

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,

Plaintiff,

vs.

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

Defendants.

CIVIL ACTION No.: 05-CV-12237WGY

**DEFENDANTS' PROPOSED REPLY TO AMGEN INC.'S
POST-HEARING MEMORANDUM**

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche") respectfully submit this brief memorandum in response to Amgen Inc.'s Post-Hearing Memorandum in Opposition to Defendants' Motion to Dismiss for Lack of Subject Matter Jurisdiction filed July 13, 2006 ("Amgen's Post-Hearing Memorandum").

First, Amgen contends that it is inappropriate to consider decisions of the International Trade Commission (ITC) and the ALJ's Initial Determination on § 271(e)(1) because it has no preclusive effect on this Court. As noted in Defendants' Motion for Leave to File Under Seal the Recent Decision of the ITC Regarding Defendants' Section 271(e)(1) Safe Harbor Defense, filed July 11, 2006,¹ Defendants filed the ITC Initial Determination "[b]ecause this decision deals

¹ Defendants' motion was granted on July 7, 2006, and the ITC ALJ Initial Determination was filed under seal with this Court on July 13, 2006 ("ITC Decision"). See Certificate of Service of Sealed Document, dated July 13, 2006, Document 102.

with the very same issue currently pending before this Court” and “Roche believes it would be beneficial for the Court to have the ITC’s opinion as part of the record of this case.” Roche does not contend that the ITC’s decision is binding on this Court, but it is clear, as Amgen acknowledges, that a “[d]istrict court can attribute whatever persuasive value to the prior ITC decision that it considers justified.” *Texas Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1569 (Fed. Cir. 1996). Indeed, a prior decision of similar factual issues in an ITC action cannot be ignored in a subsequent district court action. *Id.*; *Minnesota Mining and Mfg. Co. v. Beautone Specialties Co., Ltd.*, 117 F.Supp.2d 72, 83 (D. Mass. 1999) (Lasker, J.). Several courts have taken into account prior ITC decisions when confronting similar factual or legal issues. *See, e.g., Beautone*, 117 F.Supp.2d at 83; *Fuji Photo Film Co. Ltd. v. Jazz Photo Corp. Inc.*, 173 F.Supp.2d 268, 274 (D.N.J. 2001) (“In analyzing the prior decisions in this matter this Court is mindful of the findings and opinions rendered by the ALJ and ITC”). Accordingly, Roche submitted the ALJ’s Initial Determination for the Court’s consideration in deciding Defendants’ motion to dismiss.

Second, Amgen contends that the ALJ’s decision does not consider the issue of imminence or imminent importation of CERA. The ALJ decision has been filed under seal with this Court as it contains confidential propriety information, therefore Roche will not repeat here the portions of the ALJ’s decision related to Amgen’s arguments on imminence.² Instead, Roche points to the following relevant pages of the Initial Determination to assist the Court: pp.3-5; 19-20.

² Moreover, Amgen’s misguided insistence to analogize this case with *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997) has been thoroughly briefed in Roche’s prior filings, including Roche’s Reply Memorandum, dated May 1, 2006, Docket No. 62, at 9-13.

Finally, Amgen contends that Defendants have refused to agree to a “reasonable protective order that would make the ITC record available.” Amgen’s Post-Hearing Memorandum at pp. 4-5. In fact, as the attached email from Amgen attorney Linda Baxley to Roche attorney Howard Suh makes clear, Amgen’s proposal in this regard was actually an attempt by Amgen to circumvent the ITC protective order and gain access for Amgen’s employees — in-house counsel — to Roche confidential information. Amgen stated that it would not object to filing the ITC Initial Determination under seal in this Court provided, among other things, that “Amgen’s in-house counsel be allowed access to whatever documents you or we may seek to file under seal.” *See* July 11, 2006 email from Linda Baxley to Howard Suh, attached as Ex. A. Unlike, Roche’s request to file a specific document — the ALJ’s decision, — with this Court, Amgen wanted Roche to agree to Amgen’s filing of any number of unspecified, highly confidential Roche documents and information, and not only to this Court, but to allow Amgen’s in-house counsel access to all these documents and information — in direct violation of the ITC Protective Order. *See* ITC Protective Order ¶ 3, attached hereto as Ex. B (permitting access to confidential business information produced in the matter only to outside counsel for the parties to the investigation, court reporters and other necessary clerical personnel, technical experts hired by outside counsel, and the ITC, ALJ, and ITC staff or authorized government agency employee). This was not a legitimate attempt by Amgen to file with this Court a document or information related to the present motion or the ALJ’s decision, but an attempt to escape the clear terms of the ITC Protective Order and share Roche confidential business information with internal Amgen personnel. Amgen’s contentions that this Court should not read and consider the ITC decision at all because not all the discovery in the ITC matter is before this Court is a hollow objection and should be rejected. The ITC decision is now before this

Court to take into consideration as the Court sees fit, and as the Court finds it relevant to Defendants' pending motion to dismiss.

DATED: Boston, Massachusetts
July 20, 2006

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

By its attorneys,

/s/ Julia Huston
Lee Carl Bromberg (BBO# 058480)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110
Tel. (617) 443-9292
jhuston@bromsun.com

Principal Counsel:

Leora Ben-Ami (*pro hac vice*)
Patricia A. Carson (*pro hac vice*)
Thomas F. Fleming (*pro hac vice*)
Howard Suh (*pro hac vice*)
Peter Fratangelo (BBO# 639775)
KAYE SCHOLER LLP
425 Park Avenue
New York, NY 10022
Tel: (212) 836-8000

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

Julia Huston

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