UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, 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.	Civil Action No.: 1:05-cv-12237 WGY

AMGEN INC.'S OPPOSITION TO DEFENDANTS' MOTION TO COMPEL THE PRODUCTION OF DOCUMENTS

I. INTRODUCTION

Roche's claims of Amgen not providing appropriate discovery is misguided. Roche's motion ignores the fact that Amgen has made a good faith effort and already produced over a million pages that are relevant and responsive to the very discovery requests they raise in this motion. With respect to Roche's argument on oncology documents, Amgen is producing relevant and responsive documents, such as hospital contract documents (which include the oncology channel) and documents bearing on market definition. Moreover, Amgen has made generous and reasonable offers to resolve this dispute in a manner that affords Roche discovery central to the allegations they have plead. Instead of seeking compromise that would allow document production on the most relevant documents to be completed on time, Roche demands inappropriately broad discovery of Amgen unbounded by time and reaching far into subject matters unwarranted by its counterclaims.

As with its overall antitrust rhetoric that ignores Roche's misappropriation of Lin's inventions, Roche's claims of Amgen not providing appropriate antitrust discovery similarly ring hollow. Amgen has produced over 1.7 million pages of documents in this litigation. To date, Amgen has produced 256,654 pages related to the recently alleged antitrust counterclaims, 209,703 pages will be served next week, and several hundred thousand more pages of related documents are being reviewed to find responsive documents so that they may be produced before the document cut-off date. (Gaede Decl., ¶ 5.) Amgen is providing fulsome discovery of responsive antitrust documents identified after a reasonable investigation.

The issue here lies not with Amgen's compliance, but with Roche's overly expansive view of relevance that violates Rules 26 (b) and (g). Those Rules, as amended in 2000, set up a three part analysis: (1) whether the discovery is relevant to the claims and defenses of the suit; (2) if not, whether the discovery sought is (a) subject matter involved in the litigation and (b) the requesting party has shown good cause; and (3) even if the foregoing is satisfied, whether the discovery is unduly burdensome and thus impermissible. A party does not meet these burdens by advancing speculative arguments, and subject matter is not "involved" in the litigation "if the

inquiry is based on the party's mere suspicion or speculation."[1] At several junctures, Roche's motion violates these parameters. To illustrate, Roche's CERA product may not legally enter the United States market until the FDA approves it, which is not expected until mid-2007. Roche has no current antitrust injury. Nonetheless, Roche's motion seeks to compel broad and burdensome antitrust discovery going back to 1985 without having established relevance or that such burden is justified.[2]

Roche's counterclaims allege that Amgen has acted improperly in selling Epogen and Aranesp to the ***nephrology*** End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) "markets." However, Roche seeks far ranging discovery into Amgen's Epogen and Aranesp sales and marketing efforts in the distinct ***oncology clinic*** channel under the guise of "oncology" discovery by seeking "all documents" related thereto. Roche is seeking extensive oncology documents, even though it does not allege "oncology" to be a "market" in its counterclaims, violating Rule 26's strictures.

Finally, and so flawed is Roche's motion, that it even moves to compel production of documents that the Court on January 3 previously denied Roche's motion to compel upon. Roche again seeks to compel production of all documents from the 1997-98 arbitration between Amgen and Ortho Biotech (Request 42). As Amgen explained before, this contract arbitration is not relevant to this patent infringement suit.

Amgen is in the process of producing hundreds of thousands of pages from central files and custodians for the alleged nephrology ESRD and CKD "markets" that Roche's antitrust counterclaims frame as relevant, including significant documentation related to hospital

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[1] *Micro Motion, Inc. v. Kane Steel Co., Inc.*, 894 F.2d 1318, 1326 (Fed. Cir. 1990).

[2] Roche's motion represents that during the meet and confer, "Roche has attempted to narrow categories of documents it seeks – most significantly by limiting the date for most requests to documents after January 1, 2002." Roche Mem. at 5. However, Roche's motion seeks "the Court to order Amgen to produce all relevant documents called for by the requests" without any mention of a date restriction. *Id*. Further, Roche's position chart for most requests fails to provide a date. *Id*. at 2-4. As drafted, Roche's requests either seek documents from 2000 forward (Document Request No. 70-72, 74), provide a 1985 date, or fail to provide any date restriction whatsoever.

contracting where there is overlap because these customers purchase for nephrology and oncology use. Roche's motion is not an attempt to obtain legitimate discovery within the proper scope of Rule 26 (b) and (g), but rather an attempt to place on Amgen a never-ending and burdensome search for irrelevant documents. Amgen request that Roche's motion be denied.

For the Court's convenience, Amgen sets forth a specific response to each request as described in Roche's summary chart. Roche Mem. at 2-4.

Doc Requests	Document Topic	Relevance
61 and 62	Documents concerning and demonstrating Amgen's share of sales in the markets Roche has alleged.	**DEFENDANTS' POSITION:** Documents demonstrating Amgen's share of the alleged relevant markets is of critical importance to establishing Amgen's market and/or monopoly power, an element common to all the antitrust claims. Documents *concerning* Amgen's share of sales in these markets is relevant (indeed important) to evidencing that they are, in fact, relevant antitrust markets. **AMGEN'S POSITION:** The requests by their terms request information on the nephrology End Stage Renal Disease (ESRD) and the Chronic Kidney Disease (CKD) channels – the nephrology channels Roche's counterclaims allege. Amgen is producing and will produce documents identified after a reasonable investigation that are (1) stored on its central servers for the employees involved in such analysis, (2) held by individual custodians likely to have such information, and (3) are generated after January 1, 2002 – 5&1/2 years before Roche's CERA product is likely to come on to the market for nephrology indications. Amgen objects to the requests as drafted because (1) they in fact call for all documents relating to such subject matter, potentially subjecting Amgen to an endless and burdensome search through its corporation for any document relating to sales in these markets and (2) would go back to 1989 when Amgen began selling Epogen. Roche has shown no need for such burdensome and overbroad discovery when, as it admits, it will not be on the market with CERA until mid 2007.
63	Documents concerning the structure or	**DEFENDANTS' POSITION:** Documents concerning the structure or parameters of markets are of critical importance to market definition

Doc Requests	Document Topic	Relevance
	parameters of the markets for ESA products for the treatment of ESRD or CKD.	and entry barriers. Because Amgen contests the relevant markets Roche alleges in its counterclaims, documents in which Amgen employees discuss the structure or parameters of ESA market(s) are critically relevant. **AMGEN'S POSITION:** The scope of the Request is focused on the nephrology ESRD and/or CKD channels, and not to all "markets for ESA products," as Roche's chart represents. Amgen is producing and will produce documents identified after a reasonable investigation that are (1) stored on its central servers for the employees involved in such analysis, (2) held by individual custodians likely to have such information, and (3) are generated after January 1, 2002 – 5&1/2 years before Roche's CERA product is likely to come on to the market for nephrology indications. In addition, Amgen is producing business and strategic plans that demonstrate Amgen's views on the market. Amgen objects to the requests as drafted because (1) they in fact call for all documents relating to such subject matter, potentially subjecting Amgen to an endless and burdensome search through its corporation for any document relating to a market, and (2) the request would go back to 1989 when Amgen began selling Epogen, subjecting Amgen to undue burdensome discovery for Roche's CERA product that is not even on the market.
64	Documents concerning the entry, potential entry, and barriers to entry of ESA products into the market(s) for ESA products.	**DEFENDANTS' POSITION:** The obstacles that new products or firms confront to successful and meaningful entry into the markets is central to demonstrating Amgen's market and/or monopoly power. Documents in which Amgen personnel discuss the barriers new entrants confront, and Amgen's erection of further entry barriers, are central to demonstrating anticompetitive effects and are precisely the type of documents being requested that Amgen is not committing to produce. **AMGEN'S POSITION:** Amgen is producing and will produce documents identified after a reasonable investigation that are (1) stored on its central servers for the employees involved in such analysis, (2) held by individual custodians likely to have such information, and (3) are generated after January 1, 2002 – 5&1/2 years before Roche's CERA product is likely to come on to the

Doc Requests	Document Topic	Relevance
		market for nephrology indications. Amgen objects to the request as drafted because (1) it in fact calls for all documents relating to such subject matter, potentially subjecting Amgen to an endless and burdensome search through its corporation for any document relating to a market, (2) the request would go back to at least 1989 when Amgen began selling Epogen, subjecting Amgen to undue burdensome discovery for Roche's CERA product that is not even on the market, and (3) the request is not limited to the nephrology ESRD and CKD channels that Roche's counterclaims allege are at issue.
65-66, 69	Documents concerning business and strategic plans, market and price analyses and projections.	**DEFENDANTS' POSITION:** Amgen business plans, market and price analyses, projections and related documents (whether final or draft) are relevant to issues of market definition, entry barriers and Amgen's market and monopoly power, Amgen's anticompetitive intent and the anticompetitive effects of its conduct, as well as damages. Amgen's price analyses are also relevant to each of these issues. **AMGEN'S POSITION:** The requests as drafted ask for all business and strategic plans, market and price analyses and projections. The requests as drafted do not use the term "concerning" such subject matter. Roche's document request define "concerning" as "relating." Amgen accordingly objects to this articulated scope. Amgen is producing and will produce the documents concerning Amgen's business and strategic plans, market and price analyses and projections for Aranesp and Epogen in the ESRD and CKD channels that are (1) stored on its central servers for the employees involved in such analysis, (2) held by individual custodians likely to have such information, and (3) are generated after January 1, 2002 – 5&1/2 years before Roche's CERA product is likely to come on to the market for nephrology indications. In addition, Amgen is producing business and strategic plans that discuss Amgen's oncology business. Amgen objects to the requests as drafted because (1) it in fact calls for all documents relating to such subject matter, potentially subjecting Amgen to an endless and burdensome search through its corporation for any document relating to a market, (2) the request would go back to at least 1989 when Amgen began selling

Doc Requests	Document Topic	Relevance
		Epogen, subjecting Amgen to undue burdensome discovery for Roche's CERA product that is not even on the market, and (3) as to Request No. 69, it is not limited to the nephrology ESRD and CKD channels that Roche's counterclaims allege are at issue
42, 43, 61-66, 69, 114, 115 , 116	Documents concerning ESAs sold for oncology indications.	**DEFENDANTS' POSITION:** Documents concerning ESAs sold for oncology are relevant to the appropriate market definition, especially as Amgen avers that the relevant market definition must account for "all customers who can and do purchase such [ESA] products." Roche, moreover, has explained that sales of drugs approved for multiple indications in other channels may nonetheless be relevant to calculating total sales and shares in CKD ESA and ESRD ESA, the two alleged relevant markets. Documents regarding oncology sales are also relevant to the anticompetitive effects in the alleged relevant markets of Amgen's conditioned discounts, because Amgen engages in the same practice in oncology, and thus the consequences of bundling in oncology are relevant to predicting the consequences of Amgen bundling in the ESRD and CKD ESA markets. The sale of ESAs in oncology – where Amgen's Aranesp battles against Ortho's Procrit – is also relevant to Amgen's probability of success in monopolizing the CKD relevant market in which Aranesp and Procrit are the only available products. Procrit's continued vitality generally (including in oncology) is relevant to whether Amgen can achieve dominance in the CKD ESA market if it succeeds in thwarting CERA. Finally, documents regarding oncology are relevant to damages because they provide a benchmark for estimating the share and profit that a new entrant – as Amgen's Aranesp was beginning in 2002 – can capture from an incumbent. **AMGEN'S POSITION:** Roche contends that the relevant markets are the nephrology ESRD and CKD. Accordingly, Amgen is producing responsive documents on Epogen, Aranesp and Roche's CERA product (which are ESAs) that are (1) stored on its central servers for the employees involved in such analysis, (2) held by individual custodians likely to have such information, and (3) are generated after January 1, 2002 – 5&1/2 years before Roche's CERA product is likely to come on to the market for nephrology indications. In addition, Amgen is producing the hospital contracts and the negotiations thereof, that include both nephrology and

Doc Requests	Document Topic	Relevance
		oncology, and documents sufficient to show market definition. Request 42 seeks all documents and electronic data concerning the arbitration between Ortho-Biotech, Inc. and Ortho-McNeil Pharmaceutical Corp and Amgen and Kirin-Amgen, Inc. As to these documents, the Court's January 3 order denied Roche's previous motion to compel further response to Request No. 42 that called for production of the Ortho arbitration documents. Roche has made no specific showing to alter that ruling. Request 43 seeks all documents and electronic data concerning the litigation between Ortho Biotech Products, L.P. and Amgen. This litigation with Ortho over Procrit generally involves the oncology clinic channel which Roche has not contended is at issue here and thus is not relevant under Rule 26. Amgen objects to further discovery of oncology, particularly in the oncology clinic channel, because Roche has not met the requirements of Rule 26 for such discovery. Nor could it where Roche will not be able to sell CERA into this channel until 2009 at the earliest.
70-72, 74	Data concerning Amgen's sales, prices, costs, and profits in native format from January 1, 2000 forward.	**DEFENDANTS' POSITION:** Amgen has agreed to produce some data regarding this issue, but not in native format. Under F.R.C.P. 34, as recently amended, a party is entitled to obtain electronically stored data in a "reasonably usable form." To the extent Amgen has such data in a form that is searchable and capable of being manipulated, Roche has a right under rule 34 to the information in that form. **AMGEN'S POSITION:** Amgen has agreed to provide documents sufficient to show such information since January 1, 2000, that relate to Epogen and Aranesp. As to format, the parties have no agreement to provide such documents in native format and the Federal Rules do not impose such an obligation. *Wyeth v. Impax Labs., Inc*., 2006 U.S. Dist. LEXIS 79761 (D. Del. Oct. 26, 2006)
114	Documents concerning contracts between Amgen and its customers for ESA products from	**DEFENDANTS' POSITION:** Documents concerning Amgen's contracts with ESA customers are central to Roche's claims that Amgen is engaged in anticompetitive plan to threaten and intimidate potential Roche customers, as well as to

Doc Requests	Document Topic	Relevance
	January 1, 2003 forward.	foreclose Roche from customers by entering into exclusive dealing arrangements. **AMGEN'S POSITION:** Amgen is producing the contracts and the negotiations thereof since January 1, 2002 in nephrology ESRD and CKD that Roche contends are at issue in the litigation. In addition, Amgen is producing the hospital contracts and the negotiations thereof, that include both nephrology and oncology, and documents sufficient to show market definition. Amgen objects to producing such documents in the oncology clinic channel where (1) Roche's alleged "markets" are ESRD and CKD and it has not articulated that the channel is relevant to its nephrology-based counterclaims and (2) Roche will not be able to sell CERA into this channel until 2009 (at the earliest) as it has not even filed a Biologic License Application with the FDA to sell CERA for such oncology indications.
42, 43	Documents from Amgen litigation in New Jersey against Ortho and its arbitration with Ortho about ESA products	**DEFENDANTS' POSITION:** These documents are of central relevance to the issue of whether Amgen's current claim that Aranesp is covered by the patents-at-issue was asserted in these proceedings. In addition, Amgen's bundled discounting practices at issue in the Ortho litigation in New Jersey are directly relevant to Roche's claim here that Amgen's bundling as to hospitals is foreclosing it from potential Roche customers. **AMGEN'S POSITION:** As to these litigation documents, the Court's January 3 order denied production of the Ortho arbitration documents on relevance grounds. Roche has made no specific showing to alter that ruling. The New Jersey litigation with Ortho over Procrit generally involves the oncology clinic channel which Roche has not contended is at issue here and thus is not relevant under Rule 26.

II. SUMMARY OF MEET AND CONFER

Several meet and confers were held to address the broad scope of Roche's antitrust document requests. During this process, several salient themes as to the breadth, burden, and one-sided positions Roche was advocating emerged. Amgen pointed out to Roche the broad scope of several requests. (Gaede Decl., Exs. 1-4.) At no juncture did Roche state that it

disagreed with Amgen's assessment of the broad scope. (Gaede Decl., Exs. 5-7.) Amgen further asked Roche how it could justify requiring Amgen to produce documents generated up to the present, when in its document productions, Roche had refused to produce documents generated after April 2006, and in fact had not produced any documents generated after January 1, 2006. (Gaede Decl., ¶ 3.) Again, Roche refused to respond, stating that it would only address specific document requests. Finally, in response to Roche's request that Amgen produce drafts, Amgen agreed it would produce them upon Roche's acknowledgement that it would produce drafts as well. (Gaede Decl., Ex. 4.) Again, Roche refused to agree, stating that it would only respond on a request by request basis.

Most importantly, Roche's final meet and confer letter of January 17, 2007, acknowledged Amgen's agreement to produce several categories of documents. However, Roche's letter continued to insist that Amgen's proposal to limit several requests to sufficient to show was unworkable. (Gaede Decl., Ex. 7.) Roche's letter further asked that if Roche was under a misapprehension as to the depth of documents Amgen was producing in this regard, including memorandum and e-mail, Amgen should inform Roche. (Gaede Decl., Ex. 7.) The next day, Amgen did inform Roche that it was under a misapprehension, as Amgen had already produced and was continuing to produce such responsive documents, including memorandum and e-mails from custodian files. (Gaede Decl., Ex. 4.) A verbal meet and confer followed, but Roche refused to agree to address the Rule 26 issues that Amgen was raising, and filed this motion. (Gaede Decl, ¶ 5.)

III. ARGUMENT

A. PROPER STANDARDS FOR DISCOVERY

"Trial courts enjoy a broad measure of discretion in managing pretrial affairs, including the conduct of discovery."[3] Courts deny motions to compel filed by parties who seek

[3] *Mack v. Great Atlantic & Pacific Tea Co., Inc.*, 871 F.2d 179, 186 (1st Cir. 1989) (quoting *In re Recticel Foam Corp.*, 859 F.2d 1000, 1006 (1st Cir. 1988)).

to enforce overly broad discovery requests.[4] Indeed, the First Circuit has noted that "[parties] ought not to be permitted to use broadswords where scalpels will suffice, nor to undertake wholly exploratory operations in the vague hope that something helpful will turn up."[5]

Rule 26(b) provides that "[p]arties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party."[6] However, even if relevant to claims or defenses, discovery is not permitted where no need for the requested document is shown or compliance would be unduly burdensome.[7] Discovery of information not "relevant to the subject matter involved" in the litigation is even more circumscribed and requires a showing of good cause.[8] Moreover, Rule 26(g) specifically requires the party or attorney seeking discovery to certify that a "reasonable inquiry" has been made that the discovery request is warranted and is not "unreasonable" or "unduly burdensome."[9]

Roche relies on old pre-2000 antitrust cases to support its unfounded claim that its overbroad and burdensome document requests are reasonable. The proper scope of discovery under Fed. R. Civ. P. 26 was amended and narrowed in December 1, 2000,[10] redefining a new

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4 *See, e.g., Great Atlantic & Pacific Tea Co.*, 871 F.2d at 186-87 (holding that it was not an abuse of discretion for a district court to deny a motion to compel answers to two interrogatories that "Were overly broad with respect to time frame, job classifications, and geographic area").

5 *Great Atlantic & Pacific Tea Co.*, 871 F.2d at 187.

6 Fed. R. Civ. P. 26(b)(1) provides in pertinent part: "Parties may obtain discovery regarding any matter, not privileged, that is **relevant to the claim or defense of any part**y . . . . For good cause, the court may order discovery of any matter relevant to the subject matter involved in the action. Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." (emphasis added).

7 Id.; see, *Micro Motion, Inc. v. Kane Steel Co., Inc*., 894 F.2d 1318, 1322 (Fed. Cir. 1990) (citing *Hickman v. Taylor*, 329 U.S. 495, 507 (1947)).

8 Fed. R. Civ. P. 26(b)(1); *see, Micro Motion,* 894 F.2d at 1323.

9 Fed. R. Civ. P. 26(g)(2) provides that "The signature of the attorney or party constitutes a certification that to the best of the signer's knowledge, information, and belief, formed after a reasonable inquiry, the request, response, or objection is: (A) consistent with these rules and warranted by existing law or a good faith argument for the extension, modification, or reversal of existing law; (B) not interposed for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of litigation; and (C) not unreasonable or unduly burdensome or expensive, given the needs of the case, the discovery already had in the case, the amount in controversy, and the importance of the issues at stake in the litigation." *See also Micro Motion*, 894 F.2d at 1323, 1327.

10 *BG Real Estate Servs., Inc. v. Am. Equity Ins. Co*., No. 04-3408A(2), 2005 U.S. Dist. LEXIS 10330, 4-5 (E.D. La. May 18, 2005).

standard that is narrower than the old, pre-2000, broader standard[11] and permitting the judges to enforce tighter limitations on discovery that is overbroad and burdensome.[12]

The 2000 changes made to Rule 26 are meant to apply to all discovery matters.[13] The amended rules are not limited to cases with certain types of legal issues, and thus apply equally to all cases including cases addressing antitrust issues.

B. AMGEN IS RESPONDING TO REQUEST NOS. 61-64 THROUGH DOCUMENTS SEARCHED FOR ON CENTRAL SERVERS AND CUSTODIANS THAT CONTAIN THE REQUESTED INFORMATION ON THE CKD AND ESRD NEPHROLOGY CHANNELS AS CALLED FOR IN THE REQUESTS

Amgen does not object to and is providing reasonable discovery within the scope of these four requests aimed at the ESRD and the CKD channels. Specifically, Amgen has searched for and is producing custodian documents from "certain employees in its sales and marketing departments responsible for the products at issue here," as Roche argues Amgen must do. Roche Mem. at 10. This includes a "search of their files and e-mails" and includes and will include "e-mails, memoranda, less formal analyses and reports, drafts" and "other internal documents discussing these matters." *Id*. at 8-10. In fact, as part of its rolling production, Amgen already has produced some of these documents, despite Roche's contention that Amgen has not done so. (Gaede Decl., ¶ 4.) Amgen is currently collecting and processing and will produce more responsive documents from these same sources. Amgen likewise has searched the central servers of these key sales and marketing groups for the ESRD and CKD channels to locate the relevant documents.

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[11] *Seaga Mfg., Inc. v. Fortune Resources Enterprises, Inc*., No. 99C50332, 2002 WL 31399408, at *3 (N.D. Ill. Oct. 24, 2002).

[12] Under the post 2000 standard, Fed. R. Civ. P. 26(b)(2)(iii) permits a judge to "limit" a discovery request by taking into account the following factors: 1) the burden or expense of the proposed discovery outweighs its likely benefit, 2) taking into account the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the litigation, and 3) the importance of the proposed discovery in resolving the issues. *UPS of Am., Inc. v. The Net, Inc.*, 222 F.R.D. 69, 71 (E.D.N.Y. 2004); *Pulliam v. Continental Cas. Co*., 2006 U.S. Dist. LEXIS 72302 (D.D.C. 2006).

[13] Fed. R. Civ. P. 26(b)(2) advisory committee's notes to 2000 Amendment; *see Thompson v. Dept. of Housing and Urban Dev*., 199 F.R.D. 168, 171 (D. Md. 2001) (summarizing the various changes to Rule 26(b)(2) from 1970 to 2000).

While complying in a reasonable and good faith manner, Amgen has not simply agreed to the scope of the requests as drafted on several grounds in order to protect itself from unfair, unduly burdensome, and vague discovery requests that violate in the first instance Roche's obligation to draft and propound document requests that comply with Rule 26 (b) and (g).

First, if not limited to relevant custodians deemed most likely to have such information and the central servers of these key groups, Amgen is effectively required to search through the entire company for responsive documents, placing undue burdens on Amgen.

Second, this potential undue burden is compounded by Roche's failure to acknowledge to the Court the broad scope of the requests. For example, during the meet and confer, Amgen pointed out to Roche that Request No. 61 effectively encompassed every document relating to sales of Amgen's Epogen and Aranesp product in the United States because such documents related to "total sales," as the literal language of the request calls for. (Gaede Decl., Exs. 1, 3 and 8.) Roche never disavowed this scope during the meet and confer. (Gaede Decl., Ex. 3.) Roche's motion argues that it only wants documents "concerning" such "sales," Roche Mem. at 2, but fails to inform the Court that its document requests redefine the word "concerning" to include the much broader scope of "relating to," and hence any document "concerning" sales would include any documents relating to sales. Roche is seeking to place on Amgen overbroad and unduly burdensome requests. (Gaede Decl., Ex. 4.)

Third, and finally, with respect to Requests No. 63 and 64, the requests cover all channels of sales in the United States, but Roche's counterclaims only identify the nephrology CKD and ESRD channels as relevant. *See* Section III.F, *infra*. Roche is attempting to obtain broad and burdensome discovery into oncology channels that are not even part of Roche's counterclaims in violation of Rule 26 strictures. Nevertheless, Amgen is producing business and strategic plans pertinent to the oncology channel.

C. AMGEN IS PRODUCING THE RESPONSIVE DOCUMENTS TO REQUESTS NOS. 65-66 AND 69

Amgen is producing "all business plans, marketing plans, sales or market projections, market analyses, market share projections, pricing plans, pricing analyses, sales plans or projections for the sale or license" of Aranesp and Epogen, as specifically called for in Requests Nos. 65 and 66.

Roche's motion raises a number of issues on these requests, none of which have merit. First, Roche contends that Amgen refuses to produce drafts of the requested documents. Amgen has withdrawn its objection on drafts of such documents, and will be producing these documents, despite Roche failing to agree that it too would produce draft documents. (Gaede Decl., Ex. 4.)

Second, Amgen has agreed to produce such documents generated effective January 1, 2002. This is despite Roche not even having entered the alleged nephrology markets with CERA as of the filing date of this motion. In fact, CERA is not expected to receive FDA approval for the nephrology indication until sometime in mid-2007 – five and a half years later. Roche's requests, however, are unbounded as to time, and thus with Epogen, effectively seek documents going back to at least 1989, when Epogen entered the market. Roche has made no showing of relevance and need to justify burdening Amgen with such broad discovery of such old information.

Third, Roche claims that Amgen has refused to produce all formal and informal documents (e-mails etc.) "discussing" these plans and projections. Roche Mem. at 10. However, Request Nos. 65, 66 and 69 on their face do not call for such documents "discussing" or relating to the identified plans, analyses and projections. Roche is asking the Court to compel production beyond the literal scope of the requests themselves.

Finally, Amgen objects to Request No. 69 because it relates to all ESAs and all markets. Roche's counterclaims are not so broad, and are limited to the nephrology ESRD and CKD channels. *See* Section III.F, *infra*. Roche's motion fails to make a proper showing of relevance under Rule 26 that broader and burdensome discovery into the oncology clinic channel is

relevant to it nephrology based claims. As mentioned above, however, Amgen is producing business and strategic plans pertinent to the oncology channel.

D. AMGEN IS PROVIDING THE DATA REQUESTED IN REQUESTS NO. 70-72 AND 74 CONCERNING AMGEN'S SALES, COSTS, PROFITS AND MARGINS FOR ITS ARANESP AND EPOGEN PRODUCTS AS RELEVANT TO ROCHE'S CLAIMS

These four requests originally call for all documents relating to Amgen's price, cost, profit and loss information on Epogen and Aranesp ***since 1985***. This includes "manufacturing costs, marketing costs, sales costs, general overhead, administrative costs" etc. Amgen does not object to reasonable discovery in this area, agreeing to provide documents sufficient to show its prices, costs, profit and loss since January 1, 2000, in the ESRD and CKD nephrology channels that Roche's counterclaims define as the relevant markets. Again, given that the CERA product is not coming on to the market until at least mid-2007, providing such documents on a sufficient to show basis stretching back to the beginning of the decade is reasonable. Amgen will also be providing basic pricing information on Epogen going further back (Aranesp did not come into the marketplace until 2001.)

Roche's motion states that Amgen must produce the data in native format, but cites no authority for Amgen being obligated to provide the data in that format. Roche Mem. at 11. Roche has not produced any of its cost data in such a format, showing that Roche does not understand the Federal Rules to impose on a party such an obligation.

Roche's request for oncology related sales and cost information also violates Rule 26 because Roche has not made a particularized showing of relevance and tying it to Roche's counterclaims. The generalized and conclusory allegations of relevance that Roche's motion makes are insufficient to meet its burden under Rule 26. *See* Roche Mem. at 11.

E. AMGEN IS PRODUCING THE RESPONSIVE DOCUMENTS TO REQUESTS NO. 114 CONSISTENT WITH THE PARTIES' AGREEMENT

Like many of Roche's other claims in this motion, Amgen is left wondering what else Roche seeks with respect to Request 114. Roche claims that it "is entitled to the contracts

and all documents evidencing their negotiation and their performance and enforcement -- not just a narrow subset." Roche Mem. at 12. Roche goes on to argue that it "is entitled to any internal correspondence concerning those contracts and any drafts of them." *Id.*

Amgen has already agreed to produce such documents and Roche was aware of this prior to filing its Motion to Compel. The January 17, 2007 letter from Roche's counsel, Mr. Mayell, states "there are some areas on which we have reached agreement….set forth below is a list of the information we understand Amgen is willing to produce." (Gaede Decl., Ex. 7.) One of the areas of agreement listed in this letter is as follows:

> Request 114: Amgen will produce contracts for the supply of Epogen and Aranesp since January 1, 2003 with dialysis, nephrology and hospital customers, including documents concerning negotiations of those contracts with the customers or any group purchasing organization representing those customers.

Id. Further, to ensure proper discovery, Amgen then represented that it would provide the internal documentation on the hospital contracting. (Gaede Decl., Ex. 4.) Why Roche felt it necessary to file a Motion to Compel with respect to a Request in which the parties had reached agreement is beyond Amgen's comprehension. Nevertheless, Amgen reaffirms that it will produce documents consistent with the parties' agreement on Request 114 as accurately reflected in Roche's January 17, 2007 letter, and Amgen's January 18, 2007, letter.

F. AMGEN IS PRODUCING DOCUMENTS PERTAINING TO ONCOLOGY BUT SHOULD NOT BE REQUIRED TO CONDUCT A BURDENSOME AND EXPANSIVE CUSTODIAL SEARCH GIVEN THAT ROCHE'S COUNTERCLAIMS ARE LIMITED TO THE ALLEGED ESRD AND CKD MARKETS

Roche's attempt to conduct broad and burdensome discovery into oncology, an area that is not related to Roche's counterclaims, should not be permitted. Roche attempts to leverage a dispute between the parties on market definition as a method for seeking as much discovery in an area that is not related to Roche's counterclaims as are ESRD and CKD, two areas that are squarely at issue. Furthermore, Roche believes that its argument that "it has not ruled out alleging an all ESA market" is a basis for seeking discovery beyond the allegations

currently in its counterclaims. Roche Mem. at 15. If this was the way discovery worked, there would be virtually no limits to the documents that would have to be collected and produced. Roche cannot seriously expect Amgen to consider all *potential* arguments that Roche may raise at a later date in determining which documents to search for. In addition, Roche will not be able to sell CERA into this channel until 2009 (at the earliest) as public reports indicate that Roche is still engaged in Phase II clinical trials for this indication without any information that it has even begun Phase III clinical trials. As such, Amgen should not be required to conduct a burdensome search of custodians related to oncology.

Nonetheless, Amgen has produced many documents that bear directly on the issue of market definition, which include documents related to oncology. Prior to the filing of Roche's Motion to Compel, Amgen informed Roche that:

> Far from 'refusing to undertake a search for, and produce' documents relating, for example, to the 'structure or parameters of the markets or submarkets for any ESA products sold in the United States," (Request 63) Amgen has searched for and produced many thousands of pages of documents relating to these matters, just as it has with respect to requests 61, 62, 63, 65, 66, and 69, including documents held by various custodians. These include e-mails, and memos that you claim have never been produced.

(Gaede Decl., Ex. 4.)

Furthermore, Roche's Motion to Compel fails to mention Amgen's agreement to produce documents related to oncology in hospitals, a setting of care in which the products at issue are used for various indications, such as nephrology and oncology. In reference to Roche's January 17, 2007 letter from Roche, Amgen stated:

> [Y]our letter ignores the fact that we agreed to produce Hospital contracts implicating both oncology and nephrology and the negotiations surrounding them. We are further prepared to provide discovery into the documentation surrounding the implementation of the Hospital contracting program provided that Roche agree to discovery of the same scope.

(Gaede Decl., Ex. 4.)

Roche's other arguments pertaining to oncology documents also are without merit. Roche's second argument for seeking extensive discovery on oncology is that "Procrit is

Aranesp's only rival for ESA oncology sales, making information and data regarding that segment, and Amgen's ability to hinder competition there, highly probative of Amgen's prospects of achieving monopoly power in the adjacent CKD ESA market." Roche Mem. at 16. Roche further contends that Amgen's "bundling of discounts" in oncology clinics is somehow relevant to Amgen's contracting practices in the market Roche has alleged. *Id*. at 6. Roche's reliance on faulty logic should not be the basis to require Amgen to undertake burdensome and unnecessary discovery. Merely because a company competes with the same competitor in two allegedly separate and distinct markets does not entitle a party to obtain information on the market that is not at issue in the case.

Consider a situation in which two national companies (*e.g.*, gasoline station operators) compete in various regions of the country. If an antitrust suit is filed against one of the companies solely for its actions in Boston, does that mean that the plaintiff would be entitled to discovery related to competition in Anchorage? Clearly, the answer is no. Similarly, the fact that Amgen and Ortho compete in oncology is not sufficient basis for Roche to seek extensive discovery with respect to that channel when the only alleged and relevant markets are CKD or ESRD.

Roche's third argument is that "[b]ecause of the interrelationship of issues, Amgen should be required to produce documents concerning its antitrust litigation with Ortho, as well as documents concerning an arbitration with Ortho…" Roche Mem. at 16.[14] The fact is that there is no "interrelationship of issues" and, thus, Amgen should not be required to produce documents pertaining to its litigation or arbitrations with Ortho.

The antitrust litigation with Ortho that Roche refers to involves Ortho's claim that Amgen had engaged in antitrust violations in the "oncology clinic market". This segment is even narrower than oncology overall given that it is specific to the clinic channel. Clearly this channel-specific segment is not in any way related to Roche's counterclaims.

[14] Amgen will address Section VIII of Roche's Motion to Compel regarding the prior litigation and arbitrations here given the overlap of Roche's arguments in Sections VII and VIII.

Roche's fourth argument for seeking oncology documents is that "analyzing the scope of Amgen's success with Aranesp - including all uses for which it is sold - could provide an important benchmark for determining CERA's profits absent Amgen's anticompetitive scheme." Roche Mem. at 17. Like many of Roche's other arguments, this one is plagued with faulty logic. Roche cannot merely "crib" off of Aranesp's success in the oncology segment and assume that CERA would have the same success in the nephrology segment. There are different indications at issue, health care reimbursement methods have changed dramatically since Aranesp's entry, the performance of each product may vary, and the competitive dynamics for the various indications have evolved in the more than five years since Aranesp entered the oncology segment. Thus, Roche's erroneous contention that oncology documents would serve as a "benchmark" is not a sufficient basis to require Amgen to search far and wide for oncology documents.

G. AMGEN SHOULD NOT BE REQUIRED TO PRODUCE DOCUMENTS FROM THE ORTHO ARBITRATION (REQUEST NO. 42) THAT DID NOT CONCERN ANTITRUST ISSUES AND DO NOT RELATE TO ESRD AND CKD MARKETS

The arbitrations with Ortho pertained to the scope of Amgen's product license to Ortho. These were not antitrust cases. The documents are not pertinent to discussions of competition issues related to ESRD, CKD, or any other indication for that matter.

Furthermore, the Court's January 3 order denied production of the Ortho arbitration documents on relevance grounds. Roche has made no specific showing to alter that ruling. Amgen should not be burdened with producing documents that are not relevant under Rule 26.

IV. CONCLUSION

For the foregoing reasons, Amgen respectfully requests that the Court deny Roche's motion to compel.

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Respectfully Submitted,

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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.

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