche's introduction of the very evidence that Amgen has placed in issue. To allow the jury to properly assess *all* relevant facts pertaining to Roche's invalidity defenses, Roche should be permitted to introduce very brief portions of Dr. Miyake's prior deposition testimony.

**II. AMGEN, NOT ROCHE, HAS PLACED DR. MIYAKE'S PRIOR TESTIMONY IN ISSUE**

During Amgen's cross examination of Dr. Lowe, Amgen's counsel created the false impression to the jury that in 1983, Dr. Miyake already had available abundant quantities of urinary EPO, to rebut Dr. Goldwasser's prior admission that he was the only source of significant amounts of urinary EPO at the time. Amgen's counsel repeatedly attempted to establish this misleading inference in questioning Dr. Lowe about Dr. Miyake's prior work. For example:

Q: Okay. Did you perform any independent investigation to determine what sources of urinary EPO there may have been available to those skilled in the art, other than Dr. Goldwasser, prior to 1984?

A: I've done literature searches on Medline to see who did have EPO other than Dr. Goldwasser.

Q: Okay. So you did a literature search. Did you see in the literature search references to someone named Miyake?

A: I did, yes.

Q: Did you call up Dr. Miyake and ask Dr. Miyake who had EPO available in 1983?

A: I'm not sure that would help me, because I'm not sure he would know what was going on, if he's going to tell me the truth. I have to rely on what's in the prior art, what's published --

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Q: I understand. But you saw that Dr. Miyake was referenced in the prior art as a person who purified EPO; right?

A: Yes, yes.

(Trial Tr. 437:20-438:13).

Q: And your understanding was, based on what you reviewed, that one of the primary sources of useable amounts of urinary EPO for sequencing was Dr. Miyake?

A: One source was perhaps Dr. -- I don't know how much protein Dr. Miyake had available at the time. It was enough to do what Fritsch wanted to do.

(Trial Tr. 451:16-21; *see also* Trial Tr. 438:25-442:11, 445:8-16, 453:7-11, 454:21-23).

Accordingly, despite the prior statements and admissions by Dr. Fritsch and Dr. Goldwasser, Amgen has left the jury with a misleading impression of Dr. Miyake's work, and Roche should be permitted to offer brief portions of Dr. Miyake's prior deposition testimony in rebuttal.<sup>1</sup>

Courts have permitted parties to introduce testimony of a witness even when that witness was not disclosed in advance in accordance with Rule 26(a). In *Queenie, Ltd. v. Nygard Int'l*, 204 F. Supp. 2d 601 (S.D.N.Y. 2002), the court permitted defendant to introduce testimony of Chung to rebut the testimony of plaintiff's witness regarding Chung's prior work. The court noted that plaintiff opened the door on this issue and "concluded that if Chung's proposed testimony were true, barring her testimony [could amount] to a fraud upon the Court." *Id.* at 603. Similarly, precluding Roche from introducing Dr. Miyake's testimony would allow the false impression created by Amgen to go uncontested and deprive the jury of the facts necessary for it to render a thorough and fair verdict. In the interest of justice, Roche should be permitted to introduce this testimony in rebuttal. *See United States v. Soto-Beniquez*, 356 F.3d 1, 37-38 (1st Cir. 2003) (noting the considerable discretion of a trial judge in allowing departures from pretrial disclosures); *Clark v. Pennsylvania R.R. Co.*, 328 F.2d 591, 593-94 (2d. Cir. 1964) ("it is a fundamental principle of pre-trial that this procedure be flexible, with power reserved to the trial judge to amend the order or permit a departure from strict adherence to the pre-trial statements of either party, when the interests of justice make such a course desirable").

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<sup>1</sup> In total, Roche merely seeks to introduce nine (9) questions and answers from Dr. Miyake's testimony which contradict the false impression Amgen has caused.

Moreover, Amgen sought relief from the Court similar to that which it now seeks to preclude Roche from obtaining. After Amgen's counsel sought to have Dr. Lowe read his expert report to the jury and counsel went to a sidebar, Amgen's counsel stated: "My problem is, your Honor, this morning you allowed Roche to put in a deposition that created the impression that as of April or May 1984 was the first time they contact Miyake." (Trial Tr. 446:18-21). He continued: "I need to be able to rebut. They're creating an impression with this witness that's false before the jury. His own report rebuts the impression they're creating." (Trial Tr. 447:5-8). The Court granted Amgen leeway on its cross examination in this respect, and Roche merely seeks the same opportunity to eliminate any chance that the jury is being left with a false impression regarding the underlying facts it needs to consider. Roche should be permitted to present the jury with all the facts on this issue.

### **III. THERE IS NO PREJUDICE BECAUSE BOTH PARTIES UNDERSTOOD THE RELEVANCE OF DR. MIYAKE'S WORK**

Amgen's claims of "undue prejudice" stem solely from the mere technicality that Dr. Miyake was not listed as a potential witness for Roche in the Joint Pretrial Memorandum. Amgen's claims are baseless. As discussed above, it is Amgen's actions that have necessitated the introduction of Dr. Miyake's prior testimony. Moreover, Amgen produced Dr. Miyake's prior deposition testimony to Roche, and Amgen was the party who questioned Dr. Miyake in his prior deposition. Amgen therefore understood the relevance of his deposition.

Furthermore, while Dr. Miyake was inadvertently not disclosed as a potential witness in the Joint Pretrial Memorandum, he was listed as a person Roche may rely on in Defendants' 35 U.S.C. § 282 Notice. (D.I. 799 at 39). Moreover, in the Joint Pretrial Memorandum filed on August 10, 2007, there were repeated references to the relevance of Dr. Miyake's work, including reference to the very issues discussed in Roche's designated testimony. (*See* D.I. 807,

p. 41 ¶2, p. 44 ¶18, p. 59 ¶99, p. 60 ¶102, p. 61 ¶106-08, p. 61 ¶111-12, p. 65 ¶17, p. 65 ¶20, Ex. B ¶164, Ex. B ¶202, Ex. B ¶217). Similarly, Amgen's own experts repeatedly relied on Dr. Miyake's work in their expert reports. (*See* Bradshaw Report (5/11/07) ¶¶ 55, 60-61, 66, 68-69, 73-74; Wall Report (5/11/07) ¶¶11, 13, 27, 30; Varki Report (5/11/07) ¶¶ 63-70, 72, 75-76, 79, 88, 132-33, 145, 185-86, 213; McLawhon Report (5/11/07) ¶¶ 63-65, 76, 102; Lodish Report (5/11/07) ¶¶ 120, 214, 216, 218, 474; Goldwasser Report (5/11/07) ¶¶ 33-34, 63-65, 86-88, 101-05, 143, 154; Eschbach Report (5/11/07) ¶¶ 53, 74, 76, 187; Capra Report (5/11/07) ¶¶ 21, 105; Bradshaw Report (6/1/07) ¶17; Friedman Report (6/26/07) ¶ 56). Accordingly, Amgen clearly understood that Dr. Miyake's prior work may be pertinent to this case and its claims of unfair surprise and undue prejudice are baseless fiction. *See Queenie*, 204 F. Supp. 2d at 603 (admitting testimony where plaintiff "knew the content of Chung's proposed testimony, and would therefore suffer no unfair surprise from the use of her testimony"); *id.* at 604 ("[o]bviously, independent of the litigation, plaintiff knew what the facts were concerning" Chung's testimony).

#### **IV. THE UNAVAILABILITY OF THE DECLARANT IS IRRELEVANT IN THESE CIRCUMSTANCES**

Amgen relies on Fed. R. Civ. P. 32(a) and Fed. R. Evid. 804(b)(1) in support of its argument that Roche should be precluded from introducing the testimony of Dr. Miyake without demonstrating his unavailability. However, Roche has made an effort to locate Dr. Miyake, including internet searches and use of tracking services on Westlaw and LexisNexis, all to no avail. It is entirely unclear where Dr. Miyake currently resides, or if he is even alive. Moreover, even if Dr. Miyake was not "unavailable," the Federal Rules of Civil Procedure and the Federal Rules of Evidence have residual exceptions that permit the introduction of evidence in the absence of unavailability if "the interests of justice" will be served by its admission. *See* Fed. R.

Civ. P. 32(a)(3)(E); Fed. R. Evid. 807. Roche has clearly demonstrated that the interests of justice will be served by the Court's admission of Dr. Miyake's prior testimony. Amgen injected the issue of Dr. Miyake's work into this case by its misleading cross examination of Dr. Lowe. The jury is now left with an incomplete framework for assessing Roche's invalidity claims, and the Court should, in the interests of justice, permit Roche to provide the jury with all the facts it needs to render its verdict.

## **V. CONCLUSION**

For the reasons stated in this memorandum, Roche respectfully requests that the Court deny Amgen's Motion *in Limine* and permit Roche to introduce very brief portions of Dr. Miyake's prior deposition testimony to provide the jury with a complete version of the relevant facts.

Dated: September 10, 2007

Respectfully submitted,

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ROCHE DIAGNOSTICS GMBH, and  
HOFFMANN-LA ROCHE INC.

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### **CERTIFICATE OF SERVICE**

I certify that, on the above date, 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 paper copies will be sent to those indicated as non registered participants.

/s/ Keith E. Toms

Keith E. Toms

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