

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.)	
_____)	

**ROCHE’S OPPOSITION TO AMGEN’S BENCH MEMORANDUM
(D.I. 1267) THAT IT IS APPROPRIATE FOR DR. LODISH
TO USE COMPUTER-MODELED DEMONSTRATIVES**

The Court should not permit Amgen to present highly misleading computer-modeled animated demonstratives , which have essentially no basis in scientific data, during its infringement case for the following reasons:

- The animations at issue purport to represent three dimensional images of Roche’s Mircera® molecule and human EPO that Amgen will use to convey to the jury that Mircera is the same as the human EPO in the patent claims. In fact, the animations, which Amgen admits are not based on “any scientific tests” are not remotely accurate representations either of Mircera or the human EPO in the claims. Rather the animations are based on a mutant form of EPO grown in bacterial cells onto which Amgen animators have drawn sugars and modified the amino acid sequence to make it seem that Mircera and human EPO are the same.
- Dr. Lodish admits that he has no personal knowledge of how the animations were created.
- Dr. Lodish fails to explain the animations in any of his five expert reports, precluding him from testifying about them to the jury.

A. The Animations Are Not Remotely Accurate Representations of the Molecules at Issue

In order to aid the jury, a demonstrative exhibit must be both “fair” and “accurate.” *Keller v. United States*, 38 F.3d 16, 32 n.10 (1st Cir. 1994) (citing *United States v. Myers*, 972 F.2d 1566, 1579 (11th Cir. 1992)); *see also Lorraine v. Markel Am. Ins. Co.*, 241 F.R.D. 534, 559 (D. Md. 2007) (a demonstrative exhibit must be sponsored by “a witness with personal knowledge of the content of the animation, upon a showing that it fairly and adequately portrays the facts”). Moreover, a demonstrative aid must not mislead the jury. *See Shipp v. Gen. Motors Corp.*, 750 F.2d 418, 427 (5th Cir. 1985) (affirming district court decision excluding demonstrative video because it would “mislead, confuse, or prejudice the jury”). Similarly, in *United States v. Buck*, 324 F3d 786 (5th Cir. 2003) -- a case relied upon by Amgen -- it is an “essential requirement” that demonstratives be “supported by evidence in the record.” *Id.* at 791 (quoting *United States v. Diez*, 515 F.2d 892, 905 (5th Cir. 1975)).

Here, the animations are anything but accurate. Rather, they represent movies of molecules fabricated by Amgen based on data that was significantly altered to make it seem that Mircera is the same as the claimed invention. The proof of this is in Dr. Lodish’s report itself.

Dr. Lodish admits in his report that it is not possible to obtain the type of scientific data regarding Mircera needed in order to create a true and accurate model. In his report, Dr. Lodish states that Mircera “has not, and indeed cannot, be captured using techniques like x-ray crystallography,” the technique that is crucial to obtaining the data to create the type of three dimensional animation that Amgen seeks to use. Lodish I at ¶ 102 n. 25. Recognizing the impossibility of using a scientific tests to accurately create what Amgen represents on the

animations, Dr. Lodish then says that “virtually any model” of Mircera is “physically plausible.” *Id.* In other words, Dr. Lodish claims it is fine to make it up as you go along.

And that’s exactly what Amgen did. Without the any accurate way of obtaining data to model Mircera, Amgen used data from a mutant form of EPO that clearly is *not* human EPO in the claims of the patents. As Dr. Lodish also admits, the source for the crystallography data that the animations are based upon is a “mutated form of human EPO” that is expressed in *E. Coli* cells -- not, as the claims required, mammalian cells. Lodish I ¶29 n. 6. The mutant EPO not only has a different amino acid sequence than the claimed human EPO, but also has no glycosylation. *Id.*

Because of these differences, the animators had to “delete” the amino acid at site 166, and mutate amino acid residues to account for the absence of glycosylation. Lodish I ¶29. These changes were made, as Dr. Lodish’s report makes clear, as part of an effort to make the animated models more representative of the Mircera and claimed human EPO molecules. *Id.* Indeed, Amgen itself has admitted that “no scientific tests were performed . . . in connection with the generation of the graphics,” and that the animation’s “representation of the attached carbohydrate and peg moities are not based on any x-ray crystallography data.” *See* Curto Declaration, Exh. B.

Without any doubt, the animations are of molecules that are not based on data regarding the Mircera molecule or even the human EPO claimed in the patents. Yet, that when viewing this movie, that is exactly the impression the jury will have -- that the fabricated molecules on the screen are accurate representations. Because the movie is inherently misleading, the Court should preclude Amgen from using it with Dr. Lodish, or any other Amgen witness.

B. Dr. Lodish Has No Personal Knowledge of the Creation of the Animations

As mentioned, in order to use a demonstrative exhibit with a witness, that witness must have personal knowledge of the demonstrative aid. *Lorraine*, 241 F.R.D. at 559; see also FRE 602 (requiring a witness to have personal knowledge of the subject matter of testimony). Here, Dr. Lodish admits that he doesn't know how the models depicted in the animations were created. In the little description of the animations found within his expert reports, Dr. Lodish avers that he had "been informed that the model used to generate the images and animations," used certain modeling tools. Lodish I ¶29. Thus, Dr. Lodish did not design the model used, did not determine that the model used was appropriate, or seemingly have any involvement in the process that led to this animation. Without any personal knowledge of the animation, Dr. Lodish may not use the demonstrative during his testimony.

C. Dr. Lodish Fails to Describe the Animation In Any of His Five Expert Reports

As explained more fully in Roche's Motion in Limine To Preclude Dr. Lodish From Presenting Animations Not Described in His Expert Reports, Dr. Lodish cannot testify about the animations because he has not explained the pertinence of this animation to his opinions in any of his five reports. Nowhere in those reports is there any meaningful description of these animations and what point he will make in reliance upon them. This Court has consistently prevented experts from using demonstrative aids that are not described and explained in their reports. The Court should make no exception here.

CONCLUSION

The Court should preclude Amgen from using the animations during the testimony of Dr. Lodish.

DATED: Boston, Massachusetts
October 4, 2007

Respectfully submitted,

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

By their Attorneys,

/s/ Thomas F. Fleming

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CERTIFICATE OF SERVICE

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/s/ Thomas F. Fleming
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