UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

AMGEN INC.'S REPORT PURSUANT TO THE COURT'S MAY 11, 2006 ORDER AND MOTION AND MEMORANDUM FOR ADDITIONAL DISCOVERY

In accordance with the Court's May 11, 2006 Order in this matter, Amgen Inc. ("Amgen") respectfully submits this report on the parties' compliance with the Court's Order to date. As set forth in detail below, Amgen respectfully requests the Court to enter an order directing the Roche defendants to comply with the Court's prior May 11 Order. In addition, Amgen respectfully requests the Court to deny Roche's pending Rule 12(b)(6) motion or, in the alternative, to grant Amgen leave to take limited additional discovery regarding the factual contentions on which defendants' base their pending Rule 12(b)(6) motion.

I. THE COURT'S MAY 11, 2006 ORDER

Pursuant to the Court's May 11 Order, the parties were directed to meet and confer with respect to the relationship "between the various Roche/Hoffman-LaRoche corporate entities and the allegedly infringing drug."

On May 12, 2006, Amgen's counsel, Rusty Day, wrote to Leora Ben-Ami, counsel for the Roche defendants, outlining the limited and specific information Amgen sought pursuant to the Order, and requesting an early conference between counsel to effectuate a timely disclosure of information. A copy of Mr. Day's May 12, 2006 letter is attached as Exhibit A.

On May 18, 2006, F. Hoffman La-Roche, Ltd. (Roche Switzerland) and Roche Diagnostics GmbH (Roche Germany) each withdrew their pending Rule 12(b)(2) motions, thereby acceding to this Court's in personam jurisdiction over both entities.

On May 19, Ms. Ben-Ami informed Mr. Day that the Roche defendants believed that their withdrawal of the pending Rule 12(b)(2) motions obviated the need for any disclosure of information in response to the Court's May 11 Order or Mr. Day's May 12 letter. Mr. Day specifically disagreed with this position, stating that Amgen had requested discovery with respect to each of Roche's pending motions. Mr. Day also noted that nothing in the Court's Order indicated that it was limited solely to issues relating to in personam jurisdiction only.

Ms. Ben-Ami stated that Roche would contact the Court to confirm whether the Order was rendered moot by the withdrawal of the 12(b)(2) motions. Mr. Day requested that he be included in any communication with the Court. To date, Amgen's counsel has not learned of any such communication with the Court.

Contrary to Roche's prior representations, Ms. Ben-Ami also confirmed that both Roche Switzerland and Roche Germany are directly involved in the packaging and export of

accused product to the United States. Ms. Ben-Ami also advised Mr. Day that if Roche decided to disclose any information to Amgen in response to the Court's May 11 Order, it would do so by Monday, May 22.

On Monday, May 22, 2006, Amgen's counsel received a request to stipulate to a temporary protective order to maintain as confidential information Roche indicated it would provide. Amgen's counsel promptly reached agreement with Roche's counsel on a stipulated form of temporary protective order to be submitted to the Court.

On Tuesday, May 23, 2006 Roche's counsel informed Amgen's counsel by email of the name of the entity that Roche asserts sponsored two Investigational New Drug ("IND") applications submitted to the FDA regarding the accused PEG-EPO product, and on Wednesday, May 24, Roche's counsel informed Amgen's counsel by email of the name of the entity that Roche asserts "submitted" the Biologic License Application ("BLA") for PEG-EPO to the FDA on April 19, 2006. Copies of the two emails are submitted herewith as Exhibits B and C.[1]

As Amgen's counsel, Mr. Day, had previously informed Ms. Ben-Ami, the information provided by Roche on May 23 regarding the sponsorship of Roche's IND applications conflicts with documentary evidence in Amgen's possession. The information provided in the May 24 email from Roche's counsel regarding "submission" of Roche's BLA fails to identify the various Roche entities that are seeking licenses from FDA to manufacture, import, promote and sell the accused PEG-EPO product.

On Tuesday, May 23, Roche's counsel also provided Amgen's counsel with duplicate copies of 5 declarations previously served on Amgen's counsel as part of Roche's motion for

[1] Roche's counsel has agreed that the information in these two emails, both originally designated by Roche as confidential, may be filed in the Court's public file.

summary determination filed in Amgen's pending ITC proceeding.[2] These declarations, whether taken separately or collectively, do not clarify the respective roles and relationships of the Roche entities with respect to the infringing PEG-EPO product. Nor do they provide unambiguous, complete answers to the specific issues posed in Mr. Day's May 12 letter.

Rather, the declarations raise more questions than they answer. For example, while one declaration indicates that one of Roche's United States entities has not previously and is not now ***selling*** the accused PEG-EPO product in the United States, it does not address whether it or any other Roche entity or third person has been or is ***using*** infringing product for non-exempt purposes. Nor does it or any other declaration address whether the other Roche defendants have previously or are now engaged in activities for the sale or non-exempt use of infringing product in the United States. And none of the declarations, separately or collectively, purports to account for all of the infringing product that has been imported or produced in the United States, let alone establish that none of that product has been or is being used for non-exempt purposes.

To the extent that Roche contends that its activities are exempt from liability for infringement pursuant to § 271(e)(1), the burden to establish the applicability of that defense for all infringing product imported into the United States falls on Roche, not Amgen. Roche's current and untested assertions are insufficient as a matter of law to carry that burden. Not only do the Roche defendants fail to account for all of the infringing PEG-EPO product that has been imported to date into the United States, but they also fail to

[2] Roche has declined Amgen's request for permission to file these declarations in the Court's public file. Accordingly, Amgen has moved the Court for an order granting leave to submit copies of these declarations under seal consistent with their designation as confidential by the Roche defendants. Copies of the declarations, all designated confidential by Roche, will be submitted under seal as Exhibits D, E, F, G, H and I if the Court grants leave to file the declarations under seal.

account for all of the uses that have been made of that product. In addition, they simply ignore the other allegations in Amgen's complaint that the Roche defendants are currently arranging for, soliciting and engaged in non-exempt use of their accused PEG-EPO product. Instead, they merely assert that some of the activities in which some of the defendants are engaged are exempt.

In the Defendants' Report filed today by the Roche defendants, they represent that they have "produced documents confirming" certain facts. But the only documents provided to Amgen are the two emails submitted herewith and the six declarations referenced above. No other documents have been produced to Amgen or its counsel. Thus, contrary to Roche's implication, no substantiating documents, such as copies of Roche's IND applications or its BLA, have been provided to Amgen.

Even the self-serving facts supposedly "confirmed" in Roche's declarations are insufficient as a matter of law to establish the § 271(e)(1) defense claimed by Roche. For example, one Roche entity asserts that there have been no sales or offers to sell PEG-EPO in the United States. Another Roche entity asserts that no sales could have occurred because FDA approval has not yet been obtained. The third Roche entity says nothing about its sales activities, even though it produces and exports PEG-EPO to the U.S. While sales for human use may not lawfully occur prior to FDA approval, that does not mean that infringing sales for diagnostic or other non-exempt use cannot and have not occurred, and nothing produced to date by Roche demonstrates that such non-exempt activities have not occurred.

As mentioned above, the burden falls to Roche to demonstrate that every use of all of its infringing product is and has been exempt. Nothing produced to date fulfills that burden.

II. MOTION FOR DISCOVERY

Amgen respectfully requests the Court to enter an order directing the Roche defendants to comply with the Court's May 11 Order by providing the specific information requested in Mr. Day's May 12 letter to Roche's counsel. A proposed form of order is filed herewith. Amgen requests that Roche be directed to provide its response in writing by Tuesday, May 30.

In addition, Amgen respectfully renews its request that the Court deny the pending motion of defendants under Rule 12(b)(6) to dismiss the complaint. In the alternative, Amgen requests the Court to enter a further order granting Amgen leave to conduct limited additional discovery to meet and rebut the factual contentions on which Roche bases its pending Rule 12(b)(6) motion. A proposed form of order is filed herewith.

As the record revealed at the time of the Court's May 10 hearing on Roche's then-pending motions, the respective roles of the various Roche entities in manufacturing, importing, distributing, testing, seeking approval and soliciting the use or sale of their accused PEG-EPO product were far from clear. By obscuring the role of each Roche entity in the manufacture, importation and use of PEG-EPO, Roche was not only able to contest this Court's in personam jurisdiction over certain defendants, but it was also able to deflect attention from the activities in which each entity is engaging that are not exempt under § 271(e). The Court acted to remove that ambiguity by entering its May 11 Order, in which it directed the parties to meet and confer to clarify which Roche entities performed what roles with respect to Roche's allegedly infringing product. In particular, as Mr. Day's May 12 letter set forth, Roche was requested by Amgen to identify what Roche entities were engaged in the manufacture, importation, distribution, investigation, regulatory approval and

solicitations to use, sell or reimburse patient usage of their PEG-EPO product in the United States.

Unfortunately, notwithstanding the Court's Order, the roles of the respective Roche entities remain ambiguous. That ambiguity has served to obscure the merits of the defendants' asserted defenses under § 271(e)(1), as well as this Court's personal jurisdiction over the foreign Roche defendants.

Because the Roche defendants seek dismissal of Amgen's complaint based on untested representations of fact, their pending motion is more properly considered under Fed.R.Civ.P.56, not Rule 12. And since the facts regarding the activities that fall outside the scope of section 271(e)(1) are uniquely within the possession and control of the Roche defendants, they ought not be permitted to use their control over those facts to deny Amgen the information Amgen needs to meet and rebut the factual contentions on which they base their 12(b)(6) motion. Amgen respectfully requests that the Court enforce its outstanding discovery order and either dismiss the pending 12(b)(6) motion or, in the alternative, grant Amgen leave to take additional discovery pursuant to Rule 56(f) to meet and rebut the factual contentions on which the pending motion rests.

III. CONCLUSION

Amgen respectfully requests the Court to order Roche to respond in writing to the Court's May 11, 2006 Order by Tuesday, May 30, 2006 and to grant the additional limited relief set forth in the enclosed proposed form of order.

Respectfully Submitted,
AMGEN INC.,
By its attorneys,

/s/ Michael R. Gottfried

D.DENNIS ALLEGRETTI (BBO#545511)
MICHAEL R.GOTTFRIED (BBO#542156)
PATRICIA R. RICH (BBO# 640578)
DUANE MORRIS LLP
470 Atlantic Avenue, Suite 500
Boston, MA 02210
Telephone: (617) 289-9200
Facsimile: (617) 289-9201

LLOYD R. DAY, JR.
DAVID M. MADRID
LINDA A. SASAKI-BAXLEY
DAY CASEBEER
MADRID & BATCHELDER LLP
20300 Stevens Creek Boulevard, Suite 400
Cupertino, CA 95014
Telephone: (408) 873-0110
Facsimile: (408) 873-0220

WILLIAM GAEDE III
McDERMOTT WILL & EMERY
3150 Porter Drive
Palo Alto, CA 94304
Telephone: (650) 813-5000
Facsimile: (650) 813-5100

MICHAEL F. BORUN
KEVIN M. FLOWERS
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive
6300 Sears Tower
Chicago IL 60606
Telephone: (312) 474-6300

Of Counsel:

STUART L. WATT
WENDY A. WHITEFORD
MONIQUE L. CORDRAY
DARRELL DOTSON
MARYSUSAN HOWARD
KIMBERLIN L. MORLEY
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320-1789
(805) 447-5000

May 25, 2006

Facsimile: (312) 474-0448

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 May 25, 2006.

_____/s/__ Michael R. Gottfried
Michael R. Gottfried