Amgen Inc. v. F. Hoffmann-LaRoche LTD et al Doc. 236

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

AMGEN INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR CLARIFICATION OF THE COURT'S DECEMBER 29, 2006 ORDER

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I. INTRODUCTION

On December 15, 2006, Amgen filed a Motion to Compel Production of Documents from Roche asking that the Court order Roche to produce documents responsive to Amgen's First Set of Requests for Production. Roche filed its Opposition on December 28 and the Court issued its ruling on December 29, 2006.

After the Court issued its ruling, though Roche produced nearly a million pages of documents, it failed to produce a single document created after 2005. While this issue was fully briefed by the parties in the context of Amgen's original motion to compel, the Court's December 29, 2006 Order does not expressly dispose of this issue. Amgen therefore seeks the Court's guidance and clarification with respect to the production of documents created after April 18, 2006.

II. MOTION FOR CLARIFICATION REGARDING ROCHE'S UNILATERAL CUT-OFF FOR DOCUMENT PRODUCTION

In its December 15 Motion to Compel, Amgen raised with the Court the fact that Roche has refused to produce responsive documents created after April 18, 2006 (the date on which Roche filed its BLA on peg-EPO).[1] Even after the Court's December 29 Order, Roche has failed to produce a single document created after 2005.[2] Roche's unilateral cut-off on its document production is remarkably one-sided because Roche expects Amgen to produce all responsive documents up through the date of production.

Roche's refusal would block all relevant discovery from the time of Amgen's Amended

[1] Roche's "compromise" is that it will produce documents relating to clinical studies that have been completed and submitted to FDA after the submission of its original BLA filing. Docket No. 199 (Roche's Opposition to Amgen's Motion to Compel the Production of Documents) at 2. As a practical matter this will pertain to few if any documents during the relevant period for fact discovery in this case.

[2] See Exhibit 2 (1/3/07 D. Fishman to P. Fratangelo) to the Declaration of Deborah Fishman in Support of Amgen Inc.'s Memorandum in Support of Its Motion to Clarify (hereafter "Fishman Decl.").

Complaint through a trial in this case. As described in Amgen's December 15 motion, Roche's refusal to produce documents generated after April 18, 2006 precludes discovery of evidence highly relevant to Amgen's liability case as well as Amgen's requested relief.[3] Without re-hashing that motion here, Roche's activities (making, importing, using, selling, offering for sale) with respect to its accused peg-EPO product that post-date the filing of its BLA are ***even more likely*** to demonstrate infringement and to rebut Roche's affirmative defense of U.S.C. § 271(e)(1) than Roche's activities that pre-date its BLA filing. Similarly, documents describing Roche's most recent activities regarding price, reimbursement, and market entry for its accused product ***are much more probative than older documents*** to demonstrate both the harm to Amgen and the public (relevant to Amgen's requested injunctive relief) and to rebut Roche's pending antitrust counterclaims that allege, among other things, barriers to market entry.

In its Opposition to Amgen's Motion to Compel, Roche offered a "compromise" that it would produce documents created after April 18, 2006 to the extent those documents related to clinical studies that have been completed and submitted to FDA.[4] Roche's "compromise" position is insufficient for a host of reasons. First, Roche's position fails to address the panoply of non-regulatory documents that are relevant to this case and even shields its on-going communications with FDA until such time as Roche deems its study to be completed. Second, as a practical matter, by Roche's own estimation, many of these "studies" will not be completed until the end of 2007 or beginning of 2008 — after the scheduled launch of MIRCERA and after a trial in this action.[5] Third, Roche's "compromise" would, by definition, exclude any of

[3] Docket No. 172 (Amgen's Memorandum in Support of its Motion to Compel the Production of Documents) at 5-7, 9, 11.

[4] Docket No. 199 (Roche's Opposition to Amgen's Motion to Compel the Production of Documents) at 2.

[5] *See* Declaration of Deborah E. Fishman in Support of Amgen Inc.'s Memorandum in Support of Its Motion to Clarify ("Fishman Decl."), Exhibit 1.

Roche's non-exempt studies that Roche is conducting but never submits to FDA.

Finally, Roche's "compromise" position is incredibly self-serving because Roche's own Requests for Production instruct Amgen to produce responsive documents in its possession that are known or available to up through its production.[6] Roche cannot have it both ways.

III. CONCLUSION

For each of the foregoing reasons, Amgen seeks the Court's clarification on Roche's unilateral refusal to produce responsive documents created after April 18, 2006 and respectfully requests that the Court:

- strike Roche's general objection No. 8;
- compel Roche to produce responsive documents and things created on and after the filing of Amgen's BLA through the date of its production and
- compel Roche to supplement its responses to the full extent provided for in the Federal Rules of Civil Procedure 26(e) and the local rules.

Dated: January 12, 2007

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[6] Docket No. 177, Exh. 5 (Defendants' First Set of Requests for the Production of Documents and Things to Amgen, Inc. at 10, ¶¶ 5-6 ("This Request is continuing in nature. Amgen shall supplement its responses to this Request, as and when additional responsive documents become known or available to Amgen, or when so requested by Roche prior to trial.").

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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 January 12, 2007.

/s/ Michael R. Gottfried
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