

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'S MOTION IN LIMINE TO PRECLUDE ROCHE
FROM USING UNRELIABLE COMPUTER-GENERATED MODELS
OF PEG-EPO AT TRIAL DUE TO ROCHE'S SELECTIVE PRODUCTION
ONLY OF MODELS THAT WERE CREATED FOR THIS LITIGATION

I. INTRODUCTION

Pursuant to Rule 37(c) of the Federal Rules of Civil Procedure, Roche should be precluded from using at trial computer-generated three-dimensional models of the peg-EPO molecule. During discovery, Amgen learned that Roche had developed such models, apparently for purposes other than (and possibly prior to) this litigation. Roche's document production included presentations and other documents containing low-resolution black-and-white still images of these models, but Roche never produced the native files (color pictures or animations showing the model) or the underlying coordinate files that are necessary to understand the scientific bases for the models. Despite Amgen's repeated requests for production of the native files and coordinate files (the "Roche Models"), Roche continually failed to produce them. Amgen even went so far as to specifically identify for Roche custodians of the models and

server/file paths where the models were stored. Instead, Roche provided a different model (including the color image and underlying coordinate file), tailor-made for this litigation by its expert, Dr. Jorgensen (the “Jorgensen Model”), that appears to be completely different than Roche’s own models.

Under Rule 37(c), the non-produced Roche Models should be excluded from trial, since Roche never produced them in discovery. Additionally, because Roche’s failure to produce the Roche Models prevented Amgen from comparing the Jorgensen Model to Roche’s own prior (non-litigation) modeling efforts, the Jorgensen Model should be excluded as well. Introduction of the Jorgensen Model without the Roche Models would effectively deprive Amgen of its right to cross examine — and potentially impeach — Roche witnesses concerning those models.

In the alternative, if the Jorgensen Model is not excluded, the jury should be instructed — at the time the Jorgensen Model is introduced — that Roche has in its possession additional models that it has refused to produce, and that the jury should feel free to draw inferences about the content of those models based on Roche’s refusal to produce them.

In addition, the Jorgensen Model should also not be displayed to the jury because it is not based upon reliable evidence and has the potential to confuse and mislead the jury. As Dr. Jorgensen himself testified, the Model is not based upon reliable factual information about the structure of peg-EPO, but instead represents mere conjecture.

In the alternative, if Dr. Jorgensen is allowed to display the Model to the jury, he should be precluded from testifying or narrating about what the Model allegedly depicts, as no such information was disclosed in his expert report.

II. FACTUAL BACKGROUND

A. ROCHE’S STRUCTURAL MODELS OF EPO AND PEG-EPO

1. The Existence and Location of the Roche Models

Amgen learned during discovery that, over a period of several years, Roche developed

computer-generated, structural models of EPO and peg-EPO,¹ including an animated modeling of peg-EPO interacting with the EPO receptor (collectively, the “Roche Models”).² The Roche Models demonstrate peg-EPO’s structure and mechanism of action from the perspective of Roche scientists.³

Numerous documents within Roche’s production reference the models or include low-resolution, grainy black-and-white pictures of the EPO and peg-EPO models.⁴ Roche’s own witnesses — Drs. Haselbeck and Jarsch — testified to the existence of the models, the individuals responsible for developing the models, and identified the central server location where 3D models could be located. Indeed, Dr. Haselbeck testified that he has, in his own files, electronic copies of the three-dimensional models of Roche’s peg-EPO product.⁵ Dr. Haselbeck indicated that there are at least two separate groups within Roche responsible for such modeling, the structural modeling group in Penzberg and another group in Basel, and named particular individuals in those groups: Dr. Shaefer, Dr. Ross, and Guy George.⁶ Dr. Haselbeck also described a common drive to which he has access where graphics and animations are kept.⁷ In

¹ Declaration of Renee DuBord Brown In Support of Amgen’s Motion *in Limine* to Preclude Roche from using Unreliable Computer-Generated Models of Peg-EPO at trial Due to Roche’s Selective Production only of Models that were created for This Litigation (“Brown Decl.”) Brown Decl. Ex. 4 (3/1/07 Haselbeck Dep. Tr. 80:11-18).

² Brown Decl. Ex. 4 (3/1/07 Haselbeck Dep. Tr. 81:22-82:11).

³ Brown Decl. Ex. 4, 5 (3/1/07 Haselbeck Dep. Tr. 73:1-74:9; 3/2/07 Haselbeck Dep. Tr. 219:12-18, 227:20-25).

⁴ Brown Decl. Ex. 9 (3/21/07 A. Bier letter to H. Heckel).

⁵ Brown Decl. Ex. 4 (3/1/07 Haselbeck Dep. Tr. 79:23-80:10).

⁶ Brown Decl. Ex. 4, 5 (3/1/07 Haselbeck Dep. Tr. 73:1-74:9; 3/2/07 Haselbeck Dep. Tr. 219:12-18).

⁷ Brown Decl. Ex. 5 (3/2/07 Haselbeck Dep. Tr. 236:23-238:15).

particular, he described a model that he had seen at the end of 2006 that he believed to be more accurate than previous models.⁸

The three-dimensional EPO and peg-EPO Roche Models discussed in the depositions of Drs. Haselbeck and Jarsch include various computer simulations, visualizations and animations (including rotating animations) of peg-EPO models.⁹

2. Roche's Failure to Produce the Roche Models Despite Amgen's Repeated Requests

Roche's EPO and peg-EPO 3D models fall squarely within numerous duly served Requests for Production of Documents and Things. Among others, the following Requests for Production are relevant to Roche's 3D Modeling:

REQUEST NO. 8: All documents and things relating to any comparison of the amino acid sequence, molecular weight, structure, spectra, post-translational modification, glycosylation, sialylation, acetylation, phosphorylation, sulfation, proteolysis, homogeneity, integrity, purity, specific activity, *in vitro* or *in vivo* biological activity, and any other physical or functional characteristic of MIRCERA with those of any other ESP, including any ESP made or sold by Amgen or its licensee(s).

REQUEST NO. 28: All documents and things relating to any comparison of peg-EPO to any nonpegylated ESP.

REQUEST NO. 31: All documents and things relating to any comparison by ROCHE or any third party between (a) the interaction of peg-EPO with erythropoietin receptors, and (b) the interaction of any other ESP with erythropoietin receptors.

REQUEST NO. 247: All documents and things regarding peg-EPO or EPO from the files of each member of the MIRCERA Preclinical Project Team, including Anton Haselbeck, Michael Jarsch, Martin Lanzendörfer, Olaf Mundigl, Michael Brandt, Thomas Schindler, Manfred Kubbies, Wolfgang Hösel, Fran Herting, and Sabina Bauer.

⁸ Brown Decl. Ex. 5 (3/2/07 Haselbeck Dep. Tr. 235:14-236:17).

⁹ Brown Decl. Ex. 15 (R005453588-590); Brown Decl. Ex. 1 (R001568705); Brown Decl. Ex. 13 (R000621829); Brown Decl. Ex. 14 (R10-000634386-4390); Brown Decl. Ex. 2 (R008744860); Brown Decl. Ex. 3 (R10-002103880); Brown Decl. Ex. 5 (3/2/07 Haselbeck Dep. Tr. 212:21-213:22); Brown Decl. Ex. 5 (3/2/07 Haselbeck Dep. Tr. 232:4-237:9); Brown Decl. Ex. 10 (3/27/07 Jarsch Dep. Tr. 65:23-25; 76:2-18); Brown Decl. Ex. 10 (3/27/07 Jarsch Dep. Tr. 98:12-99:25).

In addition to these duly served Requests, Amgen specifically requested production of Roche's modeling of EPO and peg-EPO in native file format from the moment Amgen confirmed their existence within Roche and continued to request them up until the end of fact discovery.¹⁰ In this correspondence, Amgen specified the specific computer formats the models and/or their underlying data may be stored in.¹¹ Yet, despite Amgen's repeated requests, Roche failed to produce its modeling of EPO and peg-EPO, or the underlying data.

At Dr. Haselbeck's deposition and again within a few days of the deposition, Amgen requested and identified the specific individuals that would likely be custodians of the Roche Models.¹² After a week passed with no response, Amgen asked again.¹³ Roche responded only with further requests for additional information.¹⁴ Amgen provided the requested information.¹⁵ Receiving no response, Amgen made further, repeated requests for the Roche Models.¹⁶ Despite Amgen's repeated requests, Roche failed to definitively respond that either Roche is no longer in possession of these 3D models and animations or that they were already produced in color and in native format.

Had Roche produced the data underlying the Roche Models, Amgen could have used that data to construct its own models of EPO and peg-EPO. In addition, such models could have formed the basis for examination and/or cross examination of experts.

¹⁰ Brown Decl. Ex. 4 (3/1/07 Haselbeck Dep. Tr. 76:2-7); Brown Decl. Ex. 5 (3/2/07 Haselbeck Dep. Tr. 237:10-20); Brown Decl. Ex. 10 (3/27/2007 Jarsch Dep. Tr. 91:5-14); Brown Decl. Ex. 6 (3/7/07 D. Fishman letter to T. Fleming); Brown Decl. Ex. 7 (3/15/07 A. Bier letter to T. Fleming); Brown Decl. Ex. 9 (3/21/07 A. Bier letter to Hank Heckel); Brown Decl. Ex. 11 (3/30/07 A. Bier letter to H. Heckel).

¹¹ Brown Decl. Ex. 9 (3/21/07 A. Bier letter to H. Heckel).

¹² Brown Decl. Ex. 6 (3/7/07 D. Fishman letter to T. Fleming).

¹³ Brown Decl. Ex. 7 (3/15/07 A. Bier letter to T. Fleming).

¹⁴ Brown Decl. Ex. 8 (3/20/07 H. Heckel letter to A. Bier).

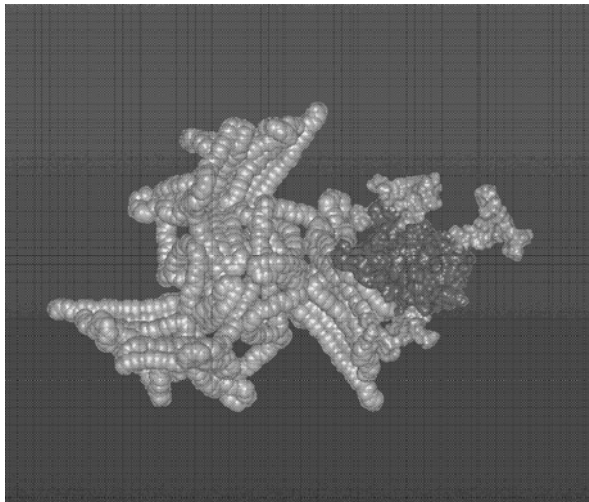
¹⁵ Brown Decl. Ex. 9 (3/21/07 A. Bier letter to H. Heckel).

¹⁶ Brown Decl. Ex. 11 (3/30/07 A. Bier letter to H. Heckel).

B. ROCHE'S PRODUCTION OF THE JORGENSEN MODEL

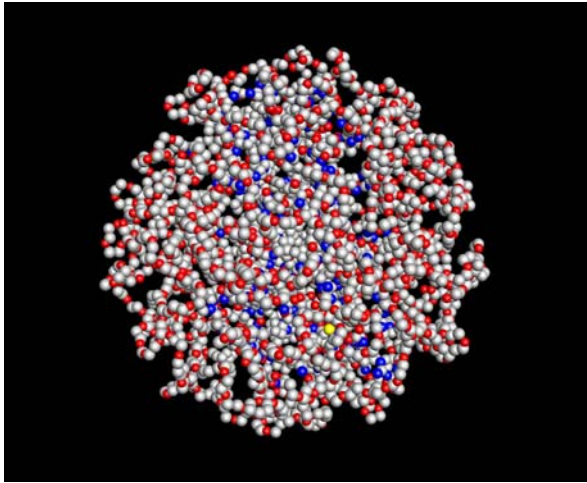
Even as it failed to produce the Roche Models repeatedly requested by Amgen, Roche arranged for one of its experts, Dr. Jorgensen, to tailor-make a model for use in this litigation. Color images of that model were produced in connection with Dr. Jorgensen's May 11, 2007 expert report and the underlying coordinate file for the model was produced when requested by Amgen. To the extent that Amgen has been able to discern the structure of the Roche Models from the black-and-white reproductions of them, it is clear that Jorgensen's model is different from Roche's models.

Fig. 1: Black-and-White Image of One of Roche's Models:¹⁷



¹⁷ Brown Decl. Ex. 1 (R001568705).

Fig. 2: Color Image of Dr. Jorgensen's Model:¹⁸



At his deposition, Jorgensen professed ignorance of Roche's models.¹⁹

C. THE ROCHE MODELS SHOULD BE EXCLUDED UNDER RULE 37(C)

Rule 26(e)(2) of the Federal Rules of Civil Procedure imposes a duty to supplement responses to requests for production:

“A party is under a duty seasonably to amend a prior response to an interrogatory, request for production, or request for admission if the party learns that the response is in some material respect incomplete or incorrect and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing.”²⁰

Here, Roche failed to supplement its responses to requests for production by failing to produce the Roche models, despite having been repeatedly notified by Amgen of this deficiency.

The Roche models were not otherwise made available to Amgen.

Rule 37(c) of the Federal Rules of Civil Procedure provides a mandatory sanction for such failure to supplement:

“A party that without substantial justification fails to ... amend a prior response to discovery as required by Rule 26(e)(2), is not, unless such failure is

¹⁸ Brown Decl. Ex. 16 (Jorgensen Expert Report, portion of Ex. C).

¹⁹ Brown Decl. Ex. 12 (5/18/07 Jorgensen Dep. 28:13-15).

²⁰ Fed. R. Civ. P. 26(e)(2).

harmless, permitted to use as evidence at a trial ... information not so disclosed. In addition to or in lieu of this sanction, the court, on motion and after affording an opportunity to be heard, may impose other appropriate sanctions ... [which] may include informing the jury of the failure to make the disclosure.”²¹

The exclusionary sanction of Rule 37(c) is a “self-executing sanction,”²² which, “in the ordinary case is mandatory preclusion.”²³ Under this black-letter principle of law, the Roche Models must be excluded.²⁴

D. THE JORGENSEN MODEL SHOULD LIKEWISE BE EXCLUDED

1. Roche’s Refusal to Produce Impeachment Evidence Mandates Exclusion of the Jorgensen Model

Following the same analysis, the Jorgensen Model must also be excluded. Roche has failed to produce its computer models and underlying data, and chose only to selectively produce a model that was custom-made for this litigation by an expert who was kept in the dark about prior modeling efforts undertaken by Roche. Under these circumstances, it would be unfair to allow Roche to manipulate the evidentiary record by such selective disclosure of computer models.

This exclusionary principle was applied in *Torres v. Lexington Ins. Co.*, 237 F.R.D. 533 (D.P.R. 2006) Torres claimed to have suffered mental anguish due to an incident at a spa in Puerto Rico, causing her to live a reclusive life following the incident. Defendants, however, identified web pages in which Torres depicted herself as leading “an active social life and an

²¹ Fed. R. Civ. P. 37(c)(1).

²² *The Hipsaver Co., Inc. v. J.T. Posey Co.*, 497 F.Supp.2d 96, 103 (D. Mass. 2007) (citing *Ortiz-Lopez v. Sociedad Espanola de Auxilio Mutuo Y Beneficiencia de P.R.*, 248 F.3d 29, 33 (1st Cir. 2001)).

²³ *Id.* (citing *Klosnoski v. Mahlab*, 156 F.3d 255, 269 (1st Cir. 1998)).

²⁴ It is irrelevant that the Roche Models might be used solely for impeachment. Rule 37(c) applies to impeachment evidence as well. In *Jeld-Wen, Inc. v. Nebula Glass Int’l, Inc.*, 2007 WL 1526649 (S.D. Fla., May 22, 2007), Jeld-Wen moved to compel production of a settlement agreement on the ground that it may constitute impeachment evidence. The court agreed, holding that “[i]mpeachment evidence is a classic example of the type of evidence that should be

aspiring singing and modeling career.”²⁵ Rather than produce these web sites in discovery, or even preserve them, Torres deleted them. The court imposed the sanction of precluding Torres from introducing evidence of ongoing mental anguish.²⁶ A similar analysis applies here. Because Roche has not produced the Roche models,²⁷ despite Amgen’s repeated requests, the Roche models are not available for impeachment, and Roche therefore should be precluded from introducing the self-serving Jorgensen Model at trial.

Due to Roche’s failure to produce the Roche Models, the jury will be unable to evaluate the credibility of Dr. Jorgensen and the Jorgensen Model by comparison with the Roche Models; therefore, Roche should not be allowed to present any of its modeling evidence (including the Jorgensen Model) to the jury.

2. Dr. Jorgensen Admitted His Model was Unreliable and it Therefore Should Not be Shown to the Jury

A demonstrative exhibit such as a computer animation must “fairly and adequately portray[] the facts” in order to be admissible.²⁸ In addition, demonstratives that may “mislead, confuse, or prejudice the jury” should be excluded pursuant to Fed. R. Evid. 403.²⁹ Furthermore, in order to be shown to the jury, a demonstrative must “accurately summarize[] testimony and other evidence ... before the jury.”³⁰

The Jorgensen Model cannot satisfy these requirements because Dr. Jorgensen himself

discoverable in litigation.” *Id.* at *2 (citing *Hickman v. Taylor*, 329 U.S. 495, 511 (1947)).

²⁵ *Torres v. Lexington Ins. Co.*, 237 F.R.D. 533 at 534 (D.P.R. 2006).

²⁶ *Id.* at 533-534.

²⁷ Due to Roche’s failure to cooperate or provide information concerning the Roche models, it is unknown whether, like the web sites in *Torres*, they have been deleted.

²⁸ *Lorraine v. Markel American Insurance Co.*, 241 F.R.D. 534, 559 (D. Md. 2007).

²⁹ *Shipp v. General Motors Corp.*, 750 F.2d 418, 427 (5th Cir. 1985) (excluding a demonstrative video attempting to demonstrate a car crash causation theory using a different vehicle and accident).

repeatedly stated, in both in his expert report and at his deposition, that there is no reliable data about the structure of CERA:

“What is not known about CERA, however, is its three-dimensional structure, or “conformation” – the overall shape of the molecule.”³¹

“[N]o experimentally determined coordinates have been reported for CERA and ***no modeling tools are available to provide reliable images of such large, complex structures.***”³²

“As I mention in my report, there is no reliable, accurate, experimental data on the structure of CERA. ... The three-dimensional structure of CERA I meant there.”³³

Dr. Jorgensen also conceded that his own Jorgensen Model images did not satisfy the standard of being a “reasonable depiction of CERA” and were “lacking in a number of areas.”³⁴ He further admitted that “we didn’t put a lot of effort into it”³⁵ and “I feel we could do a much better job on this.”³⁶ He also admitted that the model failed to depict any of the carbohydrate structures of the molecule.³⁷ Dr. Jorgensen specifically warned against relying upon the spherical-like CERA depiction he had created:

“I really don’t want you or anybody else to over interpret the significance of this picture. We haven’t worked on it. This is not publishable, let me put it that way. I would never try to write this up and send it into a journal, you know. With more work, we could get something published.”³⁸

By Dr. Jorgensen’s own admissions, it is clear that the Jorgensen Model is not a true and accurate depiction of anything at all. It is not based on any underlying scientific data. It does not

³⁰ *United States v. Buck*, 324 F.3d 786, 791 (5th Cir. 2003).

³¹ Brown Decl. Ex. 16 (Jorgensen Expert Report) p. 53 ¶ 124.

³² Brown Decl. Ex. 16 (Jorgensen Expert Report) p. 53, ¶ 125 (emphasis added).

³³ Brown Decl. Ex. 12 (5/18/07 Jorgensen Dep. 125:23-126:4).

³⁴ Brown Decl. Ex. 12 (5/18/07 Jorgensen Dep. 170:1-14).

³⁵ Brown Decl. Ex. 12 (5/18/07 Jorgensen Dep. 173:18-19).

³⁶ Brown Decl. Ex. 12 (5/18/07 Jorgensen Dep. 176:9-10).

³⁷ Brown Decl. Ex. 12 (5/18/07 Jorgensen Dep. 176:24-177:2).

accurately depict CERA. Thus, Roche should not be allowed to confuse and mislead the jury by displaying it.

In addition, Dr. Jorgensen cannot testify about his Jorgensen Model because he has not explained in his expert report the relevance or significance of any of the images he disclosed. Dr. Jorgensen's report only notes the program used to create his model, while failing to even explain what the different portions of the images are supposed to represent.³⁹ Therefore, Dr. Jorgensen should be precluded from attempting to narrate or explain any of the Jorgensen Model images as such information was never disclosed in his expert report.

III. CONCLUSION

For the foregoing reasons, Amgen requests that the Court preclude Roche from using the Roche Models, the Jorgensen Model, or any other computer-generated model or representation of peg-EPO at trial.

In the alternative, if the Jorgensen Model is not excluded, the jury should be instructed — at the time the Jorgensen Model is introduced — that Roche has in its possession additional models that it has refused to produce, and that the jury should feel free to draw inferences about the content of those models based on Roche's refusal to produce them. In addition, Dr. Jorgensen should be precluded from testifying about any features or aspects of his demonstrative images.

³⁸ Brown Decl. Ex. 12 (5/18/07 Jorgensen Dep. 177:21-178:2).

³⁹ Brown Decl. Ex. 16 (Jorgensen Expert Report) at p. 56, ¶ 29.

Dated: October 14, 2007

AMGEN INC.,

By its attorneys,

Of Counsel:

STUART L. WATT
WENDY A. WHITEFORD
MONIQUE L. CORDRAY
DARRELL G. DOTSON
KIMBERLIN L. MORLEY
ERICA S. OLSON
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320-1789
(805) 447-5000

/s/ Michael R. Gottfried

D. DENNIS ALLEGRETTI (BBO#545511)
MICHAEL R. GOTTFRIED (BBO#542156)
PATRICIA R. RICH (BBO#640578)
DUANE MORRIS LLP
470 Atlantic Avenue, Suite 500
Boston, MA 02210
Telephone: (857) 488-4200
Facsimile: (857) 488-4201

LLOYD R. DAY, JR. (*pro hac vice*)
DAY CASEBEER
MADRID & BATCHELDER LLP
20300 Stevens Creek Boulevard, Suite 400
Cupertino, CA 95014
Telephone: (408) 873-0110
Facsimile: (408) 873-0220

WILLIAM GAEDE III (*pro hac vice*)
McDERMOTT WILL & EMERY
3150 Porter Drive
Palo Alto, CA 94304
Telephone: (650) 813-5000
Facsimile: (650) 813-5100

KEVIN M. FLOWERS (*pro hac vice*)
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive
6300 Sears Tower
Chicago IL 60606
Telephone: (312) 474-6300
Facsimile: (312) 474-0448

CERTIFICATE PURSUANT TO LOCAL RULE 7.1

I certify that counsel for the parties have conferred in an attempt to resolve or narrow the issues presented by this motion and no agreement was reached.

/s/ Michael R. Gottfried

Michael R. Gottfried

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.

/s/ Michael R. Gottfried

Michael R. Gottfried