UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No.: 05-cv-12237WGY
	)	
F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GMBH, and HOFFMANN-LA ROCHE INC.,	)	
	)	
Defendants.	)	

DEFENDANTS' OPPOSITION TO AMGEN'S MOTION FOR CLARIFICATION OF THE COURT'S DECEMBER 29, 2006 ORDER

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Dated: January 17, 2007

I. Introduction

The Court's December 29, 2006 Order in response to Amgen's Motion to Compel requires no clarification as it was very clear as to which of Amgen's requests for the production of documents were denied and which were granted. As is evident from the multiple motions filed so far, the dimensions of discovery in this case are extensive, and the Court, in its order, imposed meaningful parameters to control unnecessary and irrelevant discovery requests. Amgen's motion merely seeks to reargue what the Court has already decided, and as such, Amgen's current motion for clarification is actually an attempt at a motion for reconsideration. Even then, Amgen's motion articulates no changed circumstance, no error by the Court, no omitted fact, nor any other basis to change the Court's original ruling and therefore should be denied.

II. The Court's Order Is Clear On the Dates For Responsive Roche Documents

Amgen's motion concedes that Roche has been producing documents on a rolling basis to Amgen, even faced with Amgen's overbroad and significantly far-ranging requests, now totaling over 370 in number. In response, Roche has produced over 1 million pages so far. Amgen even ignores the substantial production made in the ITC proceeding that included Roche's BLA and INDs for its accused, yet presently not approved, product. Amgen does not point this out since a good number of these ITC documents are from 2006.

Amgen may disagree with the Court's ruling, but Amgen is wrong when it contends that the Court did not address the cut-off date for producing documents generated after April 2006. Amgen's argument necessarily ignores the fact that the Court denied a significant number of Amgen's Requests for Production that encompass the time

period after the filing of Roche's BLA for MIRCERA™ in April, 2006 (see Amgen Requests 45-109, 111, 113-126, 148-150, 154-155,162-167 and 176), granted certain Amgen Requests encompassing documents after April, 2006 (see Amgen Requests 158-160), and accepted Roche's compromise position which encompasses certain clinical trial data after April, 2006, which is data from clinical trials that have been completed and submitted to the FDA. Court Order of December 29, 2006.[1]

Amgen's main point in this motion for reconsideration is the same as in its motion to compel, which is that Roche's activities after April 2006 (which are still directed toward obtaining FDA approval) are somehow "even more likely to demonstrate infringement and rebut Roche's affirmative defense of U.S.C § 271 (e)(1)." (Amgen Br. at p. 2) Amgen ignores that it already has the overwhelming majority of clinical trial data and materials in the BLA for MIRCERA, as well as detailed product characteristic and formulation data in that document and in the CERA INDs. Other than stating the argument, Amgen makes no further showing how the data it has obtained, in these and other documents through April 2006, can possibly be any less probative than the cumulative and irrelevant documents it seeks on these issues. There is no contention that any characteristics of the accused product or its uses in clinical trials has been altered or changed in any way, or how the asserted claims impact what it seeks. The Court's December 29 Order reflects that the Court rejected Amgen's same arguments when it denied most of Amgen's requests that Amgen contended were relevant to Section 271(e)(1). (*See* Amgen Requests 162-167, 176). The Amgen requests that the Court granted relating to Section 271(e)(1) focused on documents sufficient to show inventory

[1] The Court's ruling implicitly resolved Amgen's contention as to General Objection No. 8.

and current stock levels of CERA for the United States, and such documents, if any, will be provided..

Amgen's continued arguments in this new motion that post-April 2006 documents are relevant to Roche's liability under Section 271(e)(1) add nothing to the briefing already considered by this Court. As Roche explained in its prior briefing, this Court has already accepted subject matter jurisdiction in this case and the Court has adopted an accelerated case schedule, setting trial for September 2007.

III. Amgen Would Have No Basis for a Motion for Reconsideration

Regardless of Amgen's styling of its motion as one for clarification, what it really seeks is reconsideration of the Court's order, to which it clearly is not entitled. "A court should grant a motion for reconsideration of an interlocutory order only when the movant demonstrates (1) an intervening change in the law; (2) the discovery of new evidence not previously available; or (3) a clear error of law in the first order." *Davis v. Lehane*, 89 F. Supp. 2d 142, 147 (D. Mass 2000). Clearly, Amgen has not met any of these criteria as there has been no change in the relevant facts and circumstances surrounding Amgen's original Motion to Compel, nor any change in law or error of law.[2]

[2] As the Supreme Court has instructed in regard to entry of reconsideration, "courts should be loathe to do so in the absence of extraordinary circumstances such as where the initial decision was 'clearly erroneous and would work a manifest injustice.'" *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 817 (1988) (quoting *Arizona v. California*, 460 U.S. 605, 618 n. 8 (1983)). Certainly Amgen has not articulated such a basis that would justify changing the Court's original order.

IV. Roche Will Continue to Produce More Responsive Documents as Ordered by the Court

Amgen's argument that Roche will not comply with the Court's Order to produce certain responsive documents post-dating April 2006 is simply inaccurate. Roche has continued its production to Amgen, and in fact has produced far more documents than Amgen. In all, Amgen's production has been miniscule and of largely unimportant materials. As Amgen well knows, just among the approximately 400,000 plus documents already produced by Roche in the ITC Proceeding, and likewise in this action, are a multitude of documents dating from 2006. Amgen fails to make any showing of the relevance of any additional documents, and instead, as challenged by the Court in its prior ruling, makes unfocused and overbroad requests for documents with no particularized showing of need or justification. As the Court can see from the amount of materials already produced in this action, millions of pages of documents are implicated (all of which must be collected, reviewed, and produced), and Amgen should not be allowed to impose further burdens escalating these obligations.[3]

Amgen knows that Roche is working to obtain FDA approval and Amgen is fixed on invading every detail of those discussions, even though they are completely irrelevant to any issue in this case. Even still, Roche agreed to provide data on clinical trials when completed, and the Court accepted this position.

Amgen's argument as to the production of documents relating to marketing and sales also mischaracterizes the record. Roche has not received FDA approval, and as

[3] Amgen's characterization that this approach "shields its on-going communications with FDA" (Amgen Memorandum in Support of Motion for Clarification at 2) is baseless as the Court ordered compromise position also requires Roche to "update the Court of any significant events before the FDA regarding MIRCERA™, including whether approval is imminent."

such no price has been set for its product, nor have any offers for sale been made. All of that activity must await final approval. Amgen, however, is in a far different position from Roche, as Amgen is currently selling its Erythropoiesis stimulating products (Epogen® and Aranesp®; and has commercial agreements covering Procrit®). Furthermore, as to Roche's antitrust claims against Amgen, those claims focus entirely on Amgen's ongoing anticompetitive activities and practices in the United States market. Amgen, curiously, has continually stonewalled Roche in providing such discovery and has only committed to producing "final" business plans. As set forth in Roche's Opposition to Amgen's Motion to Compel, Amgen has not definitively stated that it is seeking damages and thus should narrow its requests to specific types of documents relevant to its presentation at an injunction hearing.

In light of these facts, the Court has ordered that Amgen produce its marketing and sales documents before Roche does. Roche and Amgen are still conducting meet and confers on this issue. Roche is still awaiting complete productions from Amgen of such documents. While Roche has produced nearly a million pages of documents, Amgen has produced only a fraction of that amount and refused to produce up to date marketing and sales documents. Amgen ignores that Roche has produced certain marketing and sales forecasts documents already, and given the differences in commercial positions, Roche should not be compelled to do more at this time.

VII. Conclusion

For each of the foregoing reasons, Amgen's Motion for Clarification, which actually seeks to amend the Court's Order without justification, should be denied.

Dated: January 17, 2007
Boston, Massachusetts

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,
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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 (NEF) and paper copies will be sent to those indicated as non registered participants on the above date.

/s/ Keith E. Toms
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