

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

_____	)	
AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	CIVIL ACTION No.: 05-CV-12237WGY
F. HOFFMANN-LA ROCHE LTD	)	
ROCHE DIAGNOSTICS GmbH	)	
and HOFFMANN-LA ROCHE INC.	)	
	)	
Defendants.	)	
_____	)	

**DEFENDANTS’ OPPOSITION TO PLAINTIFF’S MOTION *IN LIMINE* NO. 9:  
TO EXCLUDE THE TESTIMONY OF DEFENDANTS’ EXPERTS KADESCH  
AND LOWE REGARDING PROTEIN SEQUENCING**

Defendants F. Hoffmann-La Roche, Ltd, Roche Diagnostics GmbH and Hoffmann-La Roche Inc. (collectively “Roche”) submit this opposition to Amgen’s motion *in limine* no. 9 to exclude the testimony of Roche’s experts Dr. Thomas Kadesch and Dr. John Lowe regarding protein sequencing due to their lack of expertise.

**I. INTRODUCTION**

Amgen’s motion is predicated on the false premise that Roche’s experts, “Drs. Kadesch and Lowe have no specialized knowledge, skill, experience, training or education in protein sequencing” and thus are unable “to help the jury understand the process and its nuances.” (Amgen Br. 1-2). In fact, both distinguished researchers are

most certainly qualified to testify on protein sequencing and will “assist the trier of fact” in accordance with F.R.E. 702. Accordingly, Amgen’s motion should be denied.

## II. ARGUMENT

Federal Rule of Evidence 702 permits testimony by a “witness qualified as an expert by knowledge, skill, experience, training, or education” to testify when “scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue.” Thus, “[t]he trial court must determine that the proffered expert witness is ‘qualified as an expert by knowledge, skill, experience training or education’ before permitting his testimony to be presented to the jury.” *Gaydar v. Sociedad Instituto Gineco-Quirurgico y Y Planificacion Familiar*, 345 F.3d 15, 25 (1st Cir. 2003).

“Rule 702 has been interpreted liberally in favor of the admission of expert testimony.” *Levin v. Dalva Bros. Inc.*, 459 F.3d 68, 78 (1st Cir. 2006). Accordingly, “expert witnesses need not have overly specialized knowledge to offer opinions.” *Id.* See also *Gaydar*, 345 F.3d at 24 (“The proffered expert physician need not be a specialist in a particular medical discipline to render expert testimony relating to that discipline”); *Lauria v. National R.R. Passenger Corp.*, 145 F.3d 593, 598-99 (3d Cir. 1998) (“it is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate”); *Payton v. Abbott Labs.*, 780 F.2d 147, 155 (1st Cir. 1985) (“the fact that the physician is not a specialist in the field in which he is giving his opinion affects not the admissibility of his opinion but the weight the jury may place on it”).

Here, Amgen would have this court bar Drs. Lowe and Kadesch from testifying on protein sequencing because of their lack of first-hand experience sequencing proteins. However, both scientists are widely published authorities in the area of molecular biology generally, both have specialized knowledge regarding protein sequencing that will assist the jury and both plainly considered themselves competent to testify on the subject matter set forth in their expert reports.

Dr. John Lowe is an M.D. and is a Professor and Chair of the Department of Pathology at Case Western Reserve University School of Medicine. Dr. Lowe has more than 25 years of experience in the field of protein science and protein modification. He has served on the editorial boards of publications such as the *Journal of Biological Chemistry* and *Molecular Medicine*. In addition, he has lectured widely and has co-authored more than 135 published scientific articles.

Two of Dr. Lowe's papers are of particular note. *See* Lowe, J.B., et al. "Expression of a mammalian fatty acid-binding protein in *Escherichia coli*," *J. Biol. Chem.* 259:12696-704, 1984; Lowe, J.B., et al., "Expression of rat intestinal fatty acid binding protein in *E. coli*," *J. Biol. Chem.* 262:5931-37, 1987. These articles, which were submitted for publication in April 1984 and October 1986, respectively, both describe protein sequencing. At his deposition, Dr. Lowe testified with respect to the fatty acid binding proteins that were the subject of these papers: "I isolated them, I purified them, I ran them on gels. In one case, I sequenced them." (Tr. (6/25/07) at 19:20-21). Dr. Lowe explained that the proteins were sequenced via "Edman degradation" using a "Beckman spinning cup sequenator," though he did not personally operate the machine. (*Id.* at 20:1-12).

Thus, in the course of his work, Dr. Lowe has gained specific knowledge and experience on those scientific topics that are germane to his research, including protein sequencing. As Dr. Lowe testified: “I would say that I probably knew more than the average scientist about protein sequencing, but not as much as some individuals.” (Tr. (6/25/07) at 8:24-9:1)<sup>1</sup>.

In short, even though Dr. Lowe is not a specialist with respect to protein sequencing specifically, he is more than qualified, under Rule 702, to give scientific testimony regarding protein sequencing that will assist the jury in this case.

Dr. Thomas Kadesch was awarded a Ph.D. in biochemistry by the University of California and is a Professor of Genetics at the University of Pennsylvania School of Medicine where he has been a member of the faculty since 1984. Dr. Kadesch has co-authored more than 70 published scientific articles. From 1992-1996, Dr. Kadesch served as editor of the scientific journal *Molecular and Cellular Biology*. At his deposition, Dr. Kadesch made clear that he has conducted research on proteins and, in the course of his work, has gained an understanding of protein sequencing from reading the scientific literature. (Tr. 6/21/07 at 217:7-18). Although he is not a specialist in the field of protein sequencing in particular, as an experienced biochemist and molecular biologist with knowledge of the scientific literature on protein sequencing, Dr. Kadesch is qualified, under F.R.E. 702, to give scientific testimony regarding protein sequencing that will assist the jury in this case.

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<sup>1</sup> In fact, it is apparent that the portion of Dr. Lowe’s deposition which Amgen relies upon to demonstrate Dr. Lowe’s lack of specialization shows that Dr. Lowe specifically reserved his right to review his supplemental report, and that if anything, he was misinformed by Amgen counsel’s questioning.

It is curious that Amgen takes issue with the fact that Drs. Lowe and Kadesch incorporate into their opinions, by reference, the opinions of another Roche expert, Dr. Michael Fromm. At Amgen's insistence, the parties agreed to limit the number of expert witnesses who would be permitted to testify at trial. This agreement forced both parties to consolidate the expert opinions so that the agreed-upon number of experts would be able to address all necessary points. For example, in his July 20, 2007 expert report, Amgen's expert Dr. Vladimir Torchilin, adopted wholesale the opinions of another Amgen expert, Dr. Nandini Katre. Similarly, in his June 20, 2007 expert report, Amgen expert Dr. Harvey Lodish adopted the opinions of Dr. J. Donald Capra. The fact that Drs. Lowe and Kadesch adopted Dr. Fromm's opinions on protein sequencing is not in any way evidence that they are not themselves qualified to testify as experts on this subject.

Amgen's criticism of the testimony of Drs. Lowe and Kadesch is equally flawed. Testimony from qualified experts should not be excluded because the witness is modest in assessing his or her expertise. See *Watson v. United States*, 485 F.3d 1100, 1106 (10<sup>th</sup> Cir. 2007) (an expert should not be disqualified merely because he or she "may be too demure to trumpet his or her qualities under cross examination."). Amgen's criticism seems especially hollow in light of testimony by Amgen's own expert Harvey Lodish. In his supplemental expert report, dated June 20, 2007, Dr. Lodish opines that in 1983 "a person of ordinary skill in the art...would not have reasonably expected to successfully sequence the entire amino acid sequence of human urinary erythropoietin." (¶8). However, at his July 3, 2007 deposition, Dr. Lodish testified: "I'm not an expert in amino acid sequencing, per se." (Tr. 7/3/07 at 147:17-18). Amgen cannot expect to have

Dr. Lodish testify as an expert on protein sequencing and at the same time preclude Drs. Lowe and Kadesch from testifying on that subject.

### **III. CONCLUSION**

Contrary to Amgen's assertions, pursuant to F.R.E. 702, both Dr. Lowe and Dr. Kadesch are qualified through their extensive knowledge, skill, experience, training and education to give expert testimony on protein sequencing. Accordingly, Amgen's motion should be denied in all respects.

Dated: September 1, 2007  
Boston, Massachusetts

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,  
ROCHE DIAGNOSTICS GMBH,  
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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 paper copies will be sent to those indicated as non registered participants on the above date.

/s/ Keith E. Toms

Keith E. Toms