

**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.: 05-12237 WGY

**AMGEN INC.’S OPPOSITION TO ROCHE’S MOTION *IN LIMINE*  
TO EXCLUDE THE FACT TESTIMONY AND EXPERT TESTIMONY  
OF DR. CATLIN**

Roche waived any objection to the relevance of Dr. Catlin’s work when, during its direct examination of Dr. Bertozzi, Roche asked her to opine on the isoelectric focusing (“IEF”) test that Dr. Catlin performed, stating:

- Q. Dr. Bertozzi, have you reviewed an IEF gel that's relied on by Amgen's experts and prepared by Dr. Catlin?
- A. Yes, I have.
- Q. And what does this IEF gel compare?
- A. In my recollection, the IEF gel compares various commercial erythropoietin preparations in addition to urinary erythropoietin.
- Q. And what did this IEF analysis show?
- A. Well, the IEF analysis shows that there are structures in the commercial erythropoietins from recombinant cells that are the same as structures from urinary erythropoietin.
- Q. So from that -- from the results of that IEF gel, what do you conclude?
- A. My conclusion from that gel is that the structures in the recombinant erythropoietin are the same as structures in human urine. <sup>1</sup>

<sup>1</sup> Sept. 14, 2007 Trial Transcript, p. 1062: 4-19.

Roche cannot have it both ways. Roche elicited testimony on direct from Dr. Bertozzi that Dr. Catlin's IEF is consistent with her opinion. Roche cannot now claim that Dr. Catlin's testing is irrelevant.

Moreover, any claims by Roche related to Dr. Catlin's opinions are based on the faulty logic that he will provide expert testimony. Dr. Catlin will only testify to the factual circumstances surrounding his laboratory's testing of a variety of erythropoietin preparations and urinary erythropoietin by the IEF technique. As Dr. Bertozzi acknowledged, the IEF is a commonly used technique to "understand the structure of a glycoprotein."<sup>2</sup> Dr. Catlin will authenticate the photograph of his IEF, which Dr. Bertozzi referenced in her testimony.<sup>3</sup> There can be no dispute that Dr. Catlin was imminently qualified to perform an IEF. For the past seven years, he has supervised thousands of IEFs as part of his work in researching, developing and administering tests to detect erythropoietin in the urine of athletes.

**I. Roche Waived Any Objection To The Relevance of Dr. Catlin's Testimony When It Asked Its Expert To Opine On The Results of Dr. Catlin's Testing.**

Roche waived any objection to the relevancy of Dr. Catlin's IEF when it opened the door to this testimony by eliciting Dr. Bertozzi's opinions about Dr. Catlin's work. In response to questions Roche asked, Dr. Bertozzi told the jury that she reviewed the IEF gel that Dr. Catlin prepared and that based on that IEF "the structures in the recombinant erythropoietin are the same as structures in human urine."<sup>4</sup> Furthermore, Dr. Bertozzi testified on direct about the technique of an IEF, explaining the process and that the end result is "a picture of this IEF gel,"<sup>5</sup> and telling the jury it is "a technique that we also use to understand the structure of a

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<sup>2</sup> *Id.* at 1025: 3-11.

<sup>3</sup> *Id.* at 1062: 4-7.

<sup>4</sup> *Id.*

<sup>5</sup> *Id.* at 1026: 11 – 1027: 19.

glycoprotein.”<sup>6</sup> It is incredibly disingenuous for Roche to now claim that Dr. Catlin’s IEF test is irrelevant. Roche has told the jury Dr. Catlin’s test supports Dr. Bertozzi’s opinion, Amgen is entitled to put Dr. Catlin’s photograph of his IEF into evidence so that Amgen can later show through its own expert testimony that Dr. Bertozzi’s claim is fallacious.

Contrary to Roche’s motion, Dr. Catlin’s IEF *is* relevant to Roche’s claims regarding prior art EPO. First, as part of its rebuttal case, Amgen will offer the testimony of Dr. Ajit Varki who will explain Dr. Catlin’s IEF is relevant because of the relationship between the unpurified urinary EPO tested by Dr. Catlin and Goldwasser’s purified urinary EPO.<sup>7</sup> Second, Dr. Catlin’s experiment actually included an authentic prior art urinary EPO preparation prepared in 1972 — the “2<sup>nd</sup> IRP.” Third, although Roche claims in its motion that prior art EPO is limited to Goldwasser’s urinary EPO, the testimony Roche has elicited at trial has not been so targeted. At trial Roche’s expert Dr. Spinowitz has claimed that Dr. Lin’s product claims are anticipated by unpurified naturally occurring EPO in human plasma.<sup>8</sup> Therefore Amgen is also entitled to rebut this prior art attack. Dr. Catlin’s IEF experiment is relevant because it includes unpurified naturally occurring EPO from human urine which is a highly relevant comparator to the plasma alleged prior art.

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<sup>6</sup> *Id.* at 1025: 8-11. *See also* pp. 1087: 3-5 (confirming that an IEF can be used to study certain aspects of a glycoprotein like EPO). Incredibly, Roche claims in its motion that Dr. Catlin’s test is irrelevant because he testified the IEF does not provide any information regarding the molecular structure of the uEPO and rEPO samples tested. But Amgen has not offered Dr. Catlin to provide this testimony. Amgen will offer Dr. Ajit Varki, who will directly rebut Dr. Bertozzi’s opinions about Dr. Catlin’s IEF.

<sup>7</sup> 5/11/07 Expert Report of Dr. Ajit Varki ¶ 107.

<sup>8</sup> September 11, 2007 Trial Transcript p. 761: 12-22. Amgen does not in any way endorse Roche’s claims regarding prior art.

**II. Dr. Catlin's Has Vast Experience In Conducting IEF Tests.**

Dr. Catlin's expertise relevant to this case is his vast experience in conducting IEFs. Roche's own expert, Dr. Bertozzi, acknowledged the relevance of these tests and their accepted use to study glycoproteins like EPO.<sup>9</sup> Roche's characterization of Dr. Catlin's expertise as limited to administering doping tests for athletes is extremely misleading. The principal tool that Dr. Catlin uses to develop, administer and research EPO doping tests for athletes is the IEF. As part of this work, he has overseen thousand of IEFs involving the study of EPO. The very basis of this test is that urinary and recombinant EPOs have molecular differences which confer different physical properties that allow them to be distinguished by the IEF technique. There can be no question that Dr. Catlin is eminently qualified to perform the IEF that he conducted, and which Roche's own expert claimed supported her opinions.

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<sup>9</sup> Sept. 14, 2007 Trial Transcript, p. 1025: 8-11. *See also* pp. 1087: 3-5.

Dated: September 24, 2007

Respectfully Submitted,

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By its attorneys,

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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 on-registered participants.

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