

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

AMGEN, INC.,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 05 CV 12237 WGY
)	
F. HOFFMANN-LAROCHE LTD.,)	
a Swiss Company, ROCHE DIAGNOSTICS)	
GMBH, a German Company, and)	
HOFFMANN LAROCHE INC., a New)	
Jersey Corporation,)	
)	
Defendants.)	

**BRIEF IN SUPPORT OF AMGEN'S MOTION *IN LIMINE* NO. 23:
EXCLUDE TESTIMONY OF DANIEL SHOVAL REGARDING ERYTHROPOIETIN-
PRODUCING CELL LINES AND HIS WORK ON EPO MRNA**

I. INTRODUCTION

Amgen requests that this Court exclude testimony from Daniel Shouval on the topics of erythropoietin-producing cell lines and his work on EPO mRNA. Dr. Shouval was originally designated by Roche as an expert witness, but at the last minute was listed as a fact witness on Roche's witness list.¹ In his expert report, Dr. Shouval opined at length on the subjects of erythropoietin-producing cell lines and his work on EPO mRNA in the 1980s. During his deposition, however, he refused to answer certain questions regarding erythropoietin-producing cell lines and his work on EPO mRNA on the grounds that he was foreclosed from doing so as a result of being a party to a confidentiality agreement with a third party—the Albert Einstein College of Medicine. Apparently for the same reason, at his deposition, Roche's counsel repeatedly objected to questions as beyond the scope of Dr. Shouval's expert report, and Dr. Shouval sought to limit his responses to matters contained in his report. Such objections and limitations may have been appropriate in the context of his rendering expert opinions, but not in the context of his current status as fact witness. It appears that Roche may have re-designated Dr. Shouval as a fact witness at the 11th hour in the belief that, if he were merely a fact witness—and not an expert testifying on Roche's behalf—his testimony would be less vulnerable to motions to exclude for failure to answer questions at deposition. Dr. Shouval foreclosed any discovery into erythropoietin-producing cell lines and his work on EPO mRNA. Roche should now not be permitted to ambush Amgen at trial with such testimony, merely because at the last minute it converted its expert to a fact witness.

¹ Docket No. 807-7 at p. 2.

II. ARGUMENT

Daniel Shouval was initially disclosed as an expert on February 25, 2007.² On March 27, 2007 Dr. Shouval was additionally listed in Roche's "Defendants' Supplemental Disclosure Statement" under Fed. R. Civ. P. 26(a) as an individual likely to have discoverable information relating to "knowledge of erythropoietin-producing cell lines prior to Amgen's EPO patents."³ The following week, on April 6, 2007, Dr. Shouval submitted his expert report in the case.⁴ The report contained, among other things, a discussion of the same topics identified in the Rule 26(a) disclosure, that is, topics relating to his knowledge of erythropoietin-producing cell lines allegedly existing prior to Amgen's EPO patents.

Dr. Shouval was deposed on May 24, 2007. He refused to answer numerous questions during his deposition, including questions that bore directly on the opinions in his expert report and on the subject for which he was identified as an individual having relevant information. For example, in his expert report, Dr. Shouval opined "as to whether a person of ordinary skill in the art would have considered such a [renal carcinoma] cell line to be an obvious source of erythropoietin mRNA prior to October of 1983," and he offered the opinion that "as documented by our April 1983 Clinical Research abstract, we had conceived of using the RC-1 cell line as a source of erythropoietin."⁵ Yet, when he was asked in his deposition if anyone had tried to isolate total mRNA from the RC-1 cell line, he stated that while the information is in a text he has, he could not provide it because it is covered by his confidentiality agreement with Albert Einstein.⁶

Dr. Shouval also refused to testify on whether he could have worked on EPO mRNA

² Agreement to Abide by Protective Order signed by Daniel Shouval, February 25, 2007.

³ Defendants' Supplemental Disclosure Statement at 10, March 27, 2007.

⁴ 4/6/2007 Expert Report of Dr. Daniel Shouval.

⁵ 4/6/2007 Expert Report of Dr. Daniel Shouval at 1.

before October 1983.⁷ Moreover, he also refused to testify on other issues germane to his expert opinions and anticipated factual testimony, such as: the subject matter of agreements between Dr. Shouval and the Albert Einstein College of Medicine on the handling of cells,⁸ whether he could have worked on the subject of EPO mRNA before October 1983,⁹ the investigation of potential commercial exploitation of RC-1 cells,¹⁰ his knowledge if others had successfully cloned the EPO gene,¹¹ individuals who may have attempted to isolate total mRNA from the RC-1 cell line,¹² as well as multiple other topics and lines of questions.¹³ As indicated, Dr. Shouval based his refusal to answer on the grounds that such information was subject to a confidentiality agreement with Albert Einstein College of Medicine, and that he not yet received clearance to talk about such information. For the same reason, he also refused to produce documents material to the questions he was being asked.¹⁴

Dr. Shouval also limited his answers based on information being outside the scope of his expert report, stating “I’m not sure this is something to do with my expert opinion in terms of the situation. I mean, if I’m asked specific questions related to the expert opinion, I will be happy to answer.”¹⁵ Roche’s counsel made multiple objections and limited the lines of questions by repeated objections that the questions posed were outside the scope of Dr. Shouval’s expert

⁶ Deposition of Daniel Shouval at 252:12-253:20 (May 24, 2007)

⁷ Deposition of Daniel Shouval at 246:4-12 (May 24, 2007).

⁸ Deposition of Daniel Shouval at 42:11-43:8, 44:2-44:24, 45:10-46:2 (May 24, 2007).

⁹ Deposition of Daniel Shouval at 242:22-246:12 (May 24, 2007).

¹⁰ Deposition of Daniel Shouval at 94:11-23 (May 24, 2007).

¹¹ Deposition of Daniel Shouval at 258:12 (May 24, 2007).

¹² Deposition of Daniel Shouval at 252:22-253:15 (May 24, 2007).

¹³ See e.g., Deposition of Daniel Shouval at 51:20-52:22, 168:10-169:23, 170:7-170:21, 202:21-203:5, 227:14-229:4, 242:9-243:3, 244:22-246:12, 252:12-253:20, 258:12-258:24 (May 24, 2007).

¹⁴ See, e.g. Deposition of Daniel Shouval at 168:10-169:23 (March 27, 2007).

¹⁵ Deposition of Daniel Shouval at 51:20-52:22 (May 24, 2007). See also Deposition of Deposition of Daniel Shouval at 99:7-99:14, 146:11-146:22, 272:1-272:9, 272:15-273:2, 274:13-

report.¹⁶

Certainly an expert witness is obligated to testify fully at deposition concerning his opinions and the bases therefor.¹⁷ Moreover, under Rule 26(e)(1) each party is under a continuing duty to supplement information that is material to the case, and this duty extends to both an expert's report and deposition.¹⁸ The Court has broad discretion in meting out sanctions for failure to comply with Rule 26(e)(1) disclosures.¹⁹ Under Fed. R. Civ. P. 37(c) a party is not permitted to use as evidence at trial, at a hearing, or on a motion any witness or information that they failed to disclose under Rule 26(e)(1).²⁰ Needless to say, Roche never supplemented Dr. Shouval's expert report or deposition with the missing correspondence,²¹ and it never supplemented his deposition answers pertaining to erythropoietin-producing cell lines and his work with EPO mRNA, matters as to which he refused to answer pertinent questions during his deposition.

Roche appears intent on circumventing the rules preventing one party from ambushing the other by presenting expert opinion as to which the other party has not been able to conduct full discovery. On August 10, 2007, just twenty-five days before trial, Roche filed before the Court, as part of the joint pre-trial memorandum, Roche's "Preliminary List of Trial Witnesses" which listed Dr. Shouval as a fact witness; however the expert report of Dr. Shouval was never withdrawn.²² Presumably, Dr. Shouval's testimony as a fact witness will be related to the topic

275:5 (May 24, 2007).

¹⁶ *e.g.* Deposition of Daniel Shouval at 100:3 – 100:13 (May 24, 2007).

¹⁷ 5/2/2007 ORDER Denying Motion to Compel Continued Deposition of Dr. Thomas Strickland and Production of Related Documents.

¹⁸ Fed. R. Civ. P. 26(e)(1) (UCSC 2007).

¹⁹ *Lily LaPlace-Bayard v. Dr. Franco Battle*, 295 F.3d 157, 162 (1st Cir. 2002). Fed. R. Civ. P. 37(c) (UCSC 2007).

²⁰ Fed. R. Civ. P. 37(c)(1) (USCS 2007).

²¹ *See, e.g.* Deposition of Daniel Shouval at 168:10 – 169:23 (May 24, 2007).

²² 8/10/2007 Joint Pretrial Memorandum, Ex. F at 2.

listed in Roche's Rule 26(a) disclosure: "knowledge of erythropoietin-producing cell lines prior to Amgen's EPO patents." As discussed, that topic was covered at length in his expert report, and was among the subjects of his refusals to answer during the deposition.²³

Roche's decision to convert Dr. Shouval to a fact witness only leaves Amgen having to guess what his testimony will cover, but more particularly exposes Amgen to the risk that he will testify at trial on matters that he refused to answer questions at deposition. Such a result undermines the purpose of Rule 26 to "avoid trial by ambush."²⁴ As the First Circuit has recently reiterated, trial is meant to be "a fair contest with the basic issues and facts disclosed to the fullest possible extent."²⁵

III. CONCLUSION AND RELIEF SOUGHT

For the reasons above, Amgen requests an order excluding testimony of Daniel Shouval relating to erythropoietin-producing cell lines and his work in connection with EPO mRNA.

²³ See, e.g. Deposition of Daniel Shouval at 170:18-21 (refusing to discuss whether the cell lines could be provided to third parties); 226:10-228:5 (refusing to discuss the circumstances of a 1982 patent application that described the RC-1 cell line); 244:22-246:12 (refusing to provide information on if he worked on EPO mRNA prior to October 1983 but rather stating he was working under "the agreement" but refusing to provide details of what the agreement was.) (May 24, 2007).

²⁴ *Macaulay v. Anas*, 3231 F.3d 45, 50 (1st Cir. 2003).

²⁵ *Id.* at 52 – 53 (quoting *United States v. Procter & Gamble Co.*, 356 U.S. 677, 682, 2 L. Ed. 2d 1077, 78 S. Ct. 983 (1958)).

Respectfully Submitted,

Date: September 4, 2007

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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 4, 2007.

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