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.: 05-12237 WGY

MEMORANDUM IN SUPPORT OF PLAINTIFF AMGEN INC.'S MOTION TO PERMIT SUBMISSION OF MATERIALS PRODUCED IN THIS ACTION TO THE INTERNATIONAL TRADE COMMISSION AND THE FEDERAL CIRCUIT

Amgen seeks leave of the Court to permit it to submit evidence obtained in this proceeding in the related proceeding before International Trade Commission that is now on appeal to the Federal Circuit. The evidence, produced by Roche in this proceeding (but withheld from production during the ITC proceeding on the ground that it constituted "future activities") after Amgen had filed its appeal from the ITC decision establishes that there is a sale for importation when Roche transfers its EPO product, peg-EPO, from its various European entities to its United States affiliate, Hoffmann LaRoche, Inc., and contradicts testimony given by Roche in the ITC proceedings regarding non-exempt activities.

Because the ITC based its decision of no actual infringement or imminent importation in violation of 19 U.S.C. § 1337 on the "fact" that there was no "sale for importation," and the "fact" that Roche's Phase IIIb studies had not progressed beyond a mere concept, the contrary testimony and documents produced in this proceeding are highly relevant to Amgen's appeal, as well as its motion, in the alternative, to remand that proceeding to the ITC for further consideration of this newly discovered evidence.

While the parties agreed that the discovery conducted in the related ITC proceeding may be deemed produced in this case, there is no reciprocal provision in the parties' Amended Protective Order that permits the use of discovery obtained in this case in the ITC proceeding. Rather, the parties' Protective Order in this case provides that counsel may "utilize Discovery Materials produced under the terms of this Order for purposes of this litigation." (¶12).

There is no reason for precluding use in the ITC appeal of the discovery produced by Roche in this action. That appeal permits Roche's documents and testimony, marked as confidential by Roche, to be filed under seal, pursuant to the Protective Order in that proceeding. Indeed, the Protective Order in the ITC action is more restrictive than the Amended Protective

Order in place in this action, prohibiting anyone but the parties' outside counsel access to discovery.

Notwithstanding the level of protection that would be afforded the information Roche has designated as confidential, Roche has refused to allow Amgen to use such information in the appeal. Roche should not be allowed to use the parties' Amended Protective Order as a shield to escape the facts that it did not want to have discovered during the ITC proceeding. Amgen therefore moves for leave to submit Roche confidential discovery material produced in this case under seal to the Federal Circuit and the ITC for purposes of the related ITC proceeding.

A core issue in the ITC litigation was whether Roche engaged in any sale of peg-EPO for importation into the United States.[1] While the investigation was pending, Amgen complained that it had been denied the discovery needed to investigate this issue and, in particular, that it had been denied access to Peter Schuepbach, the person responsible for Roche's commercial supply chain.[2]

In discovery recently obtained in the action before this Court, Dr. Schuepbach provided previously unavailable testimonial evidence that the transfer of peg-EPO from Europe to the United States does in fact entail a sale of the accused product.[3]

In addition, in the ITC action, Amgen also requested discovery of Roche's activities in regard to the initiation of non-exempt IIIb studies designed to promote the commercial sale and use of peg-EPO in the United States. Roche's Iris Kingma-Johnson testified on June 13, 2006

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[1] *See generally* ITC Brief at 13-24, 48-54.

[2] Amgen Br. at 33-34.

[3] Moore Decl., Ex. 1 (Schuepbach Depo. Tr. 15:14-21). During discovery in the ITC matter, Amgen inquired about whether there had been a sale of product between the Roche entities. None of the Roche deponents could answer the question.

that Roche's IIIb trials were still in the concept stage and hence no protocol had been finalized.[4] She further testified that no investigator had been recruited and no patient had been enrolled.[5]

Contrary to this testimony, eight months later (and after Amgen filed its Petition for Review), Roche produced documents in this action before the Court showing that Dr. Kingma-Johnson's testimony was anything but candid. According to Dr. Kingma-Johnson's contemporaneous documents, as well as other internal Roche documents (all of which were the subject of Amgen's pending but ignored motion to compel in the ITC proceeding), Roche had in fact distributed IIIb protocols to health care providers and solicited clinicians to participate in its IIIb trials in February and March 2006.[6]

These facts were first revealed in documents produced by Roche in this action in February and March 2007, after Amgen had filed its Appeal. Accordingly, Amgen respectfully requests that the Court provide leave for Amgen to file copies of the confidential exhibits with the Federal Circuit in support of Amgen's request to remand the case to the ITC for further discovery and further proceedings.[7]

Under paragraph 22 of the Amended Protective Order, the "Court retains jurisdiction for purposes of enforcing the terms of this Order at any time." The Amended Protective Order

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[4] Moore Decl., Ex. 2 (Kingma Johnson Depo. Tr. at 21:3-7; 54:9-23).

[5] *Id.*

[6] Moore Decl., Ex. 3 (R10-001645630-34); Moore Decl., Ex. 4 (R11-000094863-64); Moore Decl., Ex. 5 (R003868094-113, -097); Moore Decl., Ex. 6 (R11-000094925-935, -933); Moore Decl., Ex. 7 (R10-001653176-188, -185); Moore Decl., Ex. 8 (R11-000220564-566; Moore Decl., Ex. 9 (R10-004848608-609, -608); Moore Decl., Ex. 10 (R11-000103779-783); Moore Decl., Ex. 11 (R005186997-7000); Moore Decl., Ex. 12 (R005193165-177); Moore Decl., Ex. 13 (R11-000218955-956).

[7] *Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985); *see generally Jackson v. Nicholson*, 449 F.3d 1204, 1208 (Fed. Cir. 2006) (in context of considering Veterans Administration claim, providing that the matter could be remanded for consideration of new evidence); *Davis v. Nicholson*, 475 F.3d 1360, 1364 (Fed. Cir. 2007).

further contemplates that the Court would retain jurisdiction over the disposition of the documents in circumstances where the documents may be used in contexts unrelated to case currently before the Court.[8]

For all the foregoing reasons, Amgen seeks an order permitting Amgen to file Roche documents produced as "confidential" in the action before this Court for use in support of Amgen's submissions to the International Trade Commission and the Federal Circuit.

[8] Under paragraph 21, the terms of the Amended Protective Order remain in force after the action before the Court has been terminated.

Dated: April 19, 2007

Respectfully Submitted,
AMGEN INC.,
By its attorneys,

/s/ Patricia R. Rich

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CERTIFICATE PURSUANT TO LOCAL RULE 7.1

I hereby certify that counsel for the Plaintiff has attempted to confer with counsel for the Defendants, F. Hoffman-LaRoche Ltd., Hoffman LaRoche Inc. and Roche Diagnostics GmbH, in an attempt to resolve or narrow the issues presented by this motion and that no agreement could be reached.

/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 April 19, 2007.

/s/ Patricia R. Rich
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