UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, vs. F. HOFFMANN-LA ROCHE LTD; ROCHE DIAGNOSTICS GmbH; and HOFFMANN-LA ROCHE INC. Defendants.	CIVIL ACTION No.: 05-CV-12237WGY

DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO COMPEL THE PRODUCTION OF DOCUMENTS

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Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche") respectfully submit this memorandum in support of their motion to compel the production of certain documents from Amgen Inc. ("Amgen").

I. INTRODUCTION

The stakes in this patent and antitrust case are significant. Amgen seeks to preclude Roche from competing with Amgen in markets where annual sales are in the billions of dollars. Indeed, the stakes for the public cannot be measured in purely financial terms. Amgen's goal is to deprive the public of an important new drug with important health benefits for many very ill people. Roche has counter-claimed against Amgen for its unlawful efforts both in the courts and in the marketplace to thwart Roche's pro-competitive entry. Roche's claims are particularly germane since Congress is currently investigating how current market participants are charging uses of Amgen's ESA products. Discovery is moving apace and Roche has already produced over 1 million pages of documents, while Amgen (which has apparently litigated these very same patents in other cases) lags woefully behind and has produced barely 250,000 pages of mostly insignificant documents. Yet, despite this Court's clear directive and expedited schedule (which Amgen pressed), Amgen refuses to commit to producing all but a carefully selected and vetted set of documents, claiming it would be unduly burdensome to expand its production further. Despite numerous meetings of counsel, Amgen continues to object extensively to nearly all of Roche's First Set of Requests for Production of Documents, including those that concern Roche's antitrust counterclaims, while refusing to produce the types of information that go to the heart of Roche's claims. Amgen has been a market participant for almost two decades, and has forged a strong hold on the US market for its EPOGEN® and related ARANESP® products. More particularly, in recent years, confronted with a potential threat from Roche to its solitary

control of the U.S. market for these products, Amgen has undertaken an aggressive strategy in dealing with Roche and Amgen's own customers, most of whom are centered in large dialysis centers, to block the viability of Roche's entry into the marketplace. Roche's claims involve this recent activity, and the ability to delve into the heart of these claims centers on Amgen's production of documents and things relating to Amgen's conduct.

While Roche does not currently sell its MIRCERA™ product in the United States, Amgen nonetheless has followed an unparalleled campaign to close access to key customers and block entry to this market in numerous ways.

Accordingly, despite tremendous efforts to resolve the matter with Amgen, and despite reaching agreements on some issues, with the close of discovery fast approaching, Roche is compelled to bring this motion because Amgen is refusing to commit to producing documents that go to the heart of Roche's tortious interference and antitrust claims, which the Court has recently authorized Roche to maintain in this case. Amgen doesn't seriously argue burden, as it cannot, since its recent arbitration and antitrust litigation with J&J subsidiary (Ortho) would suggest that all this information has already been collected and produced by Amgen in those cases. Likewise, Amgen cannot contend that there would be any prejudice from such production. Amgen's refusal would exclude from discovery entire categories of information relevant to those claims. For the Court's convenience, these subjects, the affected specific Requests for Production, and those subjects' relevance are presented in chart form below:

Document Topic	**Relevance**	**Doc. Request**
Documents concerning and demonstrating Amgen's share of sales in the markets Roche has alleged.	Documents demonstrating Amgen's share of the alleged relevant markets is of critical importance to the establishing Amgen's market and/or monopoly power, an element common to all the antitrust claims. Documents *concerning* Amgen's share of sales of these markets is	61 and 62

	relevant (indeed important) to evidencing that they are, in fact, relevant antitrust markets.	
Documents concerning the structure or parameters of the markets for ESA products.	Documents concerning the structure or parameters of markets are of critical importance to market definition 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.	63
Documents concerning the entry, potential entry, and barriers to entry of ESA products into the market(s) for ESA products.	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.	64
Documents concerning business and strategic plans, market and price analyses and projections.	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.	65-66, 69
Documents concerning ESAs sold for oncology indications.	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	42, 43, 61-66, 69, 114, 115 , 116

	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.	
Data concerning Amgen's sales, prices, costs, and profits in native format from January 1, 2000 forward.	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.	70-72, 74
Documents concerning contracts between Amgen and its customers for ESA products from January 1, 2003 forward.	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 foreclose Roche from customers by entering into exclusive dealing arrangements.	114
Documents from Amgen litigation in New Jersey against Ortho and its arbitration with Ortho about ESA products	These document 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.	42, 43

To briefly summarize, Roche's antitrust counterclaims allege that Amgen has attained monopoly or near monopoly power over certain markets for drugs that stimulate the production of red blood cells (termed "erythropoiesis stimulating agents," or "ESAs"), which are used to treat patients suffering from a number of specified maladies. Roche further alleges that Amgen is anticompetitively protecting its dominance by erecting unlawful barriers to entry by Roche, which has overcome substantial obstacles to develop a different drug, CERA. Roche alleges that Amgen has, and continues, to impede Roche's entry by, *inter alia*, tying up potential customers with long-term contracts that will prevent them from doing business with Roche, threatening potential customers not to do business with Roche, and by asserting in this action patents

knowingly procured by fraud on the PTO. The requested documents speak directly to central issues in Roche's claims, including market definition and market power, damages, anticompetitive effects, and Amgen's specific intent to monopolize.

Two broad issues are raised by this motion. The ***first*** issue concerns Amgen's refusal to commit to searching for and producing documents relating to matters at the heart of Roche's antitrust claims. While 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, and otherwise narrowing the terms of some of the requests -- Amgen refuses to commit to producing all documents that would be responsive even to these narrowed requests. Instead, Amgen takes the position that it can produce some cherry-picked information relating to the antitrust claims yet not commit to searching its employees' files for additional relevant information. For example, Amgen refuses to agree to search for and produce documents concerning the "structure or parameters of the markets or submarkets for any ESA products sold in the United States," including documents related to "actual or potential substitutes." (See Request 63), contending that its "final" business plans are "sufficient" to provide all the information Roche needs (see Letter of William Gaede, dated January 16, 2007, Toms Declaration, dated January 19, 2007 ("Toms Dec."), Exh. A). Amgen takes similar positions on requests for information about the relevant markets and Amgen's market power. Amgen's position that it will provide documents "sufficient to show" certain information concedes that the documents Roche is requesting are relevant. But its response is inconsistent with its obligation under the Federal Rules of Civil Procedure, and such intransigence cannot be addressed by even the most generous effort by Roche to further narrow the original requests. Thus, Roche requests the Court to order Amgen to produce all relevant documents called for by the requests discussed below and reject Amgen's

attempt to confine its production based on its own unreviewable decision that a very limited set of documents gives Roche all the information it should want.

The ***second*** issue concerns Amgen's insistence in excluding from its production any documents relating to the sale of ESAs for oncology, where one of Amgen's products at issue in this case -- Aranesp -- is sold in competition with Ortho's Procrit. Amgen's objection to producing documents related to oncology is baseless. Although Roche's counterclaims allege two markets encompassing ESA drugs available and approved for renal end-uses (ESRD and CKD), as Roche explained in its Memorandum in Opposition to its Motion to Dismiss the sales of *all* ESA products for *all* uses may be relevant to determine firms' *shares* of those markets, as a drug indicated for oncology and renal use could be sold to the same customer (e.g., a hospital) and used for both purposes (Roche's Mem. in Opp. to Motion to Dismiss, 12/8/06 at 13-14, Docket No. 162). Moreover, Amgen has made clear that it will contest Roche's market definition and, as Roche also explained in opposing Amgen's Motion to Dismiss, it is too early for Roche to rule out the possibility of also defining an all ESA market, one that would obviously include oncology sales (Mem. in Opp. to Amgen's Motion to Dismiss at 14 & n.15). Indeed, in its motion to dismiss Roche's counterclaims, Amgen itself argued that Roche's market definitions are flawed because they fail to account for "all of the customers who can and do purchase such [ESA] products." (Mem. in Support of Amgen's Mot. to Dismiss Counterclaims, 11/27/06 at 7, Docket No. 151).

Documents concerning oncology also are relevant to Roche's claims of foreclosure based on Amgen's bundling of discounts across product lines, to Roche's claim that Amgen has a dangerous probability of achieving monopoly power in the CKD market, and to damages. Amgen's bundling of discounts in sales to oncology clinics and its consequences is important to

understanding how Amgen's bundling elsewhere (i.e., in hospitals) hinders CERA's ability to obtain sales in the ESRD ESA and CKD ESA markets. Amgen's anticompetitively increasing share of the market in oncology vis-a-vis Procrit is relevant to a key issue -- demonstrating that Amgen, if it succeeds in hindering CERA, has a dangerous probability of success in monopolizing the CKD –market, where Amgen's only present competition is Procrit. And the success of Amgen's entry with Aranesp against Procrit in all uses provides a natural experiment for understanding how CERA, but for Amgen's anticompetitive conduct, could thrive and thus for calculating some of Roche's antitrust damages.

II. Legal Standard

Roche is entitled to discovery of "any matter, not privileged, that is relevant to the claim or defense of any party . . . . Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." FED. R. CIV. P. 26(b)(1). "[T]he plain language of this Rule 26(b)(1) contemplates wide-ranging discovery to the fullest possible extent." *Klonoski v. Mahlab*, 156 F.3d 255, 267 (1st Cir. 1998).

"Discovery in antitrust litigation is liberally granted." *Riedel Int'l, Inc. v. St. Helens Invest., Inc.*, 633 F. Supp. 117, 119 (D. Or. 1985); *see also, e.g., Columbia Steel Casting Co. v. Portland Gen. Elec. Co.*, 1992 U.S. Dist. LEXIS 3036 (D. Or. 1992) (quoting same, overruling defendant's objection that requests were overly burdensome, and requiring defendant utility to produce documents regarding prices paid to other, non-party utilities for power); *Trans World Airlines, Inc. v. Hughes*, 29 F.R.D. 523, 524 (S.D.N.Y. 1961) ("The scope of proof is quite broad in these [antitrust] cases and under the liberal federal rules wide latitude is permitted in the deposition-discovery proceedings.").

Thus, while the scope of permissible discovery always is broad, it is especially important that, in antitrust cases, discovery be permitted from the accused monopolist regarding all evidence going to central issues such as market definition, market and monopoly power, anticompetitive effects, and damages. It seems that this is the same evidence that Amgen may rely on to defend these antitrust claims. *See, e.g., Banana Serv. Co. v. United Fruit Co.*, 15 F.R.D. 106, 108 (D. Mass. 1953) (overruling defendants' objection that interrogatories were unduly burdensome, and observing that "[i]t is well known that the preparation and proof of anti-trust cases requires the study and investigation of a multitude of facts and documents").

In all cases, the mere fact that a discovery request imposes a burden or expense on a party is not sufficient to avoid complying. Fed. R. Civ. P. 26(b)(2). As shown below, in the case of Amgen, a large pharmaceutical company with ample resources (and at least three major law firms acting on its behalf) and an apparently unlimited budget for offensive litigation, where billions of dollars and the public health are at stake, that burden cannot possibly be met.

III. Amgen Should Respond to Requests 61-64, Which Seek Documents Concerning the Relevant Markets, Amgen's Position in Them, and Potential Entrants

Requests 61-64 seek sales figures and other documents concerning Amgen's market share of ESA sales in the ESRD and CKD markets (Requests 61-62), concerning Amgen's analysis of the markets and submarkets for ESA products (Request 63), and concerning entrants, potential entrants and entry barriers (Request 64).[1] These requests seek not just final, vetted documents setting forth Amgen's final position as to market share, relevant markets and entrants, but other documents, including e-mails, memoranda, less formal analyses and reports, drafts

[1] A complete list of Roche's Requests for Production and Amgen's Responses and Objections is contained in the Appendix A, attached hereto.

(which often contain information important to antitrust cases, such as notes) and other internal documents discussing these matters, all of which are undeniably relevant.

In response to these requests, however, Amgen has agreed only to produce a limited set of documents "sufficient to show" Amgen's view of these issues. For example, as to Requests 61 and 62, Amgen only agrees to produce documents "sufficient to show the EPOGEN® and ARANESP® sales in the ESRD and CKD (nephrology) channels in the United States since January 1, 2002." (Toms Dec. Exh. A at 3). Despite being informed by Roche that only providing documents "sufficient to show" information was not acceptable, Toms Dec., Exh. B, Amgen refused to revisit its position, contending that various documents relating to the elements of Roche's antitrust claims are contained within the documents it has produced. Toms Dec., Exh. C.[2]

Amgen's only justification for its refusal to search for and produce a wider array of documents in response to these requests is Amgen's assertion that the requests are too broad. (*Id.*) Amgen's objection is baseless -- Roche's request for documents concerning market share, market structure and entrants is straightforward. Amgen should look for documents among its custodians discussing these topics of critical importance to the antitrust claims. Amgen's response -- that it will produce documents sufficient to show market share and the parameters of the market -- is plainly inconsistent with its obligations under the Federal Rules to look for and produce ***all*** responsive documents, not just a sampling.

"It is well known that the preparation and proof of anti-trust cases requires the study and investigation of a multitude of facts and documents." *Banana Serv. Co. v. United Fruit Co.*, 15

[2] Roche has in good faith attempted to narrow the scope of its antitrust-related document requests, but, other than reaching agreement in some limited areas, Amgen has not committed to producing all responsive documents. *See* Toms Dec., Exh. D.

F.R.D. 106, 108 (D. Mass. 1953) (overruling defendants' objection that interrogatories were unduly burdensome); *see also, e.g.*, *Hanover Shoe, Inc. v. United Shoe Mach. Corp.*, 207 F. Supp. 407, 409 (D. Pa. 1962) (rejecting antitrust defendant's objection that producing reports would be overly burdensome, and reasoning that "[a] party seeking discovery is not required to prove that documents contain material evidence, but it is sufficient if it is reasonably probable that they do"), *disapproved on other grounds as stated in*, *United States v. Leggett & Platt*, 542 F.2d 655, 659-60 (6th Cir. 1976).

In meet and confer discussions, Amgen has never explained what burden would be involved in searching for these documents -- nor has it itself proposed any manner of narrowing the request or its search for responsive documents. Presumably, Amgen has certain employees in its sales and marketing departments responsible for the products at issue here. Production would require search of their files and e-mails, as is customarily done in major antitrust cases. Amgen has many, many lawyers, and is a multi-billion dollar drug company with ample resources.

IV. Amgen Should Respond to Requests 65-66 and 69, Which Seek Business Plans, Marketing Plans, Analyses, and Projections Regarding the Relevant Markets.

Roche is entitled to review the business plans, marketing plans, analyses, and projections regarding the ESA products that these requests seek, including drafts and documents concerning these types of documents. In response to these requests, Amgen asserts a number of boilerplate objections including overbreadth and relevance, and Amgen has agreed only to produce "the final nephrology 'business, marketing, pricing and strategic plans' generated from January 1, 2002." (Toms Dec., Exh. A at 4.) Amgen omits projections, and also refuses to conduct any further search for drafts, e-mails and other documents discussing these plans and projections.

This refusal deprives Roche of any discovery into the candid views of Amgen's marketing personnel, relegating Roche to only the final reports Amgen describes in its letter.

V. Amgen Should Respond to Requests 70-72, and 74 Which Seek Data in Native Format Concerning Amgen's Sales, Costs, Profits and Margins for ESA Products

It is important to Roche's claims that it obtain thorough discovery concerning Amgen's marketplace position. At a minimum, this requires the production of documents, including electronic documents in reasonably usable format, that show:

> (1) Amgen's sales to individual purchasers, including hospitals, clinics, and group purchasing organizations;
>
> (2) the prices and any discounts or rebates given to Amgen's customers;
>
> (3) Amgen's costs of production, including costs associated with marketing and selling its ESA products; and
>
> (4) Amgen's profit margins.

(Roche Requests 70-72, 74).

Roche is entitled to discovery of such information covering all segments into which Amgen's ESA products are sold, including the oncology segment. This information speaks directly to the appropriate market definitions, Amgen's market and/or monopoly power, the anticompetitive effects of Amgen's actions, Amgen's ability to control prices, the impact of a new entrant, and Roche's damages. Particularly where common costs may be spread over several segments or markets, such data must be provided for all ESA sales. Moreover, because this data is important for the consideration of economics experts and may be kept in databases with multiple related files, Roche requests that it be produced in its native format.

VI. Amgen Should Comply with Request 114, Which Seeks Amgen's ESA Contracts and Related Documents Including Internal Correspondence Regarding Those Contracts.

Amgen does not deny that Roche is entitled to its contracts for the sale and supply of its ESA products, and its communications with its customers about those contracts and enforcement of their restrictive terms. Nor could it -- the contracts themselves and Amgen's communications with its customers (Roche's future CERA customers) form part of the very wrongful conduct that is challenged by Roche's antitrust and tortious interference claims. They also are relevant to Amgen's market power and its ability to force onerous and restrictive terms on its customers.

Despite this unquestionable relevance, however, Amgen has agreed only to produce its "contracts on the supply of EPOGEN® and ARANESP® generated since January 1, 2003 in the dialysis, nephrology and hospital context," and "documents on the negotiations of such contracts." (Toms Dec., Exh. A at 4) Furthermore, Amgen agrees to produce these limited documents only to the extent its "customers do not object." (*Id.*)

While Roche in an effort to reach an accomodation agreed with a time limitation for this request of January 1, 2003 forward, Roche nevertheless is entitled to the contracts and all documents evidencing their negotiation and their performance and enforcement -- not just a narrow subset. Roche also is entitled to any internal correspondence concerning those contracts and any drafts of them. The requested documents are reasonably calculated to discover admissible evidence concerning Amgen's alleged antitrust violations and tortious interference, including:

- Any of Amgen's exclusive dealing arrangements with third parties with respect to its ESA products;
- Amgen's actions to dissuade, discourage or forestall any purchaser of ESA products from purchasing ESA products from Roche in the future;

- Amgen's sales and marketing tactics threatening retaliation for use of Roche ESA products;
- Amgen's actual or contemplated plans to respond to any potential sales by Roche or another potential competitor;
- Amgen's use of discounting on other products (such as Neulasta and Neupogen) to impede competition for ESA products; and
- Amgen's discounting practices, which are plainly relevant to the issue of Amgen's market power and CERA's likely penetration upon release.

Once again, responsive documents surely could be found through a straightforward review of Amgen's marketing and sales files — a review that cannot be characterized as unduly burdensome in the antitrust context, and which should be carried out in response to all of Roche's requests. Amgen has made no showing whatsoever of any undue burden, particularly given the stakes in this litigation.

It appears that Amgen's only objection to production of these documents, again, is undue burden. For the same reasons discussed above, the standard for this objection cannot be met in this case. *See* Fed. R. Civ. P. 26(b)(2). Moreover, Amgen presumably has sales and legal personnel responsible for negotiating and implementing sales contracts for these products, and review of those files is standard in this type of case. Indeed, it is inconceivable that Amgen is not already reviewing those files to locate documents helpful to its defense.

VI. Roche Should Be Permitted Discovery Concerning ESA Oncology Sales.

The principles above, and cases applying those principles, do not support Amgen's effort to exclude from production documents relating to the sale, marketing, and use of its ESAs for oncology for a number of reasons.

First, documents concerning oncology are relevant to the definition of the relevant market for purposes of Roche's antitrust claims. Market definition is an intensely factual issue

that requires evidence concerning cross-elasticity of demand and whether products are reasonably interchangeable from the perspective of consumers. *See, e.g., United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 395 (1956). Evidence concerning the sale of products for closely-related uses, and how those sales relate to and/or affect the price of products sold into the candidate relevant market, is important to the market definition inquiry, as well as whether the candidate market is recognized to be distinct from other uses to which the product is put. *See, e.g., U.S. Anchor Mfg., Inc. v. Rule Indus., Inc.*, 7 F.3d 986, 995 (11th Cir. 1993) ("The boundaries of such a submarket [which may be a relevant market] may be determined by examining such practical indicia as industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors." (*quoting Brown Shoe Co. v. United States*, 370 U.S. 294, 325 & n.42 (1962))).

Therefore, Courts routinely allow broad market-definition related discovery, including discovery of information well beyond the party's candidate relevant market. "In determining the relevant market, the court may decide that a particular . . . product . . . is properly within the relevant market. Consequently, it would be necessary for plaintiff to have discovery with respect to such a product beyond that which defendant concedes is proper." *United States v. IBM Corp.*, 66 F.R.D. 180, 185 (S.D.N.Y. 1974) (allowing plaintiff discovery regarding defendant's products that were not directly at issue); *see also, e.g., Morgan Smith Auto. Prods., Inc. v. Gen. Motors Corp.*, 54 F.R.D. 19, 20 (E.D. Pa. 1971) (allowing discovery concerning all of defendant's automobiles, not just Chevrolets, and allowing discovery going back ten years regarding antitrust allegations); 1 AM. BAR ASS'N SECTION OF ANTITRUST LAW, ANTITRUST LAW DEVELOPMENTS (FIFTH) at 968, § I.4.a.(3) (2006) ("Where the definition of the relevant product market is

disputed, for example, ***courts generally allow discovery of products or product lines beyond the specific product at issue***. [¶] Information on products other than the product directly at issue may be discoverable if there is evidence that the defendant's business practices in those other products may have reduced competition in the product market directly at issue." (emphasis added)).

Critically, Amgen has not accepted Roche's definitions of the ESA markets relevant to this action. Indeed, in support of its motion to dismiss Roche's counterclaims, Amgen argued that Roche's ESRD and CKD market definitions are flawed because they fail to account for "all of the customers who can and do purchase such [ESA] products." (Mem. in Support of Amgen's Mot. to Dismiss Counterclaims, 11/27/06 at 7, Docket No. 151). Amgen cannot have it both ways, arguing that Roche's proffered market definitions should be rejected because they do not account for ESA consumers outside the ESRD and CKD segments, while simultaneously prohibiting discovery into any other segments. Moreover, Roche has explained that (i) it has not ruled out alleging an all ESA market and (ii) Amgen's *share* of the narrower ESRD ESA and CKD ESA markets might include sales made for *other* uses where the product has multiple indications (Roche's Mem. in Opp. to Motion to Dismiss 13-14 & n.15, Docket No. 162). Thus, Roche is entitled to full discovery into all uses for which the relevant products are sold so that it can prove the relevant markets for its claims, calculate sales and shares within those markets, and respond to Amgen's contentions that the relevant market is broader and/or that Amgen lacks market or monopoly power in such markets.

Second, evidence concerning the sale and marketing of ESAs for oncology use and Amgen's conduct respecting ESA oncology customers are relevant to Amgen's dangerous

probability of monopolizing the CKD market for ESAs,[3] an element of Roche's attempted monopolization claim. *See Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447 (1993).[4] Roche alleges that Amgen has been capturing sales from Ortho's Procrit in the CKD ESA market -- currently the only two participants in that market. 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. Thus, the fact that Roche does not anticipate obtaining an oncology indication for CERA for several years is irrelevant, because it is well-established that an antitrust ***"[p]laintiff's inquiries should not be restricted to the narrow limits of time and place within which this monopoly allegedly had its direct impact on plaintiff's business."*** *Banana Serv. Co.*, 15 F.R.D. at 109 (emphasis added) (allowing discovery regarding defendants' general business activities in areas other than the product at issue to show that those activities were part of a system to achieve and maintain monopoly power).[5]

Third, Because 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 (Requests 42 and 43).

Fourth, Amgen's sales for oncology are relevant to Roche's claim for damages. Amgen began selling an ESA for oncology use – its Aranesp product – beginning in 2002. Prior to that time, the only ESA available for that use was Ortho's Procrit, under license from Amgen. The

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3 Amgen has a 100% monopoly position in the ESRD market.

4 Monopoly power includes the "power to control prices or exclude competition." *See United States v. E. I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956).

5 Evidence concerning sales and competition in oncology is also relevant because competition or the lack thereof in the oncology may impact Amgen's ability to exclude rivals elsewhere (e.g., in CKD). If Amgen succeeds in vanquishing the CERA threat, whether Procrit can contest Amgen's march to monopoly in the ESA CKD market could depend on Procrit's ability to achieve sufficient scale economies generally, including in oncology.

competitive impact of Aranesp in oncology is thus relevant to assessing CERA's likely success – absent Amgen's anticompetitive conduct – in the ESRD ESA market, where Amgen currently has a complete monopoly, as well as relevant to the potential impact of CERA in the CKD market. In short, 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.

Accordingly, there is no justification for excluding from its production documents concerning oncology — particularly when the appropriate market definition is contested. Amgen should be required to produce documents relating to the sale, marketing, and use of its product for oncology, as well as documents relating to its disputes with Ortho as demanded in requests 42 and 43.

VIII. Amgen Should Produce Documents Regarding Its Prior Litigations and Arbitrations with Ortho

Amgen has failed to provide adequate discovery for Roche's Requests for Production Nos. 42 and 43 regarding the Ortho-Biotech v. Amgen arbitration and District Court of New Jersey case.[6] While not providing any documents responsive to these requests in the ITC and in

[6] **REQUEST FOR PRODUCTION NO. 42:**

All Documents and Electronic Data Concerning the arbitration before the America Arbitration Association, No. 51 13300242 97, between Ortho-Biotech, Inc. and Ortho-McNeil Pharmaceutical Corp. as claimants and Amgen and Kirin-Amgen, Inc. as respondents, Including all draft and final versions of forms submitted to the arbitrators, all docketed documents and official correspondence and drafts of such documents; all memoranda of law and drafts of memoranda; Including also transcripts from depositions and interviews, all discovery Including interrogatories, responses and objections to interrogatories, document requests, responses and objections to document requests, requests for answers and responses and objections to answers; expert reports; subpoenas; all Documents and other Things relied upon as demonstrative exhibits or evidence in the arbitration; all external references relied upon; and any other Document, Electronic Data, or Communication related to this action as well as any other Document, Electronic Data, or Communication related to any subsequent appeals or adjudications arising from the aforementioned arbitration.

its first wave of production, Amgen has offered in its most recent production a handful of incomplete hearing transcripts and a pair of memorandums. This is plainly and obviously insufficient. To the extent Amgen objects to producing these documents because of protective orders in place in the two proceedings, Roche refers to a January 11, 2007 letter from Walter M. Luers of Patterson Belknap Webb & Tyler, LLP to Gasper LaRosa of Kaye Scholer. In this

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AMGEN'S RESPONSE:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: Because the above-identified arbitration does not relate to any claim regarding enforcement of the patents-in-suit, this Request is irrelevant, overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Amgen further objects to this Request to the extent that the disclosure of documents responsive to this request would cause Amgen to violate a protective order entered into by an arbitrator or tribunal (the American Arbitration Association) in another judicial proceeding and to which Amgen is still bound. Amgen does not understand how the referenced arbitration concerning the interpretation of contracts is relevant to any claim or defense in this action; but, Amgen is willing to negotiate with Defendants to the extent Defendants believe otherwise in an effort to identify what, if any, subset of documents is relevant to this action.

REQUEST FOR PRODUCTION NO. 43:

All Documents and Electronic Data Concerning Ortho Biotech Products, L.P. v. Amgen, Inc., Civ A. No. 3:05-cv-04850-SRC-JJH, D.N.J., Including all draft and final versions of pleadings, all docketed documents and official correspondence and drafts of such documents; all memoranda of law and drafts of memoranda; Including also transcripts from depositions and interviews, interrogatories, responses and objections to interrogatories, document requests, responses and objections to document requests, requests for answers and responses and objections to answers; expert reports; subpoenas; all Documents and other Things relied upon as demonstrative exhibits or evidence at trial; all external references relied upon; and any other Document, Electronic Data, or Communication related to this action as well as any other Document, Electronic Data, or Communication related to any subsequent appeals or adjudications arising from the aforementioned civil action.

AMGEN'S RESPONSE:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: Because the above-identified action does not relate to any claim regarding enforcement of the patents-in-suit, this Request is irrelevant, overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Amgen further objects to this Request to the extent that the disclosure of documents responsive to this request would cause Amgen to violate a protective order entered into by a court in another judicial proceeding and to which Amgen is still bound. Amgen does not understand how the referenced action is relevant to any claim or defense in the action; but, Amgen is willing to negotiate with Defendants to the extent Defendants believe otherwise in an effort to identify what, if any, subset of documents is relevant to this action.

letter, Mr. Luers states that Johnson & Johnson has "agreed to give Amgen permission to produce responsive J&J documents that are in Amgen's possession." Given J&J's asserted compliance, Roche fails to see any remaining roadblocks to complete discovery. As the arguments in the Ortho arbitration and litigation (particularly with regard to whether Aranesp was or was not covered by Amgen's EPO patents) are clearly germane to the current action (at least inasmuch as Amgen should be estopped from making inconsistent arguments in this case), Roche is entitled to a full production on these requests.

IX. Conclusion

For all of the foregoing reasons, Roche respectfully requests that the Court compel Amgen to produce documents as set forth in the Proposed Order accompanying this motion.

Dated: January 19, 2007

F. HOFFMANN-LA ROCHE LTD,
ROCHE DIAGNOSTICS GMBH, and
HOFFMANN-LA ROCHE INC.

By its Attorneys,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and, due to the federal holiday, paper copies will be sent to those indicated as non-registered participants on the above-referenced date.

/s/ Keith E. Toms
Keith E. Toms

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