UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

EXHIBIT A

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

[PROPOSED] AMGEN'S REPLY IN SUPPORT OF ITS MOTION *IN LIMINE* NO. 13: TO EXCLUDE EVIDENCE AND ARGUMENT REGARDING ROCHE'S FDA FILINGS AND COMMUNICATIONS WITHHELD THROUGHOUT FACT DISCOVERY

Roche does not dispute that it repeatedly refused to produce to Amgen during the discovery period its supplemental BLA filings, its communications with FDA, and its clinical data underlying those filings. Instead, Roche's Opposition feebly offers that its untimely and self-serving production was warranted based on safety issues raised by Amgen in the context of its injunction expert reports, notwithstanding the fact that these issues were raised as early as November of 2005 when Amgen filed its initial complaint seeking injunctive relief. Roche's lame justification is irrelevant and ignores the fact, as more fully set forth in Amgen's Motion (Docket No. 856), that Amgen has repeatedly sought and been denied access to any Roche filing with FDA made after April 18, 2006. By this reply, however, Amgen simply seeks to correct Roche's mischaracterization of questions posed during the deposition of Roche's expert, Dr. Jeffrey Borer, regarding the late-produced documents attached to Dr. Borer's expert report.

On May 22, 2007, Amgen objected to Roche's attempt to allow its experts—and only its experts—to rely on unproduced documents that painted a one-sided picture of communications with the FDA.[1] Amgen stated that it would "not ask questions concerning these previously withheld documents." Furthermore, counsel stated that it "reserves the right to re-depose Roche's experts if these previously withheld documents are not excluded from evidence."[2] In its opposition, Roche implies that counsel for Amgen somehow opened the door to the admission of Roche's previously withheld documents by questioning Dr. Borer at his deposition regarding the matters discussed therein: "Amgen's counsel asked the expert to whose report the three documents in question were attached as exhibits, Dr. Jeffrey Borer, about the documents at his deposition."[3]

Roche's implication is simply false. In the deposition testimony cited in support of Roche's opposition, Amgen's counsel inquired only as to the origin of the documents on which Dr. Borer based his opinions, and whether the documents had been sent to the FDA—no inquiry was made into the data or conclusions therein.[4] Such questions were appropriate to determine whether Roche should have affirmatively produced the documents during fact discovery. The

[1] *See* 5/22/07 Letter from Moore to Fleming, Exh. 6 to Fishman Decl. (Docket No. 858).

[2] *Id*. at 3.

[3] 9/3/07 Roche's Opp'n to Amgen's Mot. in *Limine* No. 13 (DN 856): Exclude Evidence and Argument Regarding Roche's FDA Filings and Communications Withheld Throughout Fact Discovery (Docket No. 972), at 5.

[4] *See* 5/22/07 Deposition of Jeffrey Borer, at 49:6-51:14; 54:3-56:23; 58:9-59:18, attached hereto as Exh. 1 to Decl. of Aaron R. Hand in Supp. of Amgen's Reply In Support of Its Motion In *Limine* No. 13: To Exclude Evidence and Argument Regarding Roche's FDA Filings and Communications Withheld Throughout Fact Discovery. These documents, as well as other late-produced documents, were also attached to at least the reports of Roche witnesses Steven Fishbane and Richard Flavell No questions were asked of these witnesses during their depositions.

implication that Amgen somehow waived its right to object to the introduction of Roche's hand-picked, self-serving, and previously withheld documents is without merit.[5]

Moreover, Roche's suggestion that providing Amgen with some self-serving selection of safety documents as attachments to its expert reports after the close of fact discovery satisfies its discovery obligation such that it may now rely on those documents in support of its experts' opinions on the subject ignores the fact that those documents were never produced during fact discovery and that Roche has never made a full production of responsive documents. As discussed in Amgen's moving papers, Roche cannot now seek to introduce or rely on the very documents that it withheld from production during the discovery period.

Because Roche denied Amgen discovery on its safety data and documents and because Amgen did not open the door during expert deposition discovery to these opinions or their bases coming into evidence, Amgen respectfully requests that the Court preclude from evidence at trial the FDA-related documents that were withheld during fact discovery and the expert opinions relying on those requested but withheld documents, as set forth in Amgen's Motion (Docket No. 856).

[5] Furthermore, whether or not the documents were discussed at the deposition of Dr. Glenn Chertow is irrelevant—because *Roche's counsel* questioned Dr. Chertow about the documents and *Roche's counsel* introduced them as exhibits during that deposition.

Dated: September 20, 2007

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: (857) 488-4200
Facsimile: (857) 488-4201

LLOYD R. DAY, JR
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

KEVIN M. FLOWERS
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive
6300 Sears Tower
Chicago IL 60606
Telephone: (312) 474-6300
Facsimile: (312) 474-0448

Of Counsel:

STUART L. WATT
WENDY A. WHITEFORD
MONIQUE L. CORDRAY
DARRELL G. DOTSON
KIMBERLIN L. MORLEY
ERICA S. OLSON
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320-1889
(805) 447-5000

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 20, 2007.

/s/ Michael R. Gottfried
Michael R. Gottfried