UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GMBH, AND HOFFMANN-LA ROCHE INC., Defendants.	Civil Action No. 05-CV-12237 WGY

November 6, 2006 motion allowed on terms. See pp. 6-7 infra. The parties shall settle the final form of the order and submit it to the Court.
William G. Young
District Judge

DEFENDANTS' CROSS-MOTION FOR PROTECTIVE ORDER AND OPPOSITION TO AMGEN'S MOTION FOR ENTRY OF PROTECTIVE ORDER

Defendants F. Hoffmann-LaRoche Ltd., Roche Diagnostics GmbH, and Hoffmann LaRoche Inc. (collectively, "Roche") respectfully cross-move for the entry of a two-tier protective order in the form attached hereto as Exhibit A to govern discovery and handling of confidential documents in this matter, and oppose the motion of Amgen Inc. ("Amgen") to enter Amgen's proposed Protective Order.[1]

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At the outset, Roche wants to bring to the Court's attention that it has discovered inconsistencies between certain of the declarations and representations submitted in support of Amgen's motion, and documents produced by Amgen in the ITC proceeding. Particularly, (as

[1] Amgen's motion does not accurately reflect Roche's current position, as it was filed while the parties were still negotiating the terms of a possible protective order, and only a single tier of confidentiality was contemplated by the parties at that time. In a good faith effort to narrow the issues before the Court, however, Roche has continued to negotiate towards mutually agreeable terms even after Amgen filed its premature motion, and Roche now proposes a two-tier order to balance the interests of the parties and resolve the issues. After a meet and confer, Amgen again rejected Roche's proposal.

discussed in more detail infra pp. 9-12) these documents call into question statements made by Amgen's in-house attorneys who contend that they are not involved in or participate in competitive decision making processes, and while these same declarants are identified in Amgen documents as members of a committee of Amgen non-legal employees entitled "Competitive Anemia Task Force" (sometimes referred to as "Competitive Anemia Team" or "CAT"), the purposes of which committee include Amgen product positioning and marketing.[2] This is the very reason Roche proposes a two-tier protective order precluding Amgen employees from any access to Roche highly confidential and sensitive competitive business information.

Consequently, a significant difference between Roche's proposed protective order and Amgen's proposed order is that Roche believes that certain of Roche's highly sensitive documents relating to its pending application for CERA with the United States Food and Drug Administration ("FDA") should not be disclosed to Amgen employees, including in-house counsel, while Amgen would have all documents accessible to even in-house counsel. Amgen's in-house counsel are engaged in patent prosecution and other competitive decision making activities, and the risk of disclosure of the most sensitive Roche information to business executives inside Amgen is too great to allow unfettered access to Amgen's in-house counsel. Roche therefore proposes a two-tier protective order which limits access of the most sensitive documents of either side to outside counsel, experts retained by outside counsel, and of course the Court. Other confidential documents would be accessible to these groups plus certain

[2] Roche has filed a separate motion with this submission to put one of these documents from the ITC proceeding before the Court; the other document is appended to this motion as Exhibit G.

designated in-house counsel at each party.[3] This proposal protects the most sensitive of Roche's information as it was protected in the ITC, yet allows access by Amgen's in-house counsel to the majority of Roche confidential documents, alleviating the claimed hardship in Amgen's motion and declarations filed in support. Despite this, Amgen has rejected Roche's proposal on this issue.

There is no dispute that Roche's CERA product is still undergoing FDA review. There is also no dispute that Amgen and Roche are fierce competitors in the markets in which CERA and Epogen will compete if CERA receives approval. Amgen has stated publicly that it will do anything it can to prevent Roche from entering a market that Amgen has monopolized for over 20 years. Amgen chief executive Kevin Sharer has stated regarding dealing with Roche's entry in the United States market, "The fact that they're having trouble in oncology is cold comfort . . . **[w]e have to stop them altogether.**" [emphasis added][4]

If Amgen were permitted to interfere and delay Roche's product's approval with the FDA, then Amgen would have succeeded in their goal of stopping Roche, and there would be no need for this litigation. Just recently, although it is the only supplier on the market, Amgen entered into a five year contract with a Large Dialysis Center, Fresenius, which was readily understood in the industry to be a blatant attempt to thwart any effort to have Roche's new and

[3] Roche's actual applications to the FDA for CERA, including its Biologics License Application ("BLA") for use of CERA to treat anemia of chronic kidney disease and two Independent Drug Applications ("INDs") for CERA (one for chronic kidney disease and one for oncology) require certain additional restrictions, previously agreed to by the parties, beyond those for the higher level of the proposed two-tier protective order as more fully discussed infra.

[4] *Amgen's "strategic intention" is to acquire – CEO*, Reuters, Mar. 1, 2006, attached as Ex. B; *see also Amgen profit up 14% on sales gain*, L.A. Times, Oct. 24, 2006, attached as Ex. C (quoting Sharer as saying that "Amgen plans to do 'every single thing that we aggressively and legally can do' to defend its anemia drug patents").

different product enter the End Stage Renal Disease (ESRD) market.[5] As this Court is no doubt aware, the delicate give and take of the approval process is intended to be confidential and highly secretive. *See Webb v. Dep't of Health & Human Servs.*, 696 F.2d 101, 103 (D.C. Cir. 1982). The threat of harm from disclosure to Amgen of such sensitive information, accessible to so many Amgen employees is far too great a risk with a product that is not yet approved for marketing.

A two-tier protective order is particularly appropriate here because Amgen agreed in a related proceeding to restrict access to **all** confidential documents to outside counsel only (thus having a single tier of protection, to which Amgen's in-house counsel was **not** provided access). In the proceeding between these parties on the same patents before the International Trade Commission ("ITC"), *In the Matter of Certain Products and Pharmaceutical Compositions Containing Recombinant Human Erythropoietin*, the parties came to terms on a protective order which completely shielded Roche's confidential information from Amgen's in-house counsel. In fact, acknowledging the extreme sensitivity of certain of Roche's FDA filed documents, Amgen and Roche also agreed to the terms of a side letter agreement imposing the same limitations on the handling of Roche's sensitive FDA filed materials during that action that Roche proposes here.

The Protective Order which Amgen agreed to in the related ITC action did not allow in-house counsel to have access to Roche's most sensitive FDA materials or other highly sensitive and confidential information, yet Amgen did not complain or seek relief from the ALJ from the terms of that agreed upon Protective Order. A copy of the ITC Protective Order and

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[5] *Kidney Dialysis Center Deal With Amgen Blocks Roche*, N.Y. Times, Oct. 20, 2006, attached as Ex. D.

accompanying side letter agreement are collectively attached hereto as Ex. E. Amgen now proposes to turn the ITC protective order on its head, by maintaining a single tier of protection but allowing Amgen's in-house counsel to see everything within that tier. Amgen's proposed protective order would have the effect of reducing the protection of highly sensitive confidential Roche information, and unacceptably and unnecessarily increases the risk that such secret information will be even inadvertently communicated beyond those that need to know the information to conduct this litigation – Amgen's outside patent litigation counsel. Roche's protective order, on the other hand, provides Amgen's in-house counsel with far greater access to information and documents than was permitted in the ITC, and fully and fairly balances the rights of the parties.

I. DIFFERENCES BETWEEN THE PARTIES' PROPOSED PROTECTIVE ORDERS

The chart Amgen included in its motion overstates the few differences remaining between the parties, which may be summarized as follows:

PROTECTIVE ORDER PROVISION	AMGEN'S POSITION	ROCHE'S POSITION
Levels of Confidentiality	One level: • Confidential – six employee in-house counsel entitled to see **ALL** confidential information from Parties and non-parties	Two level: • (1) Highly Confidential – outside counsel; experts retained by outside counsel • (2) Confidential – outside counsel; experts retained by outside counsel, and four[6] employee in-house counsel entitled to see certain confidential information from Parties and non-parties
Use of ITC discovery	Provides that all discovery produced in the related ITC action will be deemed produced in this action, thus presumably making all such documents immediately accessible to Amgen's in-house counsel.	Roche agrees that discovery produced in the related ITC action should be deemed produced in this action, but Roche wants the opportunity to designate the documents pursuant to an appropriate two-tier protective order entered in this case.

[6] Amgen proposes that six of its in-house counsel have access to Roche's confidential documents and information. However, the six declarations submitted by Amgen's proposed in-house counsel are conclusory and almost verbatim in their contentions. Not one of the declarations states that the declarant possesses unique scientific or technical information that Amgen's experienced and able outside counsel and retained experts do not possess. Roche submits that such a representation could not be made under oath. There is no reason for "six" in-house counsel to have access to the lower confidentiality level in the proposed order, and Roche instead believes that a lesser number, perhaps four, is more appropriate and more than adequate.

Handling of Defendants' BLA and IND documents	Treated the same as all other documents marked as "Confidential."	One complete hard copy and **10 fully text searchable electronic copies** maintained on non-networked computers, and may **not** file confidential information either under seal or in the public record absent a specific directive of the Court.
Filing of Confidential Information with Court	Designating party must seek leave of court for opposition's papers to be filed under seal; **burden on Court** to grant leave to file under seal within 3 days or documents will be made public.	Local Rule 7.2 applies and filing party must confer with designating party 3 business days before filing papers containing other's confidential information; filing party must seek leave of court to file under seal.

II. IMBALANCE OF HIGHLY SENSITIVE DOCUMENTS – ROCHE IS THE PARTY THAT WILL NEED TO PRODUCE THE VAST MAJORITY OF THE TRULY SENSITIVE DOCUMENTS IN THIS CASE

Amgen's outside counsel have had Roche's FDA informational crown jewels (its BLA and INDs on CERA) since June 1, 2006, almost 5 months. Roche had only filed its BLA with the FDA for approval of CERA to be used to treat patients suffering from anemia due to chronic kidney disease in April 2006. Even though those documents were not pertinent to the issue under review for summary determination in the ITC (the § 271(e)(1) safe-harbor), under appropriate restrictions, Roche produced these highly confidential materials. Roche's application is currently pending before the FDA and will be pending during the majority of the duration of discovery in this case. There are also ongoing discussions with the FDA. Roche is also currently conducting clinical trials for the use of CERA on cancer patients suffering from anemia due to chemotherapy. These ongoing trials may lead to a future filing with the FDA for the use of CERA in this context. Information related to pending and future FDA filings is

extremely sensitive, and deserving of the highest level of protection. *See, e.g.*, 21 C.F.R. § 601.51(d)(1) (if a BLA has not yet been approved, "no data or information contained in the file is available for public disclosure before such license is issued").[7] Roche understands that Amgen contends that it is entitled to review much of this information as part of its infringement case, and the two-tier protective order proposed by Roche represents an accommodation that allows Amgen access to the appropriate relevant documents for the purpose of litigating this case.

Since the accused infringing product in this case is Roche's CERA, Amgen does not face the same level of disclosure of critical information that is faced by Roche. Some of Amgen's information has been the subject of prior lawsuits, such as *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, Civ. A. No. 97-10814-WGY (D. Mass.), and *Amgen, Inc. v. Chugai Pharm. Co.*, Civ. A. No. 87-2617-Y (D. Mass.). Furthermore, Amgen's claim that it "produced its regulatory documents to Defendants in the ITC without such restrictions, relying on the Protective Order in place to protect it," (D.I. #128 at 7 n.16), is misleading and irrelevant. Only a small percentage of the documents produced by Amgen in the ITC related to regulatory submissions, and importantly, unlike Roche's production, Amgen's production contained no

[7] In addition, with respect to New Drug Applications ("NDA") (identical form to BLA, but traditional name given to chemical, not biologic, based new drugs) the D.C. Circuit has noted that:

> If a [drug] manufacturer's competitor could obtain all the data in the manufacturer's NDA, it could utilize them in its own NDA without incurring the time, labor, risk, and expense involved in developing them independently. Premature disclosure of NDA data is . . . discouraged by the existence of criminal sanctions . . . contained in both the Food, Drug, and Cosmetic Act and the Trade Secrets Act.

Webb v. Dep't of Health & Human Servs., 696 F.2d 101, 103 (D.C. Cir. 1982); *accord Judicial Watch, Inc. v. Food & Drug Admin.*, 449 F.3d 141 (D.C. Cir. 2006) (quoting same); *Safe Flight Instrument Corp. v. Sundstrand Data Control, Inc.*, 682 F. Supp. 20, 22 (D. Del. 1988) ("Courts dress technical information with a heavy cloak of judicial protection because of the threat of serious economic injury to the discloser of scientific information.").

regulatory documents constituting pending IND, NDA or BLA submissions or supplements – documents that are highly sensitive and confidential, and that are not accessible through a Freedom of Information Act (FOIA) request. *See, e.g.*, 21 C.F.R. § 601.51(d)(1).[8]

The vast majority of the truly sensitive information in this case is Roche proprietary, confidential information and should not be made available to employees of Roche's competitor, Amgen.

III. AMGEN'S IN-HOUSE COUNSEL SHOULD NOT BE GIVEN ACCESS TO ROCHE'S MOST HIGHLY CONFIDENTIAL DOCUMENTS AND INFORMATION

A. AMGEN'S IN-HOUSE COUNSEL ARE INVOLVED IN IP DECISION-MAKING AND PATENT PROSECUTIONS

All of Amgen's in-house counsel of record in this case are members of the Intellectual Property and Litigation group within Amgen. These Amgen employees are responsible for, *inter alia*, prosecuting patents within Amgen that can then be used against competitors such as Roche, and their roles are inextricably intertwined with Amgen's business strategies. For example, two documents produced by Amgen in the ITC Proceeding show that Mary Susan Howard and Wendy A. Whiteford (both of whom report to another proposed in-house person, Stuart Watt) are among several Amgen business personnel on Amgen's ***"Competitive Anemia Task Force - Core Team"***, which is responsible for positioning and

[8] Amgen also did not produce any documents relating to its Aranesp® product, and the FDA issues surrounding a proposed change in its approval which culminated in an announcement describing how the approval of that product was being delayed pending a new clinical trial. *See FDA wants another Aranesp trial*, BioCentury Extra, Oct. 13, 2006, attached as Ex. F.

marketing of Amgen's anemia treatments in the U.S. market and responding to new competitors, particularly Roche, in the anemia treatment market.[9]

The stated mission of the Competitive Anemia Task Force is to:

- "Maintain up to date intelligence of Roche strategies and plans, including clinical trials;"
- "Develop sustainable competitive position for Amgen brands"
- "Develop an monitor implementation of global play book of activities designed to ensure our success."

See Competitive Anemia Task Force – Core Team, Ex. G. This document list Ms. Wendy Whiteford as a member of the "core team" carrying out these functions. Basically, it appears that the role of this committee to gather information on Roche, and to use this information to develop Amgen's "global play book" to compete against Roche, which directly contradicts Wendy Whiteford's claim that she is not involved in Amgen's competitive decision making.[10] Thus, these documents significantly undermine and contradict the assertions made in Amgen's Motion and illustrates precisely the danger that Roche's motion seeks to avoid.

In addition, all of Amgen's proposed in-house counsel are patent attorneys and/or supervise patent attorneys involved in patent prosecutions for Amgen. Stuart Watt was

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[9] The document entitled "***Competitive Anemia Task Force - Core Team***" is attached as Exhibit G. Although marked confidental, Amgen has consented to its disclosure under the terms of the ITC Protective Order. Roche seeks leave to file the other document under seal.

[10] Ms. Whiteford's declaration states, "I do not have responsibility for ***and do not participate in*** 'competitive decision making' such as pricing, clinical trial design, regulatory proceedings, and the like." Whiteford Dec. ¶ 7 (emphasis added). This is directly contradicted by position on a committee the goal of which is to "develop sustainable competitive position for Amgen brands."

personally and integrally involved in the prosecution of the patents-in-suit, and is likely to be a fact witness in this action.[11]

Amgen presently has ongoing patent prosecution in the same subject matter as this litigation, and relating to the very patents asserted in this case. "Several courts have determined that advice related to patent prosecution and advice on the scope of patent claims constitute competitive decision-making." *Andrx Pharms., LLC v. GlaxoSmithKline, plc,* 236 F.R.D. 583, 585 (S.D. Fla. 2006) (emphasis added); *see also Chan v. Intuit, Inc.*, 218 F.R.D. 659, 661-62 (N.D. Cal. 2003) (protective order barred patent prosecution counsel from participating in prosecution of patent for period of two years after the conclusion of the action; "If counsel in the case at bar receives confidential information that could pertain to future patent prosecution, counsel would have to compartmentalize the information so that it does not inform counsel's decisions pertaining to those future patent prosecutions."); *In re Papst Licensing, GmbH, Patent Litig.*, 2000 U.S. Dist. LEXIS 6374, 2000 WL 554219 (E.D. La. 2000) (finding patent prosecution constituted competitive decision-making and required attorney to refrain from patent prosecution for one year after the conclusion of the litigation, including appeals); *Commissariat A L'Energie Atomique v. Dell Computer Corp.*, 2004 U.S. Dist. LEXIS 12782, 2004 WL

[11] Stuart L. Watt is a patent attorney admitted to practice before the PTO and is the head of Amgen's Intellectual Property Law Group with "overall responsibility for securing protection for Amgen's intellectual property and enforcing that protection through litigation" Decl. of Stuart L. Watt, submitted with Amgen's motion for entry of protective order, ¶¶ 3 and 7. Kimberlin L. Morley is a patent attorney involved in patent prosecution for Amgen. Decl. of Kimberlin L. Morley, ¶¶ 3-4. Darrell C. Dotson is also a patent attorney admitted to practice before the PTO. Decl. of Darrell C. Dotson, ¶¶ 1, 3, and 6. Wendy A. Whiteford is a patent attorney and supervisor of Darrell C. Dotson and Kimberlin Morley in their patent prosecution duties. Decl. of Wendy A. Whiteford, ¶¶ 3 and 6. MarySusan Howard is a patent attorney admitted to practice before the PTO. Decl. of MarySusan Howard, ¶ 3. Monique L. Cordray is also a supervising patent attorney who reports directly to Stuart Watt. Decl. of Monique L. Cordray, ¶¶ 1 and 3.

1196965, at *2 (D. Del. 2004) ("Prosecuting patent applications 'involves decisions of scope and emphasis' that implicate competitive decision-making.") (quoting *Motorola, Inc. v. Interdigital Tech. Corp.*, 1994 U.S. Dist. LEXIS 20714, at *11 (D. Del. 1994)).

Amgen's lawyers are involved in patent prosecution, and they and their supervisors cannot be given access to Roche's most confidential information. *See Chan,* 218 F.R.D. at 662 ("the Court must consider whether counsel might inadvertently use confidential information obtained in the course of this litigation to shape advice regarding the scope of patent claims as part of the prosecution of patents for any party to this action, to the detriment of the opposing party, its competitor. If so, then such counsel should either be denied access to confidential information or be precluded from patenting for a party.").

B. AMGEN'S LAWYERS WILL CONVEY ROCHE'S MOST SENSITIVE INFORMATION BY GIVING THE LEGAL ADVICE AMGEN ADMITS THESE LAWYERS WILL PROVIDE

Amgen's contention that the in-house lawyers which it wishes to receive access to all of Roche's most sensitive documents are in Amgen's Intellectual Property and Litigation Group and, despite all being involved in patent prosecution, are not involved in "competitive decision making for the company" is disingenuous and simply inadequate to ensure the confidentiality of Roche's highly confidential documents. Amgen claims it needs to give these in-house counsel access to Roche's confidential documents "to provide professional legal advice to Amgen's senior management." (D.I. #128, Amgen's Motion for Entry of Protective Order, at 4). This is demonstrably false. Just a few months ago, Amgen mounted a full yet ill-advised and unfounded campaign against these very defendants on these very patents in the ITC. At no time did Amgen argue that its in-house attorneys needed access to Roche information to address that action. Amgen's protests of such a vital need now are convenient and belied by its own actions. Moreover, this Court is familiar with the expertise and experience that Amgen's outside counsel

bring to bear in this litigation, involving in large part the same area of technology, patents and history as previously litigated cases.

Moreover, having all these in-house patent attorneys having access to such vital information is just the danger that a two-tiered system is intended to avoid. As the case Amgen relies upon, *U.S. Steel Corp. v. United States*, explains, "competitive decision making" is "shorthand for a counsel's activities, association, and relationship with a [party] that are such as to involve counsel's advice and participation in any or all of the [party's] decisions (pricing, product design, etc.) made in light of similar or corresponding information about a competitor." 730 F.2d 1465, 1468 n.3 (Fed. Cir. 1984). Allowing Amgen's in-house counsel to see the highest level of confidential Roche documents, and then provide legal advice to Amgen management will inevitably convey this confidential information and allow Amgen to use its access to this information for an improper purpose. Since management knows these individuals have seen documents they themselves cannot see, management will understand the basis of the advice and deduce, rather clearly, what information is contained in Roche's confidential documents. *Brown Bag Software v. Symantec Corp.*, 960 F.2d 1465, 1471 (9th Cir. 1992) (in denying access of adversaries' confidential information to in-house counsel, court had to consider "whether Brown Bag's [in-house] counsel could lock-up trade secrets in his mind, safe from inadvertent disclosure to his employer once he had read the documents"). Simply put, confidential Roche information will be transmitted in these exchanges. This is particularly true in this case where Amgen's management has indicated that it must be very aggressive to stop Roche's plans to market CERA.[12]

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[12] See Ex.B; most recently in an October 23, 2006 interview: "Chief Executive Kevin Sharer said in an interview that Amgen plans to do 'every single thing that we aggressively and legally (continued...)

Even given the best intentions of Amgen's in-house counsel to not transmit confidential information, by giving legal advice based on Roche's highly confidential documents, they will inevitably disclose highly confidential Roche information. This information will then be used by Amgen executives in making business decisions affecting its competitor, Roche. *Brown Bag Software*, 960 F.2d at 1471 (professional integrity of in-house counsel and his promise to store confidential information in a locked file cabinet ***insufficient*** to allow in-house counsel access to adversary's confidential documents). In the face of the clear and palpable danger, Amgen's proposal is inherently unfair, particularly since Roche is the party with truly sensitive documents related to a pending application for a new drug before the FDA – there is no comparable risk to Amgen.

C. THE PROBABILITY OF INADVERTENT DISCLOSURE IS UNACCEPTABLY INCREASED BY ALLOWING AMGEN EMPLOYEES ACCESS TO ROCHE'S MOST CONFIDENTIAL INFORMATION

It is apparent from the Amgen declarations, that Amgen's proposed in-house counsel are part of a functional group within the same department, are all located in Amgen's headquarters in Thousand Oaks, California, and meet regularly with Amgen management in California. There is a significant difference between outside counsel who meet formally and occasionally with their client having access to highly confidential information and in-house counsel, who see business executives in the hallway, regularly go to meetings, and otherwise engage in the normal workplace activities at which anyone can err and reveal information that

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can do' to defend its anemia drug patents. [Analyst] Geoffrey Porges said fending off Cera was key to Amgen's fortunes. "The major issue hanging over this company is the threat of competition," he said." See Exhibit C.

they are prohibited from revealing.[13] This is particularly true here where the announced collective Amgen corporate mission to stop Roche at every turn is so great, that employees possessing protected information are under extraordinary pressure. The risk and danger is too great given the balance of the extremely low need shown in Amgen's motion. *U.S. Steel*, 730 F.2d at 1468 ("Inadvertence, like the thief-in-the-night, is no respecter of its victims. Inadvertent or accidental disclosure may or may not be predictable. To the extent that it may be predicted, and cannot be adequately forestalled in the design of a protective order, it may be a factor in the access decision."); *See also Andrx Pharms*, 236 F.R.D. at 585 ("Even if the competitor's counsel acted in the best of faith and in accordance with the highest ethical standards, the question remains whether access to the moving party's confidential information would create 'an unacceptable opportunity for inadvertent disclosure.'" (quoting *Mikohn Gaming Corp. v. Acres Gaming Inc.*, 50 U.S.P.Q. 2d 1783 (D. Nev. 1998))).

In arguing that its in-house counsel should have access to all of Roche's confidential information, Amgen states that "[t]here 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 prior litigations. (D.I. #128 at 5). With all that is at stake, it is unfair to ask Roche to assume the heightened risk of disclosure, even inadvertent or accidental, when there is no need, much less a compelling need for such access by these individuals to Roche's highly confidential information.

D. AMGEN WILL BE COMPLETELY AND ADEQUATELY REPRESENTED IN THIS LITIGATION IF IN-HOUSE COUNSEL ARE DENIED ACCESS TO ROCHE'S MOST SENSITIVE INFORMATION

[13] When employees work together in such regular and convenient quarters, the chance of an inadvertent or accidental disclosure of protected information is greatly increased.

There is no doubt that Amgen will still be fully and competently represented in this action if Roche's highly confidential business information is restricted to Amgen's many outside counsel. *See A. Hirsh, Inc. v. United States,* 657 F. Supp. 1297, 1305 (Ct. Int'l Trade 1987) ("in view of retained counsel's competence, it is not clear how plaintiff's position will be prejudiced by excluding [in-house counsel] from access to the nonpublic part of the agency record"). Amgen incredibly asserts that Amgen's in-house lawyers need access to all of Roche's highly confidential information because they were involved in prior litigations involving Amgen's EPO patents, while Amgen's outside litigation counsel were not "actively involved" in these prior proceedings. (D.I. #128 at 5). This assertion is inaccurate.

Members of Amgen's current outside litigation counsel have been involved with and played an active role in each and every prior U.S. proceeding involving Amgen's EPO patents. As this Court is well aware, Amgen's attorneys at Day Casebeer Madrid & Batchelder LLP, Lloyd R. Day, Jr., David M. Madrid, Linda A. Sasaki-Baxley and Deborah E. Fishman litigated before this Court in *Amgen, Inc. v. Hoechst Marion Roussel, Inc. & Transkaryotic Therapies, Inc,*, Civ. A. No. 97-10814-WGY (D. Mass.), together with counsel at Marshall, Gerstein & Borun LLP, Michael F. Borun and Kevin M. Flowers. That case, involving many of the same patents asserted by Amgen in the current litigation, has been ongoing for over nine years, and is still pending in this Court. These same attorneys were also involved in the appeals in that case before the Federal Circuit, Nos. 01-1191, 01-1218 and 05-1157. Attorneys at Marshall Gerstein, including Michael F. Borun, were before this court in *Amgen, Inc. v. Chugai Pharm. Co.*, Civ. A. No. 87-2617-Y (D. Mass.), and before the Federal Circuit in its appeal, Nos. 90-1273, 90-1275. Current Day Casebeer Attorneys (then at Cooley Godward LLP), including Lloyd R. Day, Jr., David M. Madrid and Linda A. Sasaki-Baxley, argued before this Court in

Amgen, Inc. v. Genetics Institute, Civ. A. No. 94-11818-WGY (D. Mass.), before the Federal Circuit in its appeal, No. 95-1247 (Fed. Cir.), before the Western District of Washington in *Amgen, Inc. v. Elanex Pharms.*, Civ. A. No. C93-1483D (W.D. Wash. 1996), and before the District of Delaware in *Ortho Pharmaceutical Corp. v. Amgen, Inc.*, Civ. A. No. 89-34-JJF (D. Del.). Likewise, D. Dennis Allegretti (now at Duane Morris LLP) has represented Amgen in every one of these cases. To say that Amgen's outside counsel were not "actively involved" in these proceedings is significantly understating history.

To suggest that Amgen's formidable array of outside attorneys, from quite a few different firms (including patent boutique firms), who have repeatedly represented Amgen with respect to its EPO patents, including several cases before this Court, are not sufficiently familiar with Amgen's EPO patents, do not have the requisite technical knowledge, and cannot completely and adequately represent Amgen in its patent infringement action against Roche taxes credulity and can be readily rejected based upon this Court's own observations.[14] *See Autotech Tech. Ltd. Partnership v. Automationdirect.com, Inc.*, 237 F.R.D. 405, 413 (N.D. Ill. 2006) (restricted access for in-house counsel did not impair party's ability to litigate where outside counsel was highly regarded, had significant firm resources, and had represented party for many years); *Intel Corp. v. VIA Technologies, Inc.*, 198 F.R.D. 525, 528-9 (N.D. Cal. 2000)

14 Amgen's experienced and sophisticated outside counsel, who have represented Amgen in numerous similar litigations, and are unquestionably familiar with the subject matter at issue, are yet another reason why Amgen's reliance on *U.S. Steel* is misplaced. *See* 730 F.2d at 1468 ("Because the present litigation is extremely complex and at an advanced stage . . . forcing [plaintiff] to rely on newly retained counsel would create an extreme and unnecessary hardship."). Amgen also clearly miscites and misstates the holding in *In re Sibia Neurosciences*, 1997 U.S. App. LEXIS 31828, *8-10 (Fed. Cir. 1991) (unpublished). (D.I. #128, Amgen's Motion for Entry of Protective Order, at 3, n.4). Amgen cites the case as support for not denying access to confidential documents to in-house counsel, when the case clearly deals with access for outside counsel.

(no showing that in-house counsel's restricted access would somehow hinder outside counsel's handling of the case); *Norbrook Labs. Ltd. v. G.C. Hanford Mfg. Co.*, 2003 WL 1956214, at *5 (N.D.N.Y. April 24, 2003) ("[Defendant] is not unduly prejudiced by [in-house counsel's] restricted access, because other outside counsel have been involved in the litigation from its outset, and they are fully familiar with the facts and disputes at issue.").

Amgen's outside patent litigation counsel, and their retained experts, can more than adequately represent Amgen in this suit without Amgen's in-house counsel having access to Roche's most confidential information. *Andrx Pharms*, 236 F.R.D. at 585 ("Where parties to a lawsuit are commercial competitors, and one of them moves for protection against misuse of its confidential technical information, the court must balance the risk to the moving party of inadvertent disclosure against the risk that the protective order will impair the prosecution or defense of the other party's claims." (quoting *Mikohn Gaming*, 50 U.S.P.Q. 2d 1783)). Although the declarations of Amgen's in-house counsel claim they need access to do their jobs, none of them claim that limiting their access will impair Amgen's ability to be adequately represented by outside counsel. This is the only relevant factor, and Amgen's outside counsel can more than adequately represent Amgen in this action.

Roche's proposed discovery order more than adequately provides access by Amgen's lawyers to Roche's highly confidential information, and they can fully litigate this case using those documents. Roche's proposal of a two-tier protective order allows designated in-house counsel access to all but the most highly sensitive confidential documents, which would be marked with a higher level legend, such as HIGHLY CONFIDENTIAL – FOR OUTSIDE COUNSELS' EYES ONLY. Allowing access of **ALL** documents to in-house counsel simply is inadequate to protect the most sensitive information.

IV. ROCHE SHOULD BE ALLOWED TO DESIGNATE ITC DISCOVERY PURSUANT TO THE TERMS OF THE PROTECTIVE ORDER IN THIS CASE

Roche agrees that documents produced by both parties in the ITC action should be treated as if produced in the present action, but Roche should be given the opportunity to designate those documents with the appropriate level of confidentiality pursuant to the protective order entered in this case. Some of Roche's documents produced to Amgen in the ITC action are not confidential, many are confidential but can be accessed by Amgen in-house counsel, and some are highly confidential and should not be available to Amgen's in-house counsel.

V. ROCHE'S BLA AND INDs ARE THE MOST SENSITIVE DOCUMENTS IN THE CASE AND REQUIRE ADDITIONAL RESTRICTIONS

In the ITC action, Amgen demanded that Roche produce to Amgen full copies of the CERA BLA and the two Independent Drug Applications ("IND") for CERA that have been filed with the FDA (one IND for chronic kidney disease and one for oncology). After negotiating necessary and appropriate additional confidentiality safeguards, Roche complied with this discovery, even though these documents had little to do with the issue of the § 271(e)(1) safe harbor that was under immediate consideration by the ITC Commission. Even Amgen acknowledged that these FDA materials are among the most sensitive of Roche documents and information. Amgen's professed need for certain of these documents and information in this action may be defensible, but Amgen can have no right to use this highly confidential information for any other purpose. If it would provide a means of fulfilling Amgen's CEO's mandate of stopping CERA from being sold in the United States at all costs, restricting such highly confidential and sensitive information to outside counsel only is no real impediment to Amgen at all. Additionally, Roche's product and indeed this case has generated enormous interest among the news media and various financial analysts. These organizations are

constantly trying to get access to information.[15] To ensure that Roche's most sensitive information is available to Amgen's lawyers for proper purposes, but would not be used for improper purposes or leaked, purposely or inadvertently, to any outside parties, Roche agreed to produce the BLA and IND to Amgen's lawyers with certain restrictions. In the ITC, the parties negotiated and agreed upon the terms of a side letter agreement to cover the handling of these documents in a way that protected Roche's confidentiality but provided the necessary access by Amgen's lawyers. *See* Ex. E. This agreement should continue, and its terms are reflected in Roche's proposed protective order. *See* Ex. A, ¶ 8.

It is important to note that Roche produced these key documents in the very medium requested by Amgen. Amgen's complaints to this Court are mere makeweight argument. Roche agreed to provide fully text-searchable OCR versions of the INDs and BLA on computer disks. In addition, Roche produced paper copies. Roche did everything reasonable to accommodate Amgen. Amgen agreed that this was reasonable and workable. To protect the confidentiality of these most sensitive documents, an employee of Roche's outside counsel Kaye Scholer personally flew from New York to California with the disks containing the ten electronically searchable copies, and produced these ten copies at the offices of Amgen's counsel Day Casebeer.[16] In addition, Roche repeatedly worked with Amgen to ensure that Amgen's counsel could fully search the disks.[17] The BLA is 152,681 pages (approximately 31 boxes) and the INDs are 115,790 pages (approximately 24 boxes) of documents. To ensure the

[15] At the scheduling conference held before this Court on October 23, there were well over a dozen members of the media present to cover the case.

[16] *See* July 7, 2006 letter from Peter Fratangelo to Deborah Fishman detailing production of the BLA to Amgen's counsel, attached hereto as Ex. H.

[17] *Id.*

confidentiality of these documents, Roche did not use an outside vendor to make this enormous number of copies, but instead had employees of Kaye Scholer in Los Angeles print these documents for 48 hours straight and then personally drive the more than 50 boxes of documents by van the six hours to Day Casebeer's offices in Northern California.

To facilitate Amgen's use of these highly sensitive documents, Roche allowed Amgen's counsel to make copies of the BLA and IND for use at any of the 17 depositions that Amgen took of Roche witnesses. Roche also provided a completely electronically searchable copy of the BLA on a laptop computer at each of these depositions for use by Amgen. Amgen in fact used these documents extensively in the discovery in the ITC action. Amgen used portions of this BLA or IND as 18 exhibits at 8 depositions. Amgen also appended numerous documents from the BLA and IND as exhibits in its papers submitted to the ITC Administrative Law Judge, which the Court was previously provided.

Amgen contends that it should be given the BLA in the form provided to the FDA, with hyperlinked documents. The format given to the FDA cannot be Bates numbered or have a confidentiality legend added. There is no substantive difference between the version given to the FDA and the version provided in the ITC action – they are both the same exact text, and the version provided is fully text searchable, which allows Amgen's counsel to find specific passages or sections. Amgen cannot continue to demand anything it wishes to distract and interfere with Roche's operations. The restrictions placed upon use and handling of the BLA and INDs are necessary to protect the confidentiality of these most sensitive documents and should be ordered in this action. Critically, the agreement reached between the parties regarding the BLA and INDs, despite Amgen's complaints, worked in the ITC action.

VI. AMGEN'S PROPOSAL FOR FILING OF CONFIDENTIAL INFORMATION UNDER SEAL PUTS AN UNFAIR BURDEN ON THE COURT AND IS NOT REALISTIC

Roche's proposed protective order provides that a party seeking to file information with the Court that has been designated confidential must seek permission of the Court to file the papers under seal, and must confer with the other side three (3) days prior to filing in an attempt to avoid having to go to the Court with this request. These are reasonable provisions which seek to protect truly confidential documents from public disclosure.

Amgen, on the other hand, would put the onus on the Court to act quickly lest confidential information be disclosed to the public. This is clearly an unreasonable burden to impose upon the Court and the party which designated the information confidential. Under Amgen's proposal, a party seeking to file information with the Court that has been designated confidential by the other side must confer with the other side, but provides no time before filing for this conference – thus there is no assurance that adequate time is provided to examine the documents and discuss with the client whether to agree that the information need be filed under seal. Then, according to Amgen's proposal, the filing party serves a copy of its papers on counsel and files a notice of service with the Court. The opposing party must then move within two (2) days to have the other side's motion and supporting papers be filed under seal, and the Court must grant the motion to file under seal within three (3) days or the documents will be filed in the public record with no confidentiality. Amgen would have the Court be the instrument of its desire to have confidential Roche information disclosed to the media, competitors, analysts and the public. This is unfair and unreasonable. Amgen's proposal is completely unworkable and should be denied in full. Roche's proposed protective order provides that the parties may file confidential material with the Court only in accordance with

Local Rule 7.2, and that a party may not file documents designated as confidential either under seal or in the public record in the absence of a specific directive of the Court.

VII. CONCLUSION

For all of the foregoing reasons, Roche respectfully requests that the Court deny Amgen's motion for entry of Amgen's new proposed Protective Order, and that the Court grant Roche's motion and enter Roche's proposed two-tiered Protective Order attached hereto as Ex. A.

DATED: Boston, Massachusetts
November 3, 2006

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

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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 paper copies will be sent to those indicated as non registered participants on the above date.

/s/ Julia Huston

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