UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

AMGEN INC.,	
Plaintiff,)) Civil Action No.: 1:05-cv-12237 WGY
v.))
F. HOFFMANN-LA ROCHE LTD, a Swiss Company, ROCHE DIAGNOSTICS GMBH, a German Company, and HOFFMANN LA ROCHE INC., a New Jersey Corporation,	
Defendants.))

PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION TO COMPEL DEPOSITION TESTIMONY UNDER RULE 30(b)(6) AND CROSS-MOTION FOR A PROTECTIVE ORDER

Doc. 328

TABLE OF CONTENTS

T. 1001			Pag
		CTION	
		T	
A.	Cour	ts Recognize that Complex Patent Issues Are Not Well-Suited for 30(b)(6) Depositions	
B.	Undu	Rule 30(b)(6) Topics of Roche's Motion to Compel Are Overbroad, aly Burdensome, Lack Reasonable Particularity, and/or Seek evant Testimony	6
	1.	Topic 1: Amgen is providing two witnesses that address subject matter in this topic, but maintains an objection to the extent it calls for Amgen to prepare a witness on over 120,000 pages of prosecution and opposition documents	6
	2.	Topic 2: Amgen has designated a witness as it relates to the general duties of individuals involved with the prosecution of the Asserted Patents but maintains an objection to having to prepare such a witness on any representation or statement made by such individuals over the last twenty years that relate to any erythropoietin experiment	8
	3.	Topic 3: Amgen has designated two witnesses but maintains an objection to the extent Roche is seeking Amgen to prepare a witness on information contained in approximately 25,000 pages of laboratory notebooks	9
	4.	Topic 4: Amgen has agreed to provide witnesses that cover the requested subject matter on efforts to express a glycoprotein prior to January 1, 1985	11
	5.	Topic 6: The topic is an improper contention topic that seeks Amgen's patent law contentions on inventorship contribution, conception, and reduction to practice	11
	6.	Topic 7: The topic improperly seeks patent law contentions on effective filing dates of Dr. Lin's applications	12
	7.	Topic 8: Amgen has already testified relating to Amgen's communications with Dr. Goldwasser and has no further information other than what is contained in the documents and transcripts produced	13
	8.	Topic 9: The topic improperly seeks characterizations of Aranesp® that are not relevant to the application of Dr. Lin's EPO claims to Roche's PEG-EPO Product	14
	9.	Topic 10: The topic seeks comparisons between Aranesp® and other ESAs that are not relevant to the application of Dr. Lin's EPO claims to Roche's PEG-EPO Product	15
	10.	Topics 26 and 27: The topics improperly seek lay witness testimony on Amgen's infringement contentions on the '080 and '933 Asserted Patents	16

i DM1\1080940.1

TABLE OF CONTENTS (continued)

			Page
	C.	Roche's Argument That Amgen Should Have Moved for a Protective Order Lacks Merit in View of Roche's Extensions and the Fact That the Meet and Confer Process Was Not Completed	16
	D.	In the Alternative, Amgen Requests that a Protective Order Issue	16
IV.	CON	CLUSION	17

DMI\1080940.1 -ii - (No.)

TABLE OF AUTHORITIES

	Page
CASES	
Alloc, Inc. v. Unilin Decor N.V., Nos. 02-C-1266, 03-C-342, and 04-C-121, 2006 U.S. Dist. LEXIS 65889 (E.D. Wis. Aug. 29, 2006)	4
Exxon Research & Eng'g Co. v. The United States, 44 Fed. Cl. 597 (1999)	4
In re Brand Name Prescription Drugs Antitrust Litig., No. 94 C 897, 1998 WL 808989 (N.D. Ill. Nov. 17, 1998)	5
Kalis v. Colgate-Palmolive Co., 231 F.3d 1049 (7th Cir. 2000)	7
Kimberly-Clark Corp. v. Tyco Healthcare Retail Grp., No. 05-C-985, 2007 U.S. Dist. LEXIS 16380 (E.D. Wis. Feb. 23, 2007)	4, 7, 9
Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996)	14, 15
McCormick-Morgan Inc. v. Teledyne Industries, Inc., 134 F.R.D. 275 (N.D. Cal 1991), overruled on other grounds, 765 F. Supp. 611 (N.D. Ca. 1991)	12, 13, 16
Protective Nat'l Ins. Co. v. Commonwealth Ins. Co., 137 F.R.D. 267 (D. Neb. 1989)	5
Security Ins. Co. of Hartford v. Trustmark Ins. Co., 218 F.R.D. 29 (D. Conn. 2003)	5
SmithKline Beecham Corp. v. Apotex Corp., No. 99-CV-4304, 2004 U.S. Dist. LEXIS 8990, (E.D. Pa. Mar. 23, 2004)	5, 12
Starlight Int'l, Inc. v. Herlihy, 186 F.R.D. 626 (D. Kan. 1999)	5
U.S.E.E.O.C. v. Caesars Entm't, Inc., 237 F.R.D. 428 (D. Nev. 2006).	5

iii DM1\1080940.1

T. INTRODUCTION

Roche's Rule 30(b)(6) motion to compel is an overreaching attempt to subject Amgen to a never ending series of broad, vague, and often contention depositions on ultimate issues of fact and law. Faced with these improper requests, Amgen designated witnesses – including Fu-Kuen Lin (inventor of the Asserted Patents) and Stuart Watt (V.P. Law and Intellectual Property) – on the vast majority of subject matter covered and attempted to engage Roche in a dialogue on the areas that are objectionable. Roche contends that Amgen has been stonewalling. Nothing is further from the truth. The problem is and remains with Roche's insistence that it is entitled to enforce to the letter the broad and improper swath of subject matter these topics encompass, including Amgen's complex patent law legal contentions.

For example, Topics 6 and 7 ask for Amgen's contentions on reduction to practice, conception, contribution of inventorship and effective filing dates of the six Lin Asserted Patents. However, in response to Amgen's December 11 interrogatories, Roche has yet to come forward with its invalidity contentions on a claim-by-claim, limitation-by-limitation basis as requested to disclose its invalidity defenses. In effect, Roche's motion would require Amgen to divine the bases for Roche's contentions on invalidity, then select and prepare Rule 30(b)(6) witnesses to testify on complex patent law subject in advance of Amgen even having full disclosure of what Roche's invalidity contentions are.

For example, Topic 1 requests that Amgen prepare a witness on any experiment performed or discussed at Amgen on erythropoietin through 1987, no matter how insignificant, and to further prepare a witness to testify on over 120,000 pages of the U.S. prosecution of the Asserted Patents, the European opposition on the foreign counterpart to the Asserted Patents, as well as opposition proceedings to patents held by Roche's licensor (patents which are not the subject of this litigation, nor related to these patents) that might contain any reference, explicit or

See Amgen's pending March 13 Motion to Compel from Roche a Complete Response to Amgen's Interrogatories 9, 10, and 11 (Docket No. 316) that were served on December 11, 2006.

implicit, to such experiments. Roche's motion describes this topic as "targeted, with great detail, to address the validity and enforceability of Amgen's United States patents." Roche Mem. at 5. Yet again, Amgen is faced with the prejudicial task of having to prepare a witness(es) on large swaths of material without Roche truly disclosing its claims and defenses. Nonetheless, in a good faith response, Amgen provided Dr. Strickland as a witness on certain experiments he performed, will be providing Dr. Lin on the experiments he performed pursuant to other topics, and further invited Roche to identify within the more than 120,000 pages of prosecution and opposition material which additional experiments it truly was interested in so Amgen could prepare a witness(es). Roche stonewalled and refused, filing this motion instead.

Roche's motion is replete with such overreaching. It asks the Court: (a) to compel topics that Amgen has agreed to provide testimony upon; (b) to compel topics that Amgen has informed Roche that it has no additional knowledge beyond that reflected in the produced documents and transcripts; and (c) to compel Amgen witnesses to testify on complex patent law concepts.

Despite this plain overreaching combined with continuing to hide the ball on invalidity, Amgen sought to work with Roche to narrow somewhat these overbroad and improper topics. These good faith efforts are documented in the Amgen letters attached to Roche's motion, and Amgen is designating twelve witnesses on the twenty-nine Rule 30(b)(6) topics that Roche propounded. This includes witnesses on virtually all of the topics that Roche specifically complains of in this motion. Roche ignored these good faith efforts, did not properly meet and confer, and rushed instead to file its motion in an effort to oppress Amgen.

Amgen agrees that this motion should be resolved expeditiously, and requests that the Court deny at once Roche's motion to compel. In the alternative, and to the extent even necessary, Amgen further moves for a protective order as to the scope of Roche's topics that are outside of the broad and reasonable discovery scope that Amgen is preparing witnesses on, as further detailed herein. A [Proposed] Order in line with Amgen's opposition and cross-motion is attached as Attachment B.

II. **SUMMARY OF FACTS**

On February 9, 2007 Roche served Defendants' First Notice of Deposition to Amgen Pursuant to Rule 30(b)(6). (Gaede Decl., Ex. 1.) One week after receiving Roche's 30(b)(6) Notice, Amgen responded to Roche with a letter stating that many of the topics were objectionable on their face for lacking reasonable particularity, among other issues, and notified Roche that Amgen would be serving objections the following week. (Gaede Decl., Ex. 2.) As promised, on February 23, 2007, Amgen served Plaintiff's Objections to Defendants' First Notice of Deposition Pursuant to Rule 30(b)(6). (Gaede Decl., Ex. 3.) Amgen served specific objections to the eleven topics at issue here. However, for each of the topics in dispute, Amgen agreed to provide either a witness on a reasonable and particularized scope or, when appropriate, referred Roche to Amgen's responses to Defendants' Interrogatories.

On numerous occasions Amgen articulated its objections to specific Rule 30(b)(6) topics and requested to meet and confer regarding them. An initial meet and confer was held on February 27, 2007.² On February 28, 2007, Amgen sent Roche a letter providing deposition dates, the identity of Amgen's witnesses for certain topics, and requested a meet and confer to discuss Roche's other Rule 30(b)(6) topics. (Gaede Decl., Ex. 4.) Amgen forwarded another letter identifying Rule 30(b)(6) witnesses on March 1, 2007. (Gaede Decl., Ex. 5.) On March 6, 2007, Amgen sent Roche a detailed letter addressing, topic by topic, Amgen's position on the requested deposition Topics. (Gaede Decl., Ex. 6.) On March 13, 2007, Amgen sent Roche yet another letter addressing most of the topics in dispute and further sought to resolve the issues as soon as possible. (Gaede Decl., Ex. 7.)

Amgen queried Roche as to whether a motion to quash Roche's Rule 30(b)(6) deposition notice was going to be necessary. (Gaede Decl., Ex. 8.) Roche replied that Amgen should wait pending another meet and confer. (Gaede Decl., Ex. 8.) Then, while Amgen's meet and confer

² Roche informed Amgen it would reserve on certain issues. (Gaede Decl., Ex. 6.)

letter of March 13, 2007 was pending, Roche simply filed its Motion to Compel. (Gaede Decl., Ex. 11.)

On March 2, 2007, Roche served a set of contention interrogatories that essentially track the Rule 30(b)(6) topics at issue here, as set forth in Attachment A to this memorandum. (Gaede Decl., Ex. 12.)

III. ARGUMENT

A. COURTS RECOGNIZE THAT COMPLEX PATENT ISSUES ARE NOT WELL-SUITED FOR RULE 30(B)(6) DEPOSITIONS

Rule 30(b)(6) requires a party to identify the matters on which examination is requested with "reasonable particularity." Fed. R. Civ. P. 30(b)(6). Topics in a Rule 30(b)(6) notice, such as "Amgen's basis for asserting against Roche claims in the '933 patent" (Roche's Topic 27), do not meet the requirement for identification with reasonable particularity and would not enable Amgen to adequately prepare a Rule 30(b)(6) witness. *See Kimberly-Clark Corp. v. Tyco Healthcare Retail Grp.*, No. 05-C-985, 2007 U.S. Dist. LEXIS 16380, *7 (E.D. Wis. Feb. 23, 2007) (defendant's Rule 30(b)(6) topic generally referencing "the validity of the patents-in-suit" was not specific enough to allow plaintiff to reasonably prepare a witness to testify).

In patent cases, which often have complex legal issues, contention interrogatories are to be favored over Rule 30(b)(6) depositions to obtain information related to a party's patent law contentions. *See, e.g., McCormick-Morgan Inc. v. Teledyne Industries, Inc.*, 134 F.R.D. 275 *N.D. Cal. 1991), *overruled on other grounds*, 765 F. Supp. 611 (N.D. Ca. 1991) (concluding that "appropriately framed and timed contention interrogatories" rather than depositions of alleged infringing corporation's designated employees, was appropriate method for establishing alleged infringer's contentions.); *see also Exxon Research & Eng'g Co. v. The United States*, 44 Fed. Cl. 597, 602 (1999) (finding contention interrogatories to be more appropriate than a 30(b)(6) deposition in a patent infringement case, where the legal issue may be too complex for a deponent who is not an attorney to answer questions competently); *Alloc, Inc. v. Unilin Decor N.V.*, Nos. 02-C-1266, 03-C-342, and 04-C-121, 2006 U.S. Dist. LEXIS 65889, *4 (E.D. Wis.

Aug. 29, 2006) (finding in a patent case that a "party may properly resist a Rule 30(b)(6) deposition on the ground that the information sought is more properly sought through contention interrogatories"); SmithKline Beecham Corp. v. Apotex Corp., No. 99-CV-4304, 2004 U.S. Dist. LEXIS 8990, *12 (E.D. Pa. Mar. 23, 2004) (holding that interrogatories were a more appropriate method of discovery of the bases for plaintiff's allegations of patent infringement).

Roche cites Starlight Int'l, Inc. v. Herlihy, 186 F.R.D. 626, 639 (D. Kan. 1999) for the proposition that a party presenting a Rule 30(b)(6) witness must make a good faith effort to prepare the witness. Id. Amgen agrees, and that requirement reflects precisely the problem with Roche's overbroad requests that lack reasonable particularity. Of interest here, the court in Starlight also noted that successive use of written interrogatories and depositions to require an adverse party to disgorge all relevant facts within his knowledge may too easily become an instrument for oppression, which is the case here. *Id.* at 641.^{3,4}

In part due to the particular complexity that exists in patent cases, and the potential grounds for abuse, courts scrutinize the reasonableness of Rule 30(b)(6) topics, particularly when framed to elicit a party's contentions. Routinely, as should be done here, courts either limit the

The other cases Roche cites likewise do not support Roche's position and recognize that in the intellectual property context, other means of discovery are preferable than contention Rule 30(b)(6) depositions. In Protective Nat'l Ins. Co. v. Commonwealth Ins. Co., 137 F.R.D. 267, 282 (D. Neb. 1989) the court distinguished between a witness testifying on trademark legal concepts with an accountant testifying on underlying facts. Id. at 282-283. In U.S.E.E.O.C. v. Caesars Entm't, Inc., 237 F.R.D. 428, 434-435 (D. Nev. 2006), the court agreed with E.E.O.C.'s choice of a Rule 30(b)(6) deposition over contention interrogatories, noting that "[Caesar's] ... affirmative defenses are *not complex patent issues* that call for 'quasi-legal argument.'" U.S. E.E.O.C., 237 F.R.D. at 435 (emphasis added). In Security Ins. Co. of Hartford v. Trustmark Ins. Co., 218 F.R.D. 29 (D. Conn. 2003), the issue was a reinsurance agreement, not complex patent law issues.

⁴ Roche cited In re Brand Name Prescription Drugs Antitrust Litig., No. 94 C 897, 1998 WL 808989 (N.D. Ill. Nov. 17, 1998) as granting a motion to compel where a plaintiff unilaterally limited the scope of 30(b)(6) inquiries. However nothing in the court's decision suggests that the plaintiff sought to limit the topics based on any of the issues raised by Amgen's Opposition. Rather, the plaintiff apparently intended to exclude certain deposition topics because it had previously provided testimony on those topics, albeit before the party seeking the deposition was named as a defendant. Id. at *2.

subject matter, or order that an interrogatory response be provided in lieu of a deposition. Against this legal backdrop, Amgen turns to each topic that is the subject of Roche's motion.

- В. THE RULE 30(B)(6) TOPICS OF ROCHE'S MOTION TO COMPEL ARE OVERBROAD, UNDULY BURDENSOME, LACK REASONABLE PARTICULARITY, AND/OR SEEK IRRELEVANT TESTIMONY
 - Topic 1: Amgen is providing two witnesses that address subject 1. matter in this topic, but maintains an objection to the extent it calls for Amgen to prepare a witness on over 120,000 pages of prosecution and opposition documents.

Topic 1 addresses all efforts by Amgen through 1987, either planned or carried out, to characterize⁵ any human erythropoietin (whether produced from natural sources, cell culture, or cell lines), as well as all efforts after 1987 where Amgen relied on, discussed, or referred to such characterization, whether expressly or not, in connection with the prosecution of any of Amgen's EPO patents and certain opposition proceedings in Europe.⁶ (Gaede Decl., Ex. 1.) The topic further contains nine subcategories of information on which Roche seeks testimony, including all characterization of all physical, chemical and biological properties (with 21 specific properties listed as examples), and any communication of such work at any time to any individual involved in the prosecution of Amgen's EPO Patents. ⁷ Id.

It is hard to imagine that there is anything that Amgen could have said or done with regard to the characterization of any erythropoietin preparation over the past 20 years that would not be captured by this topic, which covers more than 20 years of information and a vast volume of documents. For example, the documents just related to the prosecution of Amgen's EPO

⁵ Roche's Rule 30(b)(6) notice defines characterize as "any experimental method used." As Roche seeks to enforce the full scope of the topics, therefore, Roche seeks Rule 30(b)(6) testimony on any experiment, regardless of nature or significance, that Amgen may have performed through 1987 involving "any human erythropoietin." This unreasonable breadth to Roche's topics, as drafted, that it now seeks to compel. This highlights the

⁶ Roche's Third Set of Interrogatories include contentions interrogatories on this subject matter as well. (Attachment A; Gaede Decl., Ex. 12.)

⁷ As discussed in this Opposition's Introduction, Roche describes Topic 1 as "targeted, with great detail, to address the validity and enforceability of Amgen's United States patents." Roche Mem. at 5. Examining the actual language of the topic shows the lack of merit to characterizing this topic as being targeted.

patents and the European opposition proceedings amount to more than 120,000 pages that Roche has had since June 2006 – a scope that Roche has never disputed. (Gaede Decl., ¶ 15.)

In response, Amgen:

- (1) Designated Dr. Thomas Strickland as a Rule 30(b)(6) witness on this topic. Dr. Strickland testified on his work set forth in declarations submitted in the prosecution histories and opposition proceedings⁸; and
- (2) Asked Roche to further identify from the more than 120,000 pages of documents the experiments and characterizations that Roche was in fact interested in so that Amgen could prepare a witness. (See Gaede Decl., Exs. 6-7.)

For a Rule 30(b)(6) deposition to operate effectively, the deposing party must designate the areas of inquiry with reasonable particularity. *See Kimberly-Clark Corp.*, 2007 U.S. Dist. LEXIS 16380, at *8; *Kalis v. Colgate-Palmolive Co.*, 231 F.3d 1049, 1058 (7th Cir. 2000).

At its core, Roche appears to be interested in specific experiments that may be discussed in the prosecution and opposition proceedings at issue, but has refused to identify them. Dr. Strickland testified as a Rule 30(b)(6) witness for Amgen on the characterization of any human erythropoietin in his experiments that were submitted in Amgen's prosecution of EPO patents or opposition proceedings. Beyond Dr. Strickland's testimony, Amgen cannot prepare a witness to testify on any experiments that may have been performed, "planned," "discussed," or "relied on," much less over this broad period of time. If Roche identifies specific experiments or documents, as Amgen proposed in its meet and confer letters of March 6 and 13, Amgen will then be in a position to further prepare a witness beyond what Dr. Strickland already discussed. (Gaede Decl., Exs. 6 and 7.) Roche's request to compel topic 1 should be denied.

_

⁸ To the extent Roche is seeking testimony on the experiments disclosed in Dr. Lin's Asserted Patents, Dr. Lin will cover that information as discussed in response to Topics 3, 4, 6, and 7, *infra*.

2. Topic 2: Amgen has designated a witness as it relates to the general duties of individuals involved with the prosecution of the Asserted Patents but maintains an objection to having to prepare such a witness on any representation or statement made by such individuals over the last twenty years that relate to any erythropoietin experiment.

Topic 2 requests a witness to discuss the role of any Amgen employee or agent, their identity, and period of involvement in: (1) the prosecution of any of Amgen's EPO patents in the U.S. or Europe, and (2) in connection with any opposition proceeding or litigation in Europe involving either the foreign counterparts to Amgen's EPO patents or two Genetics Institute patents.⁹ The topic further seeks the preparation of a witness on "any representations, contentions or other statements" made by any such Amgen employee or agent regarding the characterization of any recombinant human erythropoietin produced through mammalian cell expression without regard to whether or not the representations, contentions or other statements were made in the context of the proceedings identified above. (Gaede Decl., Ex. 1.)

To appreciate the enormity of the task Roche seeks of Amgen, the Court should first understand that Amgen would be required to investigate the roles of all Amgen employees and agents in upwards of 40 different proceedings in Europe, involving more than 400,000 pages of documents and spanning more than 18 years. (*See* Gaede Decl., ¶ 17.) Assuming that Amgen could meet Roche expectations on this part of the investigation, Amgen is then held responsible for investigating and preparing a witness on all "representations, contentions or other statements" made by any such Amgen employee or agent regarding the characterization of any recombinant human erythropoietin produced through mammalian cell expression regardless of place, time, or context. Most ridiculous of all, is that Roche, its predecessor-in-interest (Boerhinger Manheim) and/or its licensor (Genetics Institute) were a party to these many proceedings and litigations. There is no doubt that Roche knows with particularity the information for which it seeks a deposition, but resists identifying it.

_

⁹ Interrogatory No. 23 in Roche's Third Set of Interrogatories seeks the same information. (Attachment A; Gaede Decl., Ex. 12.)

During the February 26 meet-and-confer teleconference, Roche stated that it would reserve testimony on this topic pending the deposition of Michael Borun, outside counsel for Amgen, with primary responsibility for prosecution of the Asserted Patents. (*See* Gaede Decl., Ex. 7.) On March 8, Roche raised the issue of a witness other than Mr. Borun to address this topic. *Id.* In response, Amgen designated Stuart Watt to testify on the identity and general role (subject to privilege) of individuals involved in the relevant patent proceedings, as Topic 2, (a)-(c) requests. *Id.* Amgen maintained its objections to the topic's scope as to "any representations, contentions or other statements" by any Amgen employee or agent on the "characterization" of EPO. Amgen further asked Roche to identify the characterizations – found in the documents produced well over 9 months ago and undoubtedly within its possession or control long before that – on which Roche sought discovery so that Amgen could meaningfully prepare a witness on any "statements."

Roche refused to provide any more specificity, violating the requirement that the request have reasonable particularity. *See Kimberly-Clark Corp.*, 2007 U.S. Dist. LEXIS 16380, at *8. Roche's tactic seems more aimed at oppressing an Amgen witness with identifying approximately 20 years of history on any "statement." This breadth cannot serve any legitimate discovery purpose. The Court should deny enforcement of the topic as drafted, and order Roche to follow Amgen's common sense solution to provide the particularity that is currently lacking.

3. Topic 3: Amgen has designated two witnesses but maintains an objection to the extent Roche is seeking Amgen to prepare a witness on information contained in approximately 25,000 pages of laboratory notebooks.

Topic 3 requests all efforts by Amgen "planned or carried out" concerning attempts to identify or conduct an analysis of any cell or tissue producing erythropoietin, or any erythropoietin derived from bodily fluids, including erythropoietin characterization, cell/tissue/erythropoietin source, all comparisons of erythropoietin, and all communications of

Amgen with any third party relating thereto. (Gaede Decl., Ex. 1.) Although the topic as written is unlimited in time, Roche stated in the February 26 meet-and-confer teleconference that it is interested in all successful and failed attempts to express human erythropoietin in any cell line with any construct and to identify any source for erythropoietin up to 1995. (See Gaede Decl., Ex. 7.)

As a compromise, Amgen designated inventor Dr. Lin as a witness on the examples described in the specification of the Asserted Patents that relate to the expression of human erythropoietin, as well as efforts to identify cells or tissue expressing or secreting erythropoietin. Id. In addition, Amgen designated Thomas Boone to testify on this topic on post-1984 expression in cell lines other than the CHO DHFR cell line, which is utilized in example 10 of the Lin patents and in Amgen's commercial manufacture. *Id.* Amgen's designations fairly meet this topic.

The Asserted Patents have priority dates in 1983 and 1984. Roche has not articulated the relevance to any issue in this case of the broad subject matter of this topic from 1985 to 1995. Nonetheless, Amgen is providing Thomas Boone on the expression of erythropoietin from 1985 to 1995. Amgen is also producing Dr. Lin. Amgen will make a good faith effort to prepare Dr. Lin, but as Amgen advised Roche, given the volume of laboratory notebooks produced that predate 1985, comprising approximately 25,000 pages of material, it is virtually impossible to prepare Dr. Lin on each and every page. (Gaede Decl., ¶ 16.)

Roche apparently contends that Dr. Lin must be so prepared, because it simply moved to compel without responding to Amgen. This shows again that the topic is not for any particularized and legitimate purpose, but is an attempt to oppress Amgen and to try to create a record of noncompliance. The motion to compel on this request should be denied beyond the subject matter that Amgen has identified Mr. Boone and Dr. Lin will testify upon.

¹⁰ Roche served contention interrogatories covering the same subject matter. (Attachment A; Gaede Decl., Ex. 12.)

4. Topic 4: Amgen has agreed to provide witnesses that cover the requested subject matter on efforts to express a glycoprotein prior to January 1, 1985.

Topic 4 addresses efforts by Amgen prior to 1985 to express any biologically active glycosylated protein or polypeptide in any mammalian cell. (Gaede Decl., Ex. 1.) Prior to Roche filing its motion to compel, Amgen had designated (1) Dr. Fu-Kuen Lin on the specific examples described in the specification of the Asserted Patents that relate to the recombinant expression of erythropoietin as a glycoprotein, and (2) Thomas Boone on the recombinant expression of glycoproteins other than erythropoietin prior to 1985. (*See* Gaede Decl., Ex. 7.) The scope of the subject matter is met, and Roche lacks any basis for moving to compel, particularly where the testimony has not yet been obtained.

5. Topic 6: The topic is an improper contention topic that seeks Amgen's patent law contentions on inventorship contribution, conception, and reduction to practice.

Topic 6 seeks a witness on the contribution of anyone to Dr. Fu-Kuen Lin's inventions, including developing the "claimed subject matter of Amgen's EPO Patents, including without limitation the date of any contribution, including the conception and/or reduction to practice" of "each claim element of the asserted claims of Amgen's EPO Patents." (Gaede Decl., Ex. 1.) In response, Amgen designated Dr. Lin to testify on the work disclosed in the specification of the Asserted Patents. (Gaede Decl., Ex. 7.) Roche served a contention interrogatory on the identical subject matter. (Attachment A; Gaede Decl., Ex. 12.)

This topic inherently seeks testimony on Amgen's patent law contentions with respect to "contributions," "conception" and "reduction to practice" of each element of the Asserted Claims. Such a contention deposition on complex patent law issues is improper under *McCormick-Morgan Inc. v. Teledyne Industries, Inc.*, particularly in view of Roche's failure to set forth its §§ 102 and 103 defenses. *See McCormick-Morgan Inc.*, 134 F.R.D. at 286-287; *see also* Amgen's pending March 13 Motion to Compel Roche's Responses to Amgen

¹¹ Roche's contention Interrogatory No. 27 seeks the same information. (Attachment A; Gaede Decl., Ex. 12.)

Interrogatories Nos. 9-11 (Docket No. 316). Indeed, here it is on the even of fact discovery closing, and with Roche having disclosed over 40 experts, and Amgen still has no idea on a claim-by-claim, limitation-by-limitation basis what Roche's invalidity defenses are under 35 U.S.C. §§102 and 103.¹²

Further, in Amgen's Supplemental Response to Roche Interrogatory No. 3, Amgen provided to Roche a detailed timeline of events results in the filing of the Lin applications and stated that Lin is the sole inventor. (Gaede Decl., Ex. 9.); see SmithKline Beecham Corp., 2004 U.S. Dist. LEXIS 8990, at *7 (ruling that certain categories of proposed deposition topics pertained to legal positions that should be ascertained by means of interrogatories rather than depositions.) Amgen should not be compelled to prepare Dr. Lin on its complex patent law contentions.

Finally, to the extent Roche intends to examine Dr. Lin on specific experiments, "protocols or procedures" that may be found amongst the approximately 25,000 pages of laboratory notebooks produced that predate 1985 that have not been identified by Roche before the deposition and within a reasonable time to prepare Dr. Lin, such a deposition lacks particularity, and is unduly burdensome. The request to compel should be denied to this extent.

6. Topic 7: The topic improperly seeks patent law contentions on effective filing dates of Dr. Lin's applications

Topic 7 requests a witness on the "earliest effective filing" date for each of the asserted claims of Amgen's EPO Patents, including "all facts and circumstances known to Amgen supporting such contention." (Gaede Decl., Ex. 1.) This is an improper request for a contention deposition. See McCormick-Morgan Inc., 134 F.R.D. at 286-287. Apparently recognizing this, Roche served an identical contention interrogatory on this topic. (Attachment A; Gaede Decl., Ex. 12.)

opening expert invalidity reports on April 6, has substantially prejudiced Amgen.

Roche has not filed an opposition brief to Amgen's motion to compel these further responses that was filed on March 13, 2007. The delay in responding fully to interrogatories that were served on December 11, combined with the closure of fact discovery on April 2, and Roche's

Amgen designated Dr. Lin on the work underlying the examples discussed in the specification of the Asserted Patents. This is in addition to the detailed facts set forth in Amgen's Supplemental Response to Roche's Interrogatory No. 3 that creates a chronology of events. (*See* Gaede Decl., Ex. 9; *see* Section III (B)(4) and (5), *supra*.)

Initially, Roche agreed this is a contention deposition. (*See* Gaede Decl., Ex. 7.) Later, Roche sought to hide that this is a contention topic by seeking a deposition on the underlying subject matter that was included in the Lin application, but revealed that it will question on facts "that *Amgen may use as support for various* possible filing dates." *Id.* In other words, Roche is still seeking Amgen's contentions – which Roche never disputed.

The simple fact remains that the topic as phrased is an improper contention topic on Amgen's contentions on the earliest filing date of the patents, and that is what Roche is seeking to have this Court compel. Interrogatories are a more appropriate discovery method for this contention information. *See McCormick-Morgan*, 134 F.R.D. at 286-287.

Amgen is providing Dr. Lin as a witness on the work disclosed in the specification. The motion to compel should be denied in so far as it requires Amgen to prepare a witness on the complex patent law questions and contentions that form Amgen's position on the "earliest effective filing date" for Dr. Lin's application, particularly in view of Roche's failure to identify with specificity its invalidity defenses that arguably make such contentions relevant. *See* pending Amgen March 13 Motion to Compel Roche's Responses to Amgen Interrogatories Nos. 9-11 (Docket No. 316.)

7. Topic 8: Amgen has already testified relating to Amgen's communications with Dr. Goldwasser and has no further information other than what is contained in the documents and transcripts produced.

Topic 8 concerns the relationship between Eugene Goldwasser and Amgen, including, communications, and the transfer, exchange, provision or supply of information, of know-how, or things to Dr. Goldwasser from Amgen concerning crude, purified or urine erythropoietin,

radioimmunoassay, iodinated EPO, EPO purification methods, and antibodies to EPO. 13 (Gaede Decl., Ex. 1.) Roche agreed to limit the time frame of this topic to prior to 1996. Amgen designated and Roche deposed Dr. Strickland as Amgen's Rule 30(b)(6) witness on this topic.

Beyond that, as Amgen informed Roche, Amgen is unable to identify a current employee who has knowledge in addition to that provided by Dr. Strickland or otherwise recorded in the documents produced and prior testimony of Amgen employees that Amgen has produced. (Gaede Decl., Ex. 7.) Therefore, there is no further oral testimony that Amgen can provide on this subject that reflects any knowledge of the company other than what exists in the documents and transcripts already produced. The motion to compel on this topic should be denied.

8. Topic 9: The topic improperly seeks characterizations of Aranesp® that are not relevant to the application of Dr. Lin's EPO claims to Roche's PEG-EPO Product.

In Topic 9 Roche seeks a witness on characterizations, including fifteen subtopics, of the active drug product in EPOGEN® and in Aranesp®. 14 (Gaede Decl., Ex. 1.) Roche agreed that Amgen provided the characterization information sought by this topic for EPOGEN®, and that a witness was not needed with respect to EPOGEN®. (See Gaede Decl., Ex. 7.) However, Roche still demands detailed characterization information for Aranesp®¹⁵. Specifically, during the meet and confer, Roche sought testimony on subtopics J-O that ask for Amgen's characterizations of Aranesp®, its interaction with the human erythropoietin receptor, pharmacokinetics, manner of clearance, and other topics. *Id.*

Roche's demand for a witness on characterizations of Aranesp® seeks information that is not relevant. Aranesp® is not an accused product. Any attempt to justify discovery of information on Aranesp® rests on an improper infringement analysis. The proper analysis

¹³ Roche's contention Interrogatory No. 34 covers the same subject matter. (Attachment A; Gaede Decl., Ex. 12.)

¹⁴ Roche served interrogatories on the same topic. (Attachment A; Gaede Decl., Ex. 12.)

¹⁵ Roche originally held this request in reserve pending the receipt of Amgen's cell lines. (Gaede Decl., Ex. 7.) The first communication from Roche on this Topic that Roche believed the receipt of the cell line was insufficient was Roche's March 8, 2007 letter. (Gaede Decl., Ex. 10.) Any delay on this Topic is due to Roche, not Amgen.

requires the application of the asserted claims to the accused Roche product and methods. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). Indeed, in the face of similar overbroad document requests, the Court on January 3, 2007 denied unfettered discovery into Aranesp's research and development, and characterization.

Roche's motion fails to articulate the relevance of the 15 Aranesp® characterization factors to Roche's non-infringement defenses that compromise Topic 9. To the extent there is some residual relevance to any injunction issue, that will be covered in the testimony of Amgen's three witnesses designated on Topic 13, which addresses Amgen's underlying, non-privileged basis for requesting a permanent injunction. (Gaede Decl., Ex. 1.) Therefore, the motion to compel on Topic 9 should be denied.

> Topic 10: The topic seeks comparisons between Aranesp® and other 9. ESAs that are not relevant to the application of Dr. Lin's EPO claims to Roche's PEG-EPO Product.

Topic 10 requests a witness on any comparisons performed by or for Amgen of the active drug product in Aranesp® to recombinant human erythropoietin, including erythropoietin precuts that are not even available in the U.S. 16 (Gaede Decl., Ex. 1.) Amgen has refused to produce a deponent as the topic seeks irrelevant information in violation of this Court's January 3, 2007 Order.¹⁷

Roche has not articulated any liability issue to which comparisons of Aranesp® to recombinant human erythropoietin are relevant. Any attempt to compare products, and justify discovery, rests on an improper infringement analysis. Infringement is not a comparison of

In its motion Roche characterizes Topic 10 merely as "in reality seek[ing] only facts underlying Amgen's claims, not Amgen's contentions." Roche Mem. at 8. Roche fails to acknowledge that any facts sought by Topic 10 are directed to Aranesp® and therefore are irrelevant to any claim or defense in this case.

¹⁷ Nonetheless, Roche served an interrogatory identical to this topic. (Attachment A; Gaede Decl., Ex. 12.)

products. It requires application of the asserted claims to the accused Roche product and methods. See Markman, 52 F.3d at 976.

Roche has asserted that this topic relates to an injunction. (See Gaede Decl., Ex. 7.) To the extent Roche may contend that some of the subtopics are potentially relevant to an injunction, Amgen's witnesses will be testifying on non-privileged facts relevant to an injunction in response to Topic 13. *Id.* Therefore, the request to compel testimony on Topic 10 should be denied as overbroad, seeking irrelevant information, and lacking reasonable particularity.

Topics 26 and 27: The topics improperly seek lay witness testimony 10. on Amgen's infringement contentions on the '080 and '933 Asserted **Patents**

Topics 26 and 27 request witnesses on Amgen's infringement contentions for asserting claims of the '080 Patent (Topic 26) and '933 Patent (Topic 27) against Roche. 18 Such contention depositions are inappropriate and should be left to interrogatories. See McCormick-Morgan Inc., 134 F.R.D. at 286-287. Amgen's supplemental response to Roche's Interrogatory No. 1 provides the grounds for asserting the claims. (Gaede Decl., Ex. 9.) If Roche perceives there is some lack of clarity in Amgen's Responses, Amgen is prepared to provide clarifying information in its interrogatory responses. Therefore, the motion to compel to provide oral testimony on these contention topics should be denied. See McCormick-Morgan Inc., 134 F.R.D. at 286-287.

C. ROCHE'S ARGUMENT THAT AMGEN SHOULD HAVE MOVED FOR A PROTECTIVE ORDER LACKS MERIT IN VIEW OF ROCHE'S EXTENSIONS AND THE FACT THAT THE MEET AND CONFER PROCESS WAS NOT COMPLETED

Roche contends that if Amgen truly believed that "the scope of discovery was illegitimate, it could have procured a protective order." Amgen was well aware of its option to move for a protective order and raised it with Roche. Amgen further sought and obtained an

¹⁸ Roche's Memorandum portrays Topic 26 as only "seeking facts underlying Amgen's assertion of the '080 patent claims." Roche Mem. at 8. A quick review of the language of Topic 26, which requires "Amgen's basis for asserting" the patent claims, proves the inaccuracy of Roche's characterization of the topic.

extension of time to move for a protective order until the meet and confer process was finished. (Gaede Decl., Ex. 11.) At no point in time did Roche state that the meet and confer process was finished, that the extensions to Amgen were withdrawn, or that Amgen should move for a protective order in light of the witnesses being provided. Instead, before the process was concluded, Roche simply filed this motion. (Gaede Decl., Ex. 11.)

D. IN THE ALTERNATIVE, AMGEN REQUESTS THAT A PROTECTIVE ORDER ISSUE

In the alternative, good cause exists for issuance of a Protective Order under Rule 26(c). As the foregoing shows, Amgen has identified witnesses, has already produced witnesses, and will produce additional witnesses if specific topics or documents are identified. The issue is not Amgen's good faith compliance, but Roche's attempt to enforce overbroad Rule 30(b)(6) topics that should be satisfied by interrogatory responses and the reasonable scope of testimony described above. Accordingly, Amgen requests that a Protective Order issue limiting the topics to the scope proposed by Amgen, as addressed above.

IV. **CONCLUSION**

For all the stated reasons, Amgen requests that the motion to compel be denied, and/or the cross-motion for a protective order be granted. Amgen's [Proposed] Order is Attachment B to this opposition and cross-motion.

DATED: March 23, 2007

Respectfully Submitted,

AMGEN INC.,

Of Counsel:

Stuart L. Watt Wendy A. Whiteford Monique L. Cordray Darrell G. Dotson Kimberlin L. Morley 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: (617) 289-9200 Facsimile: (617) 289-9201

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

William G. Gaede III (pro hac vice) McDERMOTT WILL & EMERY 3150 Porter Drive Palo Alto, CA 94304 Telephone: (650) 813-5000 Facsimile: (650) 813-5100

Facsimile: (408) 873-0220

Kevin M. Flowers (*pro hac vice*) MARSHALL, GERSTEIN & BORUN LLP 233 South Wacker Drive 6300 Sears Tower Chicago, IL 60606 Talaphana: (312) 474-6300

Telephone: (312) 474-6300 Facsimile: (312) 474-0448

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the Electronic Case Filing (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/ Michael R. Gottfried
Michael R. Gottfried