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

MOTION TO SCHEDULE RULE 16 CONFERENCE

Pursuant to Fed. R. Civ. P. 16(b) and Local Rule 16.1(A) of the Local Rules of the United States District Court for the District of Massachusetts, plaintiff Amgen Inc. ("Amgen") requests that this Court convene a scheduling conference and set a date by which the parties shall meet and confer in advance of submitting a Rule 26(f) statement. Because Amgen's Amended Complaint was filed and properly served on Defendants more than 120 days ago, Amgen respectfully requests the Court to schedule a Rule 16.1(A) conference to allow for an early assessment of the case. Since Defendants are poised to obtain regulatory approval to enter the market during the Spring of 2007, Amgen respectfully requests the conference take place in September 2006 or as soon thereafter as convenient for the Court, and that the conference address the date by which a trial on the merits of Amgen's claims for declaratory relief will be held.

Amgen filed its Complaint for Declaratory Judgment of Infringement on November 8, 2005. All of the defendants were properly served with Amgen's Complaint on or before March 22, 2006. On April 11, all of the defendants filed a joint motion to dismiss Amgen's Complaint under Federal Rules of Civil Procedure 12(b)(1) and (6), asserting that this Court did not have jurisdiction to consider Amgen's complaint for declaratory judgment because Defendants' activities did not constitute infringement under 35 U.S.C. § 271(e)(1).[1] Amgen opposed the Defendants' motion to dismiss and, in the alternative, requested discovery.

On April 18, Defendants filed a Biologics License Application ("BLA") with the Food and Drug Administration ("FDA") seeking approval to manufacture, import, market, and sell their accused peg-EPO product in the United States. Based in part on this regulatory filing, Amgen filed and served an Amended Complaint on April 25.

The Court heard oral argument on the Defendants' motion to dismiss on May 10. The next day, the Court ordered the parties to meet and confer on the corporate relationship between the defendants, as it pertains to the Defendants' peg-EPO product, and to provide a status report within ten days. On May 25 Amgen and Defendants filed separate reports with the Court. Amgen's report included a motion for additional discovery.

In this same timeframe, Amgen also requested the International Trade Commission (ITC) to investigate the Defendants' importation of peg-EPO into the United States. While the ITC has summarily determined that Defendants' infringing product made prior to June 2006 was imported for exempt purposes, that determination does not affect this Court's jurisdiction under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Unlike the ITC, which has no

[1] Roche Diagnostics GmbH and F. Hoffmann-LaRoche Ltd. also filed and later withdrew separate motions to dismiss under Federal Rule of Civil Procedure 12(b)(2).

jurisdiction to enter declaratory judgments, this Article III Court may now decide whether Defendants' announced plans to manufacture, import and sell peg-EPO in the United States will infringe Amgen's Lin patents. *Glaxo, Inc. v. Novopharm Ltd.*, 110 F.3d 1562, 1571 (Fed. Cir. 1997). Indeed, the fact that the ITC has decided that it cannot provide the relief Amgen seeks until sometime after Defendants have imported infringing product for non-exempt purposes e.g., commercial sale, makes the prompt declaration of rights in this Court all the more urgent and important.

Since June, Defendants have publicly announced that February 20, 2007 is the date by which FDA will act on Defendants' peg-EPO BLA pursuant to the "Prescription Drug User Fee Act" (21 U.S.C. § 301 et seq.) ("PDUFA"). Since June, Defendants have continued hiring a sales force of well over 100 people for the peg-EPO product at the regional management, district management and sales representative levels with a target date of October 2006 to have a complete sales force in place for a Spring, 2007 launch. Defendants also have nearly completed their hiring of thirty medical liaisons and have hired and begun training commercial account managers to support the launch of their peg-EPO product.

Since June, Defendants or their agents have also contacted nephrology clinic administrators and hospital pharmacy personnel exploring what it would take for these Amgen customers to switch to peg-EPO including surveying various EPO providers in the United States regarding their willingness to use a "Brand X" product strikingly similar to peg-EPO in place of Amgen's EPOGEN product under various pricing and contracting scenarios. Most recently, Defendants have begun a public relations campaign signaling their future market participation targeting anemia management for renal patients. These actions, as well as those detailed in

Amgen's submissions to this Court under seal, indicate that Defendants fully expect to commence the commercial sale of peg-EPO in the United States by Spring 2007.

In view of the Defendants' activities and FDA's impending February 2007 action regarding approval of Defendants' BLA, Amgen respectfully requests the Court to set an expedited schedule for the parties to meet and confer and submit a statement pursuant to Fed. R. Civ. P. 26(f) in advance of a Scheduling Conference. Amgen also respectfully requests the Court to set a trial date for resolution of Amgen's claim for declaratory judgment of infringement at the Conference, and address the following additional issues:

(1) the entry of an appropriate Protective Order for information produced during discovery in this case (Amgen provided Defendants with a draft proposed Protective Order in June but has not received any response); and

(2) a pretrial schedule, including a schedule for discovery and exchange of expert reports prior to trial.

Amgen's counsel contacted Defendants' counsel requesting that they join Amgen in this motion. Defendants did not consent. At the request of Defendants' counsel, a copy of their letter responding to Amgen's request is attached hereto.

Respectfully submitted,

AMGEN INC.,
By its attorneys,

/s/ Patricia R. Rich

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September 8, 2006

CERTIFICATE PURSUANT TO LOCAL RULE 7.1

I certify that 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 Schedule Rule 16 Conference.

/s/ Patricia R. Rich
Patricia R. Rich

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 September 8, 2006.

/s/ Patricia R. Rich
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