

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No.: 05-12237 WGY
)	
)	
F. HOFFMANN-LAROCHE)	
LTD., a Swiss Company, ROCHE)	
DIAGNOSTICS GmbH, a German)	
Company and HOFFMANN LAROCHE)	
INC., a New Jersey Corporation,)	
)	
Defendants.)	
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MOTION FOR ENTRY OF PROTECTIVE ORDER

Pursuant to Fed. R. Civ. P. 26(c), plaintiff Amgen Inc. (“Amgen”) respectfully requests the Court to enter Amgen’s proposed form of Protective Order (attached hereto as Exhibit A) to govern the discovery and handling of confidential information in this matter. Amgen makes this motion in an effort to facilitate timely and orderly discovery according to the Court’s October 17, 2006 Scheduling Order (Docket No. 119). Since May, Amgen has attempted without success to reach agreement with Defendants on a stipulated form of protective order. At bottom, the fundamental disputes between the parties are whether any in-house counsel will be granted access to confidential documents produced by an opposing party, and whether the order will impose terms that materially inhibit the analysis, preparation, and presentation of evidence for trial.

Amgen first provided a proposed form of Protective Order for this matter to Defendants' counsel on May 24, 2006.¹ Amgen's counsel contacted Defendants' counsel again in June, July, September, and October seeking a response from Defendants to the form of order Amgen had proposed.² After the close of business on Friday, October 20, Defendants' counsel finally provided a proposed form of Protective Order on behalf of Defendants.³ A copy of the form of Protective Order proposed by Defendants is attached as Exhibit G.

Amgen's proposed Protective Order and Defendants' proposed Protective Order contain the following material differences:

PROTECTIVE ORDER PROVISION	AMGEN'S POSITION	ROCHE'S POSITION
Levels of Confidentiality	One level: <ul style="list-style-type: none"> • Confidential (Exhibit A, ¶¶ 3, 8)	One level: <ul style="list-style-type: none"> • Confidential – <i>outside counsel eyes only</i> (Exhibit G, ¶¶ 3)
Use of ITC discovery	Provides that all discovery produced in the related ITC action will be deemed produced in this action (Exhibit A, ¶ 12)	Not addressed.

¹ A copy of the May 24, 2006 email correspondence between Defendants' counsel Patricia A. Carson of Kaye Scholer and Linda A. Baxley of Day Casebeer Madrid & Batchelder is attached hereto as Exhibit B.

² Copies of the June 5, 2006 email correspondence from Ms. Baxley to Ms. Carson, and the July 11, 2006 email correspondence between Ms. Baxley to Mr. Howard Suh, are attached hereto as Exhibits C and D, respectively. A copy of the September 28, 2006 email correspondence from Deborah Fishman of Day Casebeer to Leora Ben-Ami of Kaye Scholer is attached hereto as Exhibit E. This proposed Protective Order is substantially the same as the draft Order first provided to Defendants' counsel in May. A copy of Ms. Fishman's October 13, 2006 letter to Mr. Thomas Fleming is attached hereto as Exhibit F.

³ A copy of the email sent to Ms. Fishman and its attachments, including Defendants' proposed Protective Order, is attached hereto as Exhibit G.

PROTECTIVE ORDER PROVISION	AMGEN'S POSITION	ROCHE'S POSITION
Handling of Defendants' BLA and IND documents	Treated the same as all other documents marked as "Confidential"	Access restricted to 1 hard copy and 10 CD copies, with no electronic copies to be maintained on any networked computer (Exhibit G, ¶ 13)
Filing of Confidential Information with Court	Designating party must seek leave of court to file under seal; burden on designating party to file if leave denied; may be disclosed in testimony or evidence at trial absent further court order. (Exhibit A, ¶¶ 15-16)	Filing party must confer with designating party 3 business days before filing papers containing confidential information; filing party must seek leave of court to file under seal; no disclosure in open court, only on <i>in camera</i> record. (Exhibit G, ¶ 2)

Levels of Confidentiality.

Under Amgen's proposed Protective Order, up to six in-house attorneys for a party may have access to confidential information provided by the other party so long as no such in-house counsel is involved in "competitive decision making" for their company.⁴ Under Defendants' proposed Protective Order, no in-house counsel may have access to any information designated as Confidential under the Protective Order.

None of the six counsel (the Amgen attorneys identified in the signature page of this pleading) who would have access to information produced by Defendants in this matter are

⁴ *U.S. Steel Corp. v. United States*, 730 F.2d 1415, 1468 (Fed. Cir. 1984) (denial or grant of attorney access to confidential information is dependent on factual circumstances, not status as in-house or outside counsel); *In re Sibia Neurosciences*, 1997 U.S. App. LEXIS 31828, *8-10 (Fed. Cir. 1991) (unpublished) (denying writ of mandamus seeking to vacate district court protective order that allowed in-house counsel access to confidential documents produced in patent litigation where counsel was not involved in "competitive decision making"); *Amgen Inc. v. Elanex Pharmaceuticals, Inc.*, 190 F.R.D. 134, 139 (W.D. Wash. 1994) (access granted to in-house Amgen counsel).

involved in competitive decision making for Amgen.⁵ Rather, each is a member of Amgen's Intellectual Property and Litigation Group within Amgen's Law Department, tasked with supporting and supervising the outside representation of Amgen in the enforcement and defense of intellectual property disputes.⁶ Each of the six counsel is responsible specifically for the support and supervision of this litigation.

To perform this responsibility, Amgen's in-house counsel need access to information in Defendants' possession regarding the manufacture, structure, use and behavior of the accused product. Such information is needed in order to assess the merits of Amgen's claims and Defendants' defenses, to support, prioritize and supervise the representation of Amgen's interests in this dispute, and to provide professional legal advice to Amgen's senior management.⁷ While the information produced in the related ITC proceeding regarding such issues was extremely limited in nature, it was designated as confidential by Defendants, thus denying access to Amgen's in-house counsel.⁸ Based on their experience in the ITC proceeding, neither Amgen's in-house nor its outside counsel believe that they can effectively fulfill their responsibilities to Amgen unless certain designated in-house counsel are granted access to the information produced in discovery subject to the terms of an appropriate protective order.⁹

⁵ See 10/23/06 Declaration of Stuart L. Watt, ¶ 8; 10/23/06 Declaration of Wendy A. Whiteford, ¶ 7; 10/23/06 Declaration of Darrell G. Dotson, ¶ 7; Amgen will file Declarations of Monique L. Cordray, MarySusan Howard, and Kimberlin L. Morley.

⁶ See Watt Dec., ¶¶ 1, 5-7; Whiteford Dec., ¶¶ 1, 5-6; Dotson, ¶¶ 1, 5-6.

⁷ See Watt Dec., ¶¶ 6-7,9-10; Whiteford Dec., ¶¶ 5-6,8-9; Dotson, ¶¶ 5-6, 8-9.

⁸ In the related ITC action, the Administrative Law Judge's standard form of protective order denied in-house counsel access to the discovery produced by an opposing party.

⁹ See Watt Dec., ¶ 9-10; Whiteford Dec., ¶ 8-9; Dotson, ¶¶ 8-9.

In many respects, members of Amgen's in-house litigation team are the lawyers most familiar with the patents-in-suit. For example, unlike Amgen's outside litigation counsel, members of Amgen's in-house team were actively involved in Amgen's prior U.S. proceedings against Genetics Institute and Chugai Pharmaceutical (now a wholly-owned subsidiary of Defendants), Elanex, and Transkaryotic Therapies, Inc. and Aventis Pharmaceuticals (formerly Hoescht Marion Roussel), as well as Amgen's many foreign proceedings enforcing the Lin Patents, including proceedings involving some of the present Defendants and their predecessors-in-interest.

Finally, there is no basis for believing that Amgen's designated in-house counsel would violate the proposed Protective Order. First, as officers of this Court,¹⁰ Amgen's in-house litigation counsel, just like Amgen's and Defendants' outside counsel, are obligated to comply with the provisions of any protective order in this case and to maintain the confidentiality of any information designated as confidential to which they have access. Second, Amgen's in-house litigation counsel have previously had access to confidential information produced by opposing parties under protective orders in a large number of patent cases around the country, including the *Amgen v. Chugai* and *Amgen v. HMR/TKT* cases in this Court.¹¹ There has never been even a suggestion that any of Amgen's in-house litigation counsel failed to comply to the utmost with the protective orders in those cases.¹² Based on this record, there is no justification for denying

¹⁰ Motions to admit *pro hac vice* for Amgen's designated in-house counsel have been concurrently filed with this motion.

¹¹ See Watt Dec., ¶ 12; Whiteford Dec., ¶ 11.

¹² *Id.*

Amgen's in-house counsel access to the confidential information that will be produced by Defendants in this case.¹³

In order to further ensure the confidentiality of Defendants' information, and to comply with the proposed Protective Order, Amgen stipulates that its designated in-house counsel will maintain any confidential information produced by Defendants in their respective locked offices.¹⁴ In addition, Amgen will dedicate one locked room exclusively to this matter and agrees to restrict access to this work room to in-house counsel under the proposed Protective Order and their support staff. Likewise, any electronic documents for this case containing confidential information produced by Defendants in this case will be stored on secure servers with restricted access under the control of an off-site vendor. Access to these servers will be restricted so that only those individuals designated under the proposed Protective Order (and their support staff) may obtain access to information designated confidential under the Protective Order.

Subject to these restrictions and whatever other or additional restrictions the Court deems prudent, Amgen respectfully submits that its designated in-house counsel should be allowed access to all documents and information produced by Defendants in this case.¹⁵

¹³ See *Amgen, Inc. v. Elanex Pharmaceuticals, Inc.*, 160 F.R.D. 134, 139 (W.D. Wash. 1994).

¹⁴ These offices are located on a floor that is dedicated to Amgen's Law Department and a smaller Corporate Compliance Department. Both of these departments are led and populated by lawyers and their support staff.

¹⁵ See *Amgen, Inc. v. Elanex Pharmaceuticals, Inc.*, *supra*, 160 F.R.D. at 139; *Fluke Corp. v. Fine Instruments Corp.*, 32 U.S.P.Q.2D (BNA) 1789, 1793 (W.D. Wash. 1994); *Safe Flight Instrument Corp. v. Sundstrand Data Control Inc.*, 682 F. Supp. 20, 22-23 (D. Del. 1988).

Use of ITC Discovery.

Amgen's proposed Protective Order explicitly provides that the discovery produced in the ITC action be deemed produced in this matter. Defendants' proposed Protective Order does not address whether the discovery produced in the related ITC action be deemed produced in this matter. Amgen believes that its proposal will allow for the most efficient and cost effective conduct of discovery in this matter. Without an order of this Court, the ITC Protective Order will prevent use of the ITC discovery in this case.

Handling of Defendants' BLA and IND.

Defendants' proposed Protective Order would not only exclude all access of in-house counsel to confidential information, but it would further restrict the access of Amgen's outside counsel to Defendants' Biological License Application ("BLA") and Investigational New Drug applications ("IND") for peg-EPO as follows:

1. Amgen's outside counsel (which includes four firms located in Cupertino and Palo Alto, California, Chicago, Illinois, and Boston, Massachusetts) are allowed only one hard copy of Defendants' BLA and INDs.
2. Amgen's outside counsel are permitted only 10 CD copies of Defendants' BLA and INDs which can only be viewed on non-networked, stand-alone computers.
3. Amgen cannot reproduce electronically Defendants' BLA and INDs.
4. Amgen must maintain the single hard copy and 10 CD copies under lock and key.¹⁶

Amgen's proposed Protective Order would impose no special restrictions on counsel's access to or copying of Defendants' BLA and INDs beyond those imposed on all information designated as confidential by a producing party. Under Amgen's proposed Protective Order, Amgen's

¹⁶ Notably, Amgen produced its regulatory documents to Defendants in the ITC without such restrictions, relying on the Protective Order in place to protect it.

outside and in-house counsel would be required to maintain in confidence any and all designated information produced by Defendants pursuant to the provisions of the order.

In the ITC proceeding, in the context of a truncated discovery period in which Amgen was allowed 28 days to serve and obtain discovery to respond to Defendants' motion to dismiss, Amgen's counsel made a number of concessions to Defendants' counsel in order to obtain and expedite Defendants' prompt production of their regulatory filings. However, as the experience obtained in the ITC proceeding demonstrates, the restrictions Defendants seek to impose on access to and use of the Defendants' regulatory submissions are simply infeasible and unworkable.

Restricting Amgen's counsel to a single paper copy would mean that:

- Only one of four firms representing Amgen would have ready access to the paper copy;
- No independent expert would have access to a paper copy other than at the single firm's office;
- No working copies of the document could be created or used by the lawyers, experts and their staffs assigned to investigate, analyze and summarize the relevant implications and evidentiary significance of the regulatory documents produced by Defendants.

Defendants' proposed form of Protective Order would also preclude Amgen's counsel from creating any archive copies of the documents produced for evidentiary purposes. This is particularly disturbing since the BLA and IND documents produced to Amgen in the ITC proceeding were not produced in sequential order, but instead were in many cases produced in scrambled page order, thus necessitating hundreds of hours of clerical work to sort and re-organize the pages that were produced in order to place them in proper sequence and context.

Restricting Amgen's counsel to 10 (ten) CD copies of the BLA/IND hosted only on standalone computers would mean that the data contained in Defendants' regulatory submissions cannot be effectively abstracted and analyzed in order to assess the evidentiary significance of

the information contained in the documents. In the ITC proceeding, the limited portions of the BLA and IND submissions produced by Defendants collectively comprised over 300,000 pages. Once Defendants make a complete production of their BLA/IND documentation, the total count is likely to exceed 500,000 pages of documentation.

As explained in greater detail below, the above numbers do not include the electronic hyper-links and associated data and text files that were submitted to FDA in the electronic version provided to the Agency. The investigation and analysis of such complex, highly technical and voluminous records requires the effective collaboration of teams of lawyers, experts and paralegals, each systematically sharing and compiling the results of their investigation and analysis in order to discern and document the evidentiary significance of the information contained within the Defendants' regulatory submissions. The software and analytical tools required to perform such collaborative investigation and analysis require the use of networked computers capable of hosting large databases and running sophisticated analytical tests. Constraining Amgen to use 10 separate CDs on 10 standalone computers is akin to building the Big Dig with 10 backhoes.

In addition, the constraints that Defendants propose would very likely prevent Amgen from accessing and using the same electronic copy of the BLA/INDs that Defendants submitted to FDA, but did not produce to Amgen. In negotiating the production of Defendants' regulatory submissions in the ITC proceeding, Amgen insisted on the production of an electronically searchable copy of Defendants' BLA. Unbeknownst to Amgen at the time, but certainly known to Defendants, Defendants had submitted their BLA to FDA in April 2006 in an electronically searchable and hyper-linked format, that included electronic hyper-links within the text of the BLA to external files, data reports and patient records referenced in the text of the BLA. Rather

than produce this electronic version of the BLA to Amgen, Defendants instead created a scanned, OCR (optical character read) version of their BLA submission and produced CDs containing that OCR version to Amgen's counsel over an eight day period. Critically, however, the OCR version contained none of the hyper-text links that were contained in the electronic version submitted to FDA, thus making it impossible to identify or locate any of thousands of references made in the OCR version of the BLA, but not included with it.¹⁷

For these reasons, as well as the fact that all of Amgen's counsel are officers of this Court and thus subject to this Court's jurisdiction if they do not comply with the confidentiality obligations set forth in Amgen's proposed Order, Amgen's in-house counsel are not competitive decision makers for Amgen, and Amgen's in-house counsel require the same access to information produced in this litigation as outside counsel, Amgen respectfully submits that the Court should enter the Protective Order proposed by Amgen.

Filing of Confidential Information.

As reflected in the difference between Amgen's proposed Protective Order (Exhibit A, ¶¶ 15-16) and Defendants' proposed Protective Order (Exhibit G, ¶ 2), Defendants' proposed Protective Order would require three business days advance notice of a party's intent to file any paper containing designated information, and would further require *in camera* treatment of all information designated as confidential by either party. Amgen's proposed form of Protective Order imposes no such restrictions or requirements, but instead creates a presumption in favor of public access to the information submitted to the Court, and places the burden on the proponent of confidential treatment to seek a court order requiring such treatment.

¹⁷ For example, see Ms. Victoria Smith's June 4, 2006 letter to Mr. Suh (attached hereto as Exhibit H); Ms. Fishman's June 6, 2006 letter to Mr. Suh (attached hereto as Exhibit I)

CONCLUSION

The experience gleaned from prior cases demonstrates that the form of Protective Order proposed by Amgen (attached as Exhibit A) contains provisions that are more than adequate to protect the parties' interests and rights in maintaining the confidentiality of information produced in this case, while also permitting the parties (including their in-house litigation counsel) to have access to the information they need to prepare their respective cases for trial. The concerns that Defendants have expressed about some of these provisions are unfounded. Consequently, Amgen respectfully requests that this Court enter the attached Order.

Respectfully submitted,
AMGEN INC., Plaintiff
By its attorneys,

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October 23, 2006

CERTIFICATE PURSUANT TO LOCAL RULE 7.1

I certify that, as set forth in the exchange of letters and emails between the parties, which are attached hereto as Exhibits B-G, counsel for the parties have conferred in an attempt to resolve or narrow the issues presented by this motion and that counsel for F. Hoffman-LaRoche Ltd., Hoffman LaRoche Inc., and Roche Diagnostics, GmbH do not consent to Amgen filing its Motion for Entry of Protective Order.

/s/Michael R. Gottfried

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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 and paper copies will be sent to those indicated as non-registered participants on October 23, 2006.

/s/ Michael R. Gottfried

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