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 CV 12237 WGY

BRIEF IN SUPPORT OF AMGEN'S MOTION *IN LIMINE* NO. 13: EXCLUDE EVIDENCE AND ARGUMENT REGARDING ROCHE'S FDA FILINGS AND COMMUNICATIONS WITHHELD THROUGHOUT FACT DISCOVERY

I. INTRODUCTION

Amgen moved not once, not twice, but three times to compel Roche to produce its supplemental FDA submissions and on-going communications regarding its accused peg-EPO product. At each turn, Roche vigorously opposed providing Amgen with this discovery, contending that it was unduly burdensome, and consequently withheld production of these documents throughout the fact discovery period. The Court, in denying Amgen's motion to compel, presciently noted:

> Naturally, no party may introduce in evidence any document called for in discovery and not produced, nor any data derived from such document. Likewise, the Court will view with extreme skepticism any later proffered discovery.[1]

Roche is now putting that admonition to the test.

More than five weeks after the close of fact discovery, Roche served five expert reports that each relied on selected portions of Roche's supplemental data and submissions to FDA, all of which had been withheld from Amgen during the discovery period. At the same time Roche served these expert reports, it provided to Amgen for the first time selected portions of its supplemental BLA (Biologics License Application) submissions cited in its expert reports. Even then, Roche failed to produce all responsive documents, but only carefully selected and self-serving documents.

The Court has previously ruled that "No Witness May Rely on Evidence Withheld from Discovery."[2] Having fought for and won the right to withhold from discovery its supplemental FDA submissions and communications, Roche cannot now backdoor into evidence through its

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[1] 1/22/07 Electronic Order Denying Amgen's Motion for Clarification.

[2] 5/16/07 Electronic Order in regard to [Docket No. 425] MOTION to Strike Infringement Allegations in Amgen's Expert Reports.

experts' testimony self-serving portions of precisely those materials withheld from Amgen during discovery in this case. Further, because Roche never produced its communications with FDA, including its product label negotiations, Roche should be precluded from presenting any argument or evidence of the potential label and approved uses for its accused peg-EPO product.

II. BECAUSE ROCHE WITHHELD FROM DISCOVERY ITS SUPPLEMENTAL BLA FILINGS AND COMMUNICATIONS WITH FDA, EXCLUSION OF THOSE MATERIALS IS A PROPER REMEDY UNDER FED. R. CIV. P. 37 (C)(1)

During fact discovery, Amgen sought all supplements and updates to Roche's Biologics License Application ("BLA") submitted to FDA as well as Roche's on-going communications with FDA:

> **Request for Production No. 39**: All documents and things comprising or relating to any supplement or amendment to ROCHE's Biologics License Application for peg-EPO since April 19, 2006, including all communications, updates, analyses and patient data related thereto.
>
> **Request for Production No. 40**: All documents and things comprising or relating to any communication, meeting or exchange of information between ROCHE and FDA regarding peg-EPO or EPO since April 19, 2006.[3]

Amgen's requests for production specifically included analyses and patient data underlying any submission to FDA. Roche objected and refused to produce its supplemental BLA submissions and its on-going communications with FDA, contending that production "unduly burdensome to Roche's efforts to gain approval."[4] Moreover, Roche opposed each of Amgen's three motions to

[3] Amgen's First Set of Requests for Production [Docket No. 156-11] Nos. 37-41. Amgen served similar but narrowed requests in its Second Set of Requests for Production (Nos. 298-301), but Roche maintained its same "unduly burdensome" objection.

[4] *See* Roche's Responses and Objections to Amgen's First Set of Requests for Production [Docket No. 167-4] Nos. 37-41; 12/28/06 Defendants' Opposition to Amgen's Motion to Compel Production of Documents [Docket No. 199] at 2; 3/1/07 Defendants' Opposition to Amgen's Motion to Enforce the Court's December 29, 2006 Order and to Compel the Further Production of Documents [Docket No. 301] at 1.

compel these materials. In opposing Amgen's motions to compel, Roche told the Court that it would produce "any supplements, amendments, updates or other filings related to the BLA when they are completed and submitted to the FDA as well as all underlying data."[5] Incredibly, at the same time Roche made these representations to the Court, it had already submitted to FDA two supplemental safety studies in September and December of 2006, yet it refused to produce these documents to Amgen.

Then, on May 11, Roche served four expert reports that cited to and relied upon nearly 2500 pages of supplemental safety data submitted to FDA in September and December of 2006 but that Roche never produced to Amgen.[6] In particular, Roche's May 11 expert reports relied on three documents submitted to FDA in support of its pending BLA on peg-EPO: (1) Special Safety Report for MIRCERA (R008888255- R008888342); (2) Adjudication of Cardiovascular Mortality in RO0503821 Clinical Trials (R008888343- R008888595); and (3) Safety Update: September 1, 2006 Clinical Cutoff (R008888596- R008890732).[7] These three documents include data collected through September 1, 2006 and Roche's own expert confirmed that at least the Special Safety Report had been submitted to FDA by September of 2006.[8] Roche had in its

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[5] 12/28/06 Defendants' Opposition to Amgen's Motion to Compel Production of Documents [Docket No. 199] at 17; 1/17/06 Defendants' Opposition to Amgen's Motion for Clarification of the Court's December 29, 2006 Order [Docket No. 246] at 5.

[6] *See* Declaration of Deborah E. Fishman in Support of Amgen's Motion in Limine to Exclude Evidence and Argument Regarding Roche's FDA Filings and Communications that It Withheld Throughout Fact Discovery (hereafter "Fishman Decl."), Exh. 1 (5/11/07 Borer Report, ¶¶ 24-25, 30-41), Exh. 2 (5/11/07 Vollmar Report, ¶¶ 58, 63, and 82), Exh. 3 (5/11/07 Lieberman Report, ¶¶ 93, and 96-98), Exh. 4 (5/11/07 Fishbane Report, ¶¶ 107, and 111-114) and Exh. 5 (6/13/07 Spinowitz Report, ¶¶ 76-77).

[7] *See* Fishman Decl., Exh. 6 (5/22/07 M. Moore letter to T. Fleming).

[8] *See* Fishman Decl., Exh. 7 (5/22/07 Borer Dep. Tr. at 50:14-51:14).

possession yet refused to produce each of these undeniably responsive documents during the discovery period.

Roche's belated production of its supplemental safety submissions to FDA was both self-serving and incomplete. While Amgen cannot know whether the three documents provided along with Roche's expert reports represent all supplemental peg-EPO submissions to FDA, it is clear that Roche has refused to produce any of its communications with FDA that would be necessary to understand and put in context Roche's supplemental BLA submissions. In particular, Roche has withheld any communications with FDA regarding the Agency's concerns about the safety and efficacy of Roche's accused product, any requests for supplemental studies, and any negotiations over Roche's proposed label for its accused product. These documents are both relevant and necessary to understand the purpose of the supplemental studies and the appropriate conclusions to be drawn from the data and analyses underlying those studies, and the potential label and approved uses of peg-EPO. Taken in its most charitable light, Roche has provided only one side of the story regarding its supplemental safety submissions and stonewalled Amgen on FDAs response to those submissions and any additional concerns that those submissions may have created.

On May 22, 2007, shortly after this back-door production, Amgen wrote to Roche and objected to the supplemental BLA documents cited in Roche's May 11 expert reports.[9] Amgen noted that the three documents were directly responsive to pending discovery requests and that Roche had refused to produce these documents during the course of fact discovery.[10] In addition, Amgen noted the self-serving and selective nature of Roche's belated production of three

[9] *See* Fishman Decl., Exh. 6 (5/22/07 M. Moore letter to T. Fleming).

[10] *Id*.

documents while at the same time Roche withheld everything else.[11] Amgen made clear that Roche could not rely on these documents for any purpose at trial.[12] Roche never responded to Amgen's letter nor did it ever seek to meet and confer on the subject.

Preclusion of these three documents and any expert testimony concerning these three documents is warranted under Rule 37(c)(1). An astonishingly similar case was considered and decided a few months ago by the Southern District of New York in *Texas Instruments Inc. v. PowerChip Semiconductor Corp*., 2007 WL 1541010 (S.D.N.Y. May 24, 2007). There, Texas Instruments moved the Magistrate Judge to preclude PowerChip and its expert witnesses from offering evidence or argument at trial regarding responsive documents that were withheld during discovery and produced only one day after PowerChip served expert rebuttal reports and only because PowerChip's experts relied on those documents for their rebuttal reports.[13] The Magistrate ruled that preclusion of these documents under Rule 37(c)(1) was mandated both because the belated production by PowerChip was responsive to Texas Instrument's discovery requests and because Powerchip's own reliance on the documents demonstrated the prejudice to Texas Instruments in not having the documents produced timely.[14]

As in *Texas Instruments*, preclusion under Rule 37(c)(1) is appropriate here as well. Having foreclosed discovery into these responsive documents, Roche cannot offer a belated and self-serving selection of its supplemental BLA submissions into evidence nor can it offer expert testimony relying on these documents that it withheld from discovery.

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[11] *Id*.

[12] *Id*.

[13] *Texas Instruments Inc. v PowerChip Semiconductor Corp*., 2007 WL 1541010, at * 5 (S.D.N.Y. May 24, 2007).

[14] *Id.* at * 14-15.

III. CONCLUSION

For each of the foregoing reasons, Amgen requests that the Court preclude from evidence at trial the following FDA-related documents that were withheld during fact discovery and the expert opinions relying on those requested but withheld documents, as set forth below:

a. Evidence and arguments relating to the safety of peg-EPO, including documents bearing production numbers R008888255- R008888342; R008888343- R008888595; and R008888596- R008890732;

b. Expert testimony relying on such documents, specifically including: 5/11/07 Borer Report, ¶¶ 24-25, 30-41; 5/11/07 Vollmar Report, ¶¶ 58, 63, and 82; 5/11/07 Lieberman Report, ¶¶ 93, and 96-98; 5/11/07 Fishbane Report, ¶¶ 107, and 111-114; and 6/13/07 Spinowitz Report, ¶¶ 76-77; and

c. Evidence and arguments relating to the potential FDA approved label and uses for peg-EPO.

Dated: August 22, 2007

Respectfully Submitted,

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By its attorneys,

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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 August 22, 2007.

/s/ Michael R. Gottfried
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