EXHIBIT 1

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

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I. INTRODUCTION

Amgen does not resist complete discovery of all relevant issues in this case and to that end, it has produced already over 1.5 million pages of documents and is preparing to produce thousands of additional documents shortly. Amgen does, however, object to Defendants' fishing expedition.

Defendants' motion evidences one of the fundamental themes in their case — their desire to elevate "peg" over EPO, in an attempt to divert this Court's attention away from the indisputable fact that their peg-EPO product contains EPO. They do so by asserting that they should be entitled to all of Amgen's research and development relating to pegylation, regardless of the protein to which the peg is attached. But, if EPO is the key that has unlocked the door to anemia treatment, then peg is a key chain; the fact that Defendants attach a key chain to that EPO key does not make relevant every other key to which a key chain might be attached.

In support of their requests for all of these keys and key chains, Defendants assert that discovery into Amgen's pegylation efforts generally is "crucial to Roche's defense of non-infringement."[1] Defendants' justification for this far-reaching discovery turns long-settled jurisprudence on its head by urging a comparison of the accused product with the patentee's products (some of which Defendants admit are not even covered by the claims).[2] Defendants' other purported justification for this discovery — to test "Amgen's view [that] pegylation is simple"[3] — is similarly wanting. Amgen's "view" of pegylation is simply not relevant to Defendants' infringement of the Lin Patents. In any event, Defendants themselves have publicly stated that pegylation techniques are well known.[4] Thus, contrary to Defendants' assertions,

[1] Defendants' Memorandum in Support of Their Motion To Compel the Production of Documents, Docket No. 172, at 6 (hereinafter "Defendants' Memo").
[2] *See Zenith Labs. v. Bristol-Myers Squibb*, 19 F.3d 1418, 1423 (Fed. Cir. 1994).
[3] Defendants' Memo at 2.
[4] Exhibit 3 ("A large amount of literature is available on pegylation, including several books and reviews.") Veronese *et al.,* Adv. Drug Delivery Reviews, Vol. 54, p. 453-456, 453 (2002); *see also* Confidential Exhibit 2 (relevant excerpts of Defendants' MIRCERA® BLA:STN 125164/0) at ITC-R-BLA-00007086–0007087 (Report No. 1005700 dated August 24, 2001).

whether pegylation is simple or difficult or whether pegylation affects the structure, composition or properties of specific molecules that are *not* accused of infringement, are not the issue — the infringement issue in the context of the patents-in-suit is whether Defendants' peg-EPO product contains EPO, which plainly it does.[5]

Defendants also seek far-reaching discovery regarding Amgen's Aranesp® product — a product that does not share the same amino acid sequence of human EPO — discovery that could literally encompass millions of documents. In response to Defendants' requests, Amgen has offered to and will produce documents that are relevant to this litigation. Specifically, Amgen agreed during the meet and confer to produce (1) Aranesp® documents relating to whether Aranesp® is a commercial embodiment within the scope of any of the claims of the Lin Patents, and (2) documents sufficient to show Aranesp®'s structure, activity, method of production and method use. Amgen will also produce a reasonable scope of Aranesp® documents related to Amgen's request for injunctive relief. In view of the Court's recent ruling on Amgen's motion to bifurcate, Amgen will additionally produce Aranesp® documents relating to Defendants' antitrust counterclaims. But Defendants want more.

To justify their overly broad requests for Aranesp® documents, Defendants argue that Aranesp® is "not covered by the patents-in-suit, likely for at least some of the same reasons . . . MIRCERA™ does not infringe the patents-in-suit."[6] Putting aside Defendants' legally improper comparison of the accused product with Aranesp® rather than the claims, Defendants' demand for unfocused discovery into all aspects of research and development of a product because it does not infringe cannot be trued with the principles of the rules of civil procedure. Failing that, Defendants offer an alternate justification for discovery into Amgen's research and development of Aranesp®, which next assumes Aranesp® is covered by the patents-in-suit. Defendant claims

[5]Confidential Exhibit 4 (Defendants' Responses to Amgen Inc.'s First Set of Requests for Admission (Nos. 1-22)) at 12.

[6] Defendants' Memo at 13.

that this discovery is "critical to Roche's invalidity defenses."[7] Defendants' conclusory incantations of relevance – regardless of whether the patents-in-suit cover Aranesp® – do not justify unbounded discovery into Aranesp®. Finally, Defendants also refer to Amgen's arbitration with Ortho. The issue for resolution in that private arbitration, however, was not whether the patents-in-suit cover Aranesp®, but whether Aranesp® was included within the terms of the Amgen/Ortho license agreement.

Discovery under Rule 26 places on the propounding party the burden to draft, propound and certify under Rule 26 (b) and (g) discovery requests that seek discovery reasonably relating to the defenses and claims in the suit. Defendants have not complied with this obligation. Instead, Defendants would simply have this Court subject Amgen to an unending and unduly burdensome search for and production of documents irrelevant to this case's issues: whether Defendants' peg-EPO product infringes one or more claims in the Lin Patents and whether Defendants can prove that these already well-scrutinized and upheld patents are somehow invalid or unenforceable. Defendants' document requests, not directed to these issues, are unreasonably broad and impose undue burdens on Amgen. Likewise, Defendants' premature filing of its motion — before the parties met and conferred on the bulk of the requests Defendants' put at issue — is plainly unreasonable and should not be rewarded.

II. SUMMARY OF THE PARTIES' POSITIONS

Document Topic	Relevance	Doc Requests
Documents relating to and demonstrating Amgen's efforts in developing pegylated compounds, including pegylated GCSF, pegylated MGDF, and pegylated NESP.	**DEFENDANTS' POSITION:** MIRCERA™, the accused drug, is a pegylated compound. Amgen's infringement position is that pegylating a compound is nothing more than a trivial and routine matter which does not change the structure and function of the compound. To the extent that Amgen has developed pegylated compounds showing that this was not the case, the evidence is relevant and necessary to challenge Amgen's infringement theory. [8]	19, 20, 27-35, 58, 59, 70 and 105-112.

[7] Defendants' Memo at 14.
[8] Defendants' Memo at 1.

Document Topic	Relevance	Doc Requests
	AMGEN'S POSITION: EPO, methods for making and using EPO, not pegylation, are at the heart of this dispute. The Lin Patents do not claim methods of pegylation, pegylated G-CSF, MGDF, or ARANESP®. Such proteins, their structure and function, and whether or how pegylation alters them are irrelevant to whether Defendants' peg-EPO product satisfies and therefore infringes the asserted claims in the Lin Patents. Further, Defendant has (i) failed to explain why Amgen's research and development of non-erythropoeisis stimulating proteins is relevant to any claim or defense in this case, and (ii) failed to meaningfully meet and confer on all document requests.	
Documents relating to and identifying the research and development of Amgen's Aransep®, including those identifying its structure and biological activity	**DEFENDANTS' POSITION:** Amgen has indicated in prescribing information that Aranesp® may be covered by at least one of the patents-in-suit, but not others. Therefore, comparisons between Aranesp® and MIRCERA™ are relevant not only to claim construction issues, but also those involving noninfringement. Moreover, to the extent there are documents showing that Aranesp® is covered by the asserted claims but not described in the patents, this information is critical to Defendants' written description and enablement defenses. Finally, Aranesp® competes directly in the marketplace with Amgen's other EPO product, Epogen®, and eventually, with Defendants' MIRCERA™ upon its FDA approval. Therefore, documents in connection with Aranesp®'s market power are relevant to Defendants' pending antitrust counterclaims. [9] **AMGEN'S POSITION:** Aranesp® is not generally at issue in this litigation, but discrete subsets of documents may be relevant, and Amgen has agreed to produce those. To the extent that Amgen has documents stating whether Aranesp® is or is not within the scope of the Lin Patents, Amgen agreed to produce those documents. Defendants' position that all Aranesp® research and development	20, 24-26, 31, 33-35, 42, 43, 45, 55, 56, 58-74, 78, 86, 87, 105, 112, 114, 117, and 118.

[9] Defendants' Memo at 1. Despite their framing of their position, Defendants primarily argue that broad discovery of Aranesp® is relevant to non-infringement if Aranesp® is not covered by the patents-in-suit or relevant to invalidity if Aranesp® is covered by the patents-in-suit.

Document Topic	Relevance	Doc Requests
	documents, as well as all communications with the FDA concerning Aranesp®, are relevant to noninfringement is an improper attempt to base the infringement analysis on commercial embodiments, rather than comparing the construed claims to the accused product. Nonetheless, Amgen further agreed to produce documents sufficient to show Aranesp®'s structure, pharmaceutical composition, and FDA approved methods of use, reflecting a reasonable approach given the burdens of producing all Aranesp® documents. Amgen will also produce documents relevant to the public interest factor for an injunction. Finally, Amgen is fully prepared to provide reasonable discovery on Aranesp® and its market power.	

III. SUMMARY OF FACTS

Defendants' motion fails to acknowledge that Amgen has already produced more than 1.5 million pages of documents in this case, and has agreed to produce thousands more. Amgen made a good-faith effort to cooperate with Defendants to produce additional documents that are responsive to their requests following the parties' December 11, 2006 meet and confer regarding 16 of the 50-plus requests listed in Defendants' motion to compel. Amgen agreed to produce:

- All documents regarding pegylation of recombinant human erythropoietin;
- All documents containing any statement by Amgen regarding whether Aranesp® falls within the scope of any claim of the patents-in-suit; and
- Documents sufficient to show the structure, activity, methods of manufacture, pharmaceutical composition, and FDA-approved methods of use of Aranesp®.[10]

Amgen also sought clarification as to the relevance of the disputed requests in its letter following the parties' meet-and-confer.[11] Amgen further asked Defendants when they wished to continue the meet and confer to discuss any issues regarding Request Nos. 67-123. Their subsequent

[10]Exhibit A to Defendants' Memo, Docket No. 172 (Letter dated December 13, 2006 from Howard Suh to William Gaede).

[11] *Id*.

letter failed to address or in any way respond to Amgen's offer of compromise or requests for clarification or to request a subsequent meet and confer.[12] Upon receiving Defendants' subsequent letter, Amgen invited them to respond to Amgen's letter.[13] Instead of responding, Defendants prematurely filed their motion to compel.[14]

IV. ARGUMENT

A. PROPER STANDARDS FOR DISCOVERY

"Trial courts enjoy a broad measure of discretion in managing pretrial affairs, including the conduct of discovery."[15] Courts have denied motions to compel filed by parties who seek to enforce overly broad discovery requests.[16] 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."[17]

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."[18] However, even if relevant to

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[12] *Id.* at Exhibit B to Defendants' Memo (Letter dated December 13, 2006 from William Gaede to Howard Suh).

[13] *Id.* at Exhibit C to Defendants' Memo (Letter dated December 13, 2006 from William Gaede to Howard Suh).

[14] Indeed, the parties did not meet and confer on Request Nos. 67-123 and or Request Nos. 10, 25-26, 29-30, 33, 45, 55, 56, 58-60, and 64-65. Nevertheless, in their opposition to Amgen's motion to compel, Defendants accuse Amgen of short-circuiting the meet and confer process. (Docket No. 199 at 3.) There, unlike here, the parties met and conferred on the requests that were the subject of Amgen's motion and Defendants had notice of Amgen's positions prior to filing of that motion.

[15] *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)).

[16] *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").

[17] *Great Atlantic & Pacific Tea Co.*, 871 F.2d at 187.

[18] 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 party** . . . . 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).

claims or defenses, discovery is not permitted where no need for the requested document is shown or compliance would be unduly burdensome.[19] Discovery of information "not relevant to the subject matter involved" in the litigation is even more circumscribed and requires a showing of good cause.[20] 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."[21] Defendants have wholly failed to meet the requirements of Rules 26(b)(1) and 26(g).

B. DOCUMENTS RELATING TO AMGEN'S PEGYLATED PROTEINS OTHER THAN EPO ARE NOT RELEVANT AND PRODUCTION WOULD BE UNDULY BURDENSOME

Defendants argue that they are entitled to virtually all Amgen documents relating to pegylation of *any* substance.[22] Defendants elevate "peg" over EPO, in an attempt to divert this Court's attention away from the indisputable fact that their peg-EPO product, contains EPO.[23] EPO, not peg, is at the heart of this dispute. Defendants infringe because they have appropriated Lin's inventions: EPO protein products and processes for producing them. They cannot escape the fact that MIRCERA™ is simply pegylated erythropoietin.[24]

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[19] *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)).

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

[21] 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.

[22] Defendants' Memo at 2-3.

[23] *Id.* at 2.

[24] Exhibit 5, Final Transcript, CCBNStreetEvents, Event Transcript RHHBY – Roche Conference call – Phase II CERA data in Renal Patients, Nov. 17, 2003; Exhibit 6 at Col. 1:64-2:14, U.S. Patent 6,583,272 (filed June 27, 2000).

Unfocused discovery into Amgen's pegylation projects is unwarranted. There can be no dispute that pegylation is a well-known and commonly used technique to increase the serum half-life of therapeutic proteins.[25] Amgen-authored publications cited in Defendants' Memorandum state as much. Defendants representations in their BLA are not to the contrary:

- See highlighted material in Confidential Exhibit 2 at ITC-R-BLA-00074400; ITC-R-BLA-00007110; ITC-R-BLA-00007088.
- See highlighted material in Confidential Exhibit 2 (relevant excerpts of Defendants' BLA) at ITC-R-BLA-00004200.

Despite their admissions regarding standard pegylation techniques, Defendants' make the unsupported assertion that "synthesis reactions using PEG molecules and proteins as starting materials creates entirely new compounds, distinct from the starting material used"[26] as if this somehow excuses their use of Amgen's patented products and processes. This assertion is particularly misplaced given Defendants' representations to the FDA concerning the relationship of the structure and function of peg-EPO as compared to other EPOs.[27] Indeed, Defendants' purported support for this proposition merely explains some benefits of protein pegylation. Moreover, infringement will be proven based on the facts surrounding the accused product and a comparison of claims to the accused product. Defendants thus will not find support for their non-infringement argument in Amgen documents related to substances other than EPO. Accordingly, Rule 26(b)(1) protects Amgen from Defendants' unjustified trolling through documents concerning products other than EPO.

Under these circumstances, Defendants' request, seeking ***all*** documents related to

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[25] Exhibit 1 (Tillman et al., *Efficacy and immunogenicity of novel erythropoietic agents and conventional rhEPO in rats with renal insufficiency*, Kidney International (2006) 69, at 60-67 at 60.

[26] Defendants' Memo at 3.

[27] Confidential Exhibit 2 at ITC-R-BLA-00007088; Confidential Exhibit 7 at ITC-R-IND-00000542.

pegylating ***any*** "compound" (the "compounds" are not even limited to proteins) are unreasonably broad, *viz* –[28]

- "All Documents and Electronic Data Concerning any ESA, any Pegylated Compounds, pegylation or any related methods currently or previously maintained by [sixty-four specific] people"[29]
- "All Documents and Electronic Data Concerning any pending United States or foreign Patent Application relating to any ESA and/or any Pegylated Compounds or related methods"[30]
- "All Documents and Electronic Data Concerning the preparation and publication of any articles not listed in Request for Production No. 32 that refer or relate to any ESA, any Pegylated Compounds, pegylation or any related methods, Including all drafts, underlying data and lab notebooks, and all Communications referring or relating thereto"[31]

Defendants simply have not — and cannot — demonstrate how unbridled discovery into Amgen's pegylation of compounds other than EPO is relevant to any claim or defense in this action.

Moreover, even if Defendants are willing to limit discovery to the compounds described in their briefs, Defendants admit that neither of Amgen's G-CSF nor MGDF proteins stimulate

[28] In its Memorandum, Defendant highlights its narrowest (and most defensible) requests. (Defendants' Memo at 7-10.) Read literally, however, these requests seek production of voluminous documents for which Defendant has not articulated relevance with any specificity. For example, Defendant seeks all documents concerning any communication between Lawrence Souza and Joan Egrie, respectively, regarding the design, development and manufacture of pegylated G-CSF (Request No. 19) or any pegylated compound (Request 20). Similarly, Request No. 32 seeks "all documents . . . Concerning the preparation of [42 enumerated articles], including all drafts, underlying data and lab notebooks…." Request No. 34, which seeks virtually all documents related to any ESA, any pegylated compound, or pegylation methods of three Amgen scientists, is likewise overbroad. Defendants' argument that these requests are "in general relevant" fails to satisfy the strictures of Rule 26(b)(1).

[29] Request 35.

[30] Request 31.

[31] Request 33.

erythropoiesis.[32] Discovery regarding these proteins is therefore in no way related to the subject matter of Lin's patents — or this litigation.

As discussed above, Defendants admit that pegylation is a standard technique, on which there is extensive scientific literature. There is no compelling justification to force Amgen to produce the enormous amounts of proprietary information on Amgen's research and development of products other than EPO. peg-GCSF is a commercial product. peg-MGDF was developed through late stage clinical trials. Obviously, in the course of preparing to obtain regulatory approval for these drugs, Amgen created vast quantities of documentation. Because it would require a gargantuan effort and expense for Amgen to produce the requested — let alone create a sideshow regarding entirely irrelevant — materials, the Court should deny Defendants' motion to compel.

C. AMGEN ALREADY AGREED TO PRODUCE A REASONABLE SCOPE OF ARANESP® DOCUMENTS.

Defendants cannot demonstrate how *all* documents regarding Aranesp® are relevant to any claim or defense in this action. Defendants' all-encompassing requests for all documents regarding Aranesp® (as well as their request for all documents regarding Amgen's efforts to pegylate any "compound") amount to no more than an attempt by Defendants to compare the accused product in this case (Defendants' peg-EPO product) with Amgen's commercial products. But, it is axiomatic that to determine infringement, the accused product or process is compared to the claims of the patent.[33] Defendants' sweeping discovery of Aranesp® is of particularly limited utility where, as here, their peg-EPO product does not contain Aranesp®,

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[32] Defendants' Memo at 5.

[33] *Zenith Labs. v. Bristol-Myers Squibb*, 19 F.3d 1418, 1423 (Fed. Cir. 1994) ("[I]t is error for a court to compare in its infringement analysis the accused product or process with the patentee's commercial embodiment or other version of the product or process; the only proper comparison is with the claims of the patent."); *Martin v. Barber*, 755 F.2d 1564, 1567 (Fed. Cir. 1985) ("Infringement, either literal or equivalence, is determined by comparing the accused device with the claims in suit, not with a preferred or commercial embodiment of the patentee's claimed invention.").

which differs from human EPO in both its amino acid sequence and glycosylation content. Yet, Defendants seek almost every document about Aranesp® ever created at Amgen:

- "All Documents and Electronic Data Concerning any submissions to or communications with any government agency or department which regulates drugs or biologics outside the United States by or on behalf of Amgen, with respect to any ESA . . . ."[34]
- "All Documents and Electronic Data Concerning any . . . communication . . . between Amgen and any third parties . . . Concerning any ESA or related methods or processes."[35]
- "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/or Epogen® for treatment of patients with ESRD [and CKD]."[36]
- "Documents concerning the costs associated with Amgen's Epogen® and Aranesp® products between 1985 and the present, Including manufacturing costs, marketing costs, material costs, sales costs, general overhead, administrative costs, packaging costs, legal costs, research costs and rebates."[37]
- "Documents concerning Amgen's sales of Epogen® and Aranesp® between 1995 and the present . . . ."[38]
- "All minutes of and notes from . . . any other Amgen meeting Concerning the research, development, and marketing of any ESA . . . ."[39]
- "All Documents and Electronic Data Concerning contracts, agreements, negotiations or discussions between Amgen and any third party . . . concerning the purchase, manufacture, source or supply of any ESA product . . . ."[40]
- "All Documents and Electronic Data Concerning resources for conducting clinical trials related to ESA drugs between 2000 and the present, including the

[34] Request 25.

[35] Request 56.

[36] Request 65 [and Request 66].

[37] Request 71.

[38] Request 72.

[39] Request 78.

[40] Request 114.

> availability of clinical investigators, investigation sites, and/or patients needed or desired for clinical trials or other research."[41]

To justify this broad-ranging discovery, Defendants point to Amgen's business relationship with Ortho Biotech Products, L.P. ("Ortho") and Amgen's arbitration with Ortho over Aranesp®, stating that "[A]mgen showed that Aranesp® was not erythropoietin."[42] It bears emphasis that Amgen's arbitration with Ortho over Aranesp® was to resolve whether Aranesp® was included in Amgen and Ortho's license agreement – not whether the asserted patents cover Aranesp®.[43]

Defendants' cursory discussion and conclusion omit any explanation of how or why Amgen's arbitration with Ortho about Aranesp® can somehow transform almost every document about Aranesp® ever created at Amgen into relevant, discoverable information in this case. Nevertheless, as noted above, Amgen is willing to produce documents that discuss whether Aranesp® falls within the scope of the claims of the patents-in-suit and documents sufficient to show the structure, activity, methods of manufacture, pharmaceutical composition, and FDA-approved methods of use of Aranesp®. Amgen will additionally produce documents reasonably related to the factors used in determining whether to grant or deny injunction relief and has invited. Amgen will also produce documents relevant to Defendants' antitrust claims following a meet and confer to define and agree to a reasonable scope of Aranesp® documents for production.

Amgen's agreement to produce these documents, however, does not render ***all*** documents related to "the research, design, and development" of Aranesp® and "the dispute between Amgen and Ortho over Aranesp®" relevant to claim construction, infringement (literal or under

[41] Request 118.

[42] Defendants' Memo at 13.

[43] *See, e.g., Ortho Pharm. Corp. v. Genetics Inst., Inc*., 52 F.3d 1026, 1029 (Fed. Cir. 1995).

the doctrine of equivalents), or any other issue in this case. Defendants have not presented any reason to find otherwise.

For similar reasons, Amgen's dispute with Ortho does not provide Defendants with an opportunity to seek discovery of all documents regarding "the research, design, and development of Aranesp®." Defendants far-fetched theory – that if Aranesp® is "not covered by the patents-in-suit, likely for at least some of the same reasons . . . MIRCERA™ does not infringe the patents-in-suit[44] or if it is demonstrated that "Amgen's Aranesp® is covered by one of more claims of the patents-in-suit . . . those claims may be invalid for lack of enablement or lack of written description because such molecules are not adequately described in the patents"[45] — does not justify their fishing expedition for all documents regarding any Amgen product (Aranesp® or otherwise) that may or may not fall within the scope of the claims and may or may not be described or enabled in the patents.[46]

D. DEFENDANTS' OVERBROAD REQUESTS SHOULD BE QUASHED

A sampling of Defendants' overly broad requests aptly illustrates their violation of Rules 26(b) and (g), justifying denial of Defendants' motion as to these requests.

- REQUEST FOR PRODUCTION NO. 24:

  > All Documents and Electronic Data Concerning any submissions to or communications with the United States Food and Drug Administration (FDA) by or on behalf of Amgen, with respect to any ESA, Including epoetin alfa, marketed and sold under the brand names Epogen®,

[44] Defendants' Memo at 13.
[45] Defendants' Memo at 14.
[46] *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 160 (D. Mass. 2001) ("As a result, contrary to what TKT proposes here, there is no requirement that the specification enable every mode for making and using the claimed products."), *aff'd in pertinent part*, 314 F.3d 1313 (Fed. Cir. 2003).

> Procrit®, Eprex®, and Erypo®, and darbepoetin alfa, marketed and sold under the brand name Aranesp®.

This request seeks production of ***all*** communications between Amgen and the FDA regarding ***any and all*** ESAs (erythropoiesis-stimulating agents), not just recombinant human EPO. Communications with the FDA regarding ESAs other than recombinant human EPO are not relevant to any claim or defense in this action, nor is each and every communication Amgen may have had with the FDA over the last twenty years regarding its recombinant human EPO product. Moreover, during the meet-and-confer process, Defendants' counsel indicated that they were seeking "all internal Amgen communications concerning all submissions to the FDA regarding EPO [and Aranesp®] regardless of their relevance."[47]

Amgen responded by inviting counsel "to narrow this to a specific communication based on [Defendants'] review of the actual FDA communications on EPO that Amgen has already produced."[48] Defendants ignored Amgen's reasonable invitation, choosing to instead prematurely plow forward by filing their motion to compel.[49]

> **REQUEST FOR PRODUCTION NO. 56:**
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> All Documents and Electronic Data Concerning any collaboration, joint venture, agreement or communication, Including any written or oral discussions and correspondence, and any drafts of the same, between Amgen and any third parties, Including Amgen's Affiliates and partners, concerning any ESA or related methods or processes.

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[47] Exhibit C to Defendants' Memo, Docket No. 172 (Letter dated December 13, 2006 from William Gaede to Howard Suh) at 3.

[48] *Id*.

[49] In discussing Request 24 in its Memorandum, Defendants state for the first time that "Amgen's communications with the FDA regarding Aranesp®, including any statement it may have made regarding whether Aranesp® was equivalent to erythropoietin or comparisons of the bioavailability, safety, efficacy and/or other properties of Aranesp® with other ESAs is relevant to the issues of validity in this case including obviousness. This information is also relevant to infringement for the reasons discussed above." Defendants' Memo at 16. As explained above, Amgen has agreed to produce documents relating to whether Aranesp® falls within the scope of any of the claims in the patents-in-suit. Defendants have failed to explain why any "comparisons of the bioavailability, safety, efficacy and/or other properties of Aranesp® with other ESAs" is relevant to a claim or defense in this case.

This request encompasses ***every*** communication Amgen has ***ever*** had with ***any*** third party relating to Epogen® or Aranesp®. Compliance with this request as written would be unduly burdensome (Amgen enters into tens of thousands of agreements with third parties every year regarding Epogen and Aranesp®), and it is not reasonably calculated to lead to the discovery of admissible evidence. Moreover, Amgen is prohibited from disclosing information concerning such agreements to other third parties such as Defendants by the terms of the agreements themselves. To the extent Amgen has not already done so, Amgen agreed to produce documents sufficient to identify the collaboration and joint venture agreements between Amgen and any third parties concerning recombinant human EPO, and agreed to produce additional non-privileged documents responsive to the request that contain information relevant to a claim or defense in this action.

Prior to filing its motion to compel, Defendants never specifically raised Amgen's objections to Request No. 56 with Amgen as part of any meet-and-confer process (other than addressing the issue of the purported general relevance of Aranesp® and third party confidentiality in general.) Defendants instead ignored Amgen's objection regarding overbreadth of the request, ignored Amgen's invitation to discuss narrowing the scope of the request, and filed their motion to compel.

REQUEST FOR PRODUCTION NO. 114:

All Documents and Electronic Data Concerning contracts, agreements, negotiations or discussions between Amgen and any third party, Including any Health Care Provider, concerning the purchase, manufacture, source or supply of any ESA product, Including requirements contracts, exclusive

dealing arrangements, discounts, bundled discounts across product lines, rebates and/or pricing (emphasis added).

As was the case with Request No. 56, Defendants' Request No. 114 is overbroad, seeking ***every*** contract, agreement, negotiation or discussion Amgen has ***ever had*** with ***any*** third party relating to the purchase, manufacture, source or supply of Epogen or Aranesp®. Such documents have no relevance to any issue in this case, and this request is not reasonably calculated to lead to the discovery of admissible evidence. Compliance with this request as written would be unduly burdensome, as Amgen enters into tens of thousands of such agreements every year. Again, Defendants never specifically addressed Amgen's objections to Request No. 114 during the meet-and-confer process (other than addressing the issue of third-party confidentiality in general).

The foregoing requests should be quashed for their unreasonable scope,[50] Defendants failure to certify them under Rule 26(g), and their failure to meet and confer on them prior to filing their motion to compel.

[50] Further examples of Roche's overbroad requests include Requests 27-28 (All documents concerning the prosecution of unrelated and unasserted U.S. and foreign patents); Requests 29-30 (All Documents and Electronic Data Concerning the alleged conception and reduction to practice of each invention claimed in the patents listed in Requests 27-28); Request 42 ("All Documents and Electronic Data Concerning the arbitration . . . between Ortho-Biotech, Inc. and Ortho-McNeil Pharmaceutical Corp. . . . and Amgen and Kirin-Amgen, Inc. . . . Including all draft and final versions of [various documents]"); Request 43 (requesting the same for an antitrust action commenced by Ortho against Amgen concerning the U.S. oncology market in which Roche has not sought FDA approval for its peg-EPO product); Request 64 ("All Documents and Electronic Data Concerning the entry or potential entry of any ESA products [dating back to 1980, and not limited to Roche's peg-EPO product] into the markets and/or submarkets for any ESA products"); Request 69 (requesting the same "for the sale or license of any ESA designed, developed, produced, manufactured, marketed or licensed by Amgen or any third party"); Request 70 ("Documents concerning prices reported by Amgen to government entities, Including the average sale price, best price, average wholesale price and average acquisition cost for Epogen®, Aranesp®, Neulasta® and Neupogen® between 1985 and the present"); and Request 117 ("All Documents and Electronic Data [dating back to 1980] Concerning communications with Health Care Providers regarding clinical trials involving patients with anemia").

V. CONCLUSION

For the foregoing reasons, Amgen respectfully requests the Court deny Defendants' motion to compel.

December 29, 2006

Respectfully Submitted,

AMGEN INC.,

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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
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