UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GmbH, and HOFFMANN-LA ROCHE INC. Defendants.	CIVIL ACTION No.: 05-CV-12237WGY

ROCHE'S OPPOSITION TO AMGEN'S MOTION TO PRECLUDE FURTHER INTERFERENCE WITH THIRD-PARTY DISCOVERY AND COMPEL PRODUCTION OF DOCUMENTS AND DEPOSITION TESTIMONY, OR IN THE ALTERNATIVE, MOTION TO STRIKE DEFENDANTS' DEFENSE UNDER 35 U.S.C. § 271(e)(1)

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Dated: April 27, 2007

I. Introduction

The inventive title of Amgen's motion cannot disguise the dismaying fact that Amgen seeks yet another reconsideration of this Court's three prior orders defining the scope of discovery with respect to Roche's ongoing clinical trials. Amgen's fourth bite at the same apple, while failing to raise a single new argument, succeeds only at contributing to the high costs of this litigation.

Not satisfied with the extensive discovery already produced by Roche--approximately 15 million pages of documents, extensive depositions, numerous expert reports, and several volumes of responses to written discovery--Amgen continues to demand access to not-yet-complete clinical trials which Amgen knows full well do not impact any issue of alleged infringement in this case or affect the attributes of the proposed product described in Roche's April 18, 2006 BLA. *See* Defendants' Opposition to Amgen's Motion to Enforce the Court's December 29, 2006 Order and to Compel the Further Production of Documents dated March 1, 2007 (Docket No. 301), at 3-4. Amgen has now spent four months concocting new motions in a blatant attempt to circumvent the Court's Order of December 29, 2006 which adopted Roche's position that post-April 18, 2006 clinical trials are in large measure irrelevant to this lawsuit, beyond the scope of discovery, and would be unduly prejudicial and potentially disruptive to the ongoing discussions and negotiations between Roche and the FDA.

Denied discovery three times on Roche's still-ongoing FDA clinical trials, Amgen attempted an end-run around the Court's Orders by seeking this information from third parties. When Roche learned of Amgen's subterfuge, it informed the third parties of the Orders and advised their independent counsel that Roche – consistent with those Orders – would not waive their confidentiality obligations regarding ongoing clinical trials. To have acted otherwise would

have rendered those Orders, and the protections they gave to Roche's efforts to obtain FDA approval, meaningless.

Amgen now moves to preclude Roche from "interference" with third party discovery and to compel documents and deposition testimony from Roche, DaVita and Fresenius with respect to Roche's Phase IIIb clinical trials. Although it surely knows better, Amgen fosters the misimpression that it was improper for Roche to inform third parties of the Court's rulings and advise that they act consistently with them. The rationale behind shielding Roche's post-April 18, 2006 clinical trials from discovery does not turn on whether Amgen seeks this information through Roche or through third parties. Amgen cannot reasonably expect to obtain from DaVita or Fresenius information regarding Roche's ongoing clinical trials that the Court ruled could not be had from Roche.

Because nothing has changed between the December 29, 2006 Order and today--and Amgen has not explained why the sought information is any more relevant now than on the previous occasions it argued for its discovery--this Court should again deny Amgen's attempts to discover irrelevant information related to ongoing clinical trials.

In addition to being at odds with the Court's previous Orders, Amgen's motion comes too late. The discovery deadline in this case was April 2, 2007, and the schedule proposed by the parties and adopted by the Court explicitly provides that motions to compel must be made before the expiration of the applicable discovery period. Amgen's motion, filed 11 days after the discovery deadline, is clearly a motion to compel, as it openly seeks an order from this Court compelling Roche to produce documents and witnesses. If for no other reason, Amgen's motion should be denied for failure to comply with the Court's deadline for filing discovery motions.

II. Roche's Position Regarding Roche's Phase IIIb Clinical Trials Is Consistent With the Court-Adopted Compromise Position

Amgen's fourth and present motion seeks to compel Roche and third parties DaVita and Fresenius to produce documents and provide testimony concerning three of Roche's clinical studies related to its development of MIRCERA™: the Time & Motion Study (Protocol No. ML20336), the Continuum of Care Study (Protocol No. ML20337), and the Peritoneal Dialysis Study (Protocol No. ML20338).

Amgen's previous attempts to obtain information related to Roche's ongoing clinical trial activities are embodied in (1) Amgen's Motion to Compel Production of Documents dated December 14, 2006 (Docket No. 165), to which the Court issued its December 29, 2006 Order accepting Roche's compromise position as to ongoing clinical trials and communications with the FDA, (2) Amgen's Motion for Clarification of the Court's December 29, 2006 Order dated January 12, 2007 (Docket No. 235), which the Court denied in its Order dated January 22, 2007; and (3) Amgen's Motion to Enforce the Court's December 29, 2006 Order and to Compel the Further Production of Documents dated February 15, 2007 (Docket No. 281), which was also squarely denied in the Court's Order of March 2, 2007.

The information which Amgen persists in seeking is plainly not discoverable under the Court's December 29 Order, in which the Court endorsed Roche's proposal that only a subset of the post-BLA documents be produced, namely, the data from the *completed* clinical trials. The three studies at issue are ongoing Phase IIIb clinical trials and, contrary to Amgen's assertions, are

in support of Roche's FDA approval for MIRCERA™.[1] Amgen continues to ignore this Court's rulings by requesting such documents and testimony, which are beyond the scope of discovery in this case. *See* Court's Order of December 29, 2006. Amgen's motion is thus unfounded and without merit.

In its prior motions, Amgen has consistently failed to articulate any meaningful basis for the relevance of the production it seeks and offers no new arguments in its current motion.[2] Absent FDA approval, none of these discussions have any relevance at all to infringement or other issues.[3] Only if and when these studies are completed and the data are processed for submission to the FDA will they become the subject of legitimate discovery, and at that time Roche will produce any responsive documents. Amgen seeks to circumvent the Court's previous Orders, while providing no rationale for disturbing the Court's adoption of the compromise position advanced by Roche, regarding completed clinical trials (discoverable) vs. uncompleted clinical trials (not discoverable). Roche has already agreed to produce any final data from clinical trials

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[1] The documents cited by Amgen demonstrate that each of these protocols has or will be submitted to the FDA. *See* Moore Declaration, Docket No. 379, at Ex. 10, Anemia Clinical Trials Task Force, Executive Summary, at 3; Moore Declaration, Docket No. 379, at Ex. 11, Anemia Clinical Trials Task Force, Executive Summary, at 3. Further, the protocols for these clinical trials had to be first submitted to the FDA. (These documents are, among others, the subject of Roche's Motion for Leave to File Under Seal Documents Containing Defendants' Trade Secrets And Submitted In Connection With Amgen's Motion To Preclude Further Interference With Third-Party Discovery" (Docket No. 409).)

[2] Amgen implausibly cites a need for documents concerning Roche's ongoing clinical trials in order to rebut Roche's safe harbor defense. However, this Court decided that irrespective of 35 U.S.C. § 271(e)(1), Amgen alleged facts sufficient to confer jurisdiction over this case. Thus, this litigation case has proceeded in spite of Roche's safe harbor defense.

[3] In deciding whether to issue an injunction–the relief Amgen seeks– the Court will consider (1) whether there is irreparable injury to the movant; (2) the adequacy of remedies at law, such as monetary damages; (3) the balance of the hardships of the parties; and (4) the impact of an injunction on the public interest. *Ebay Inc. v. MercExchange, L.L.C.*, 126 S. Ct. 1837 (2006). Not one of these factors turns on Roche's ongoing clinical trials.

that it submits to the FDA as well as any information that changes the Chemistry Manufacturing and Controls ("CMC") section of its BLA from the April 18, 2006 submission.[4]

The Court has recognized that information about ongoing clinical trials are of no particular relevance to the current issues in this action and would be unduly prejudicial and potentially disruptive to the ongoing discussions between Roche and the FDA. There can be no dispute that ongoing clinical trials have no relevance to the issues of infringement or invalidity and therefore are not reasonably calculated to lead to the discovery of any information relevant to whether the finished MIRCERA™ product allegedly infringes Amgen's patents.[5] Amgen's asserted claims relate solely to the characteristics of the actual accused product, and even then, arguably, only to the processes by which it is made. Nothing in the not-yet-complete clinical trials and studies (whose data are constantly changing as the trials progress) relates to those issues. Roche has even produced to Amgen final data--postdating April 18, 2006--that Roche submitted to the FDA, the only data relevant to the infringement claim.

It is clear that Amgen knows and has basic information about the three trials identified in its motion, and still it can articulate no compelling new reason to revisit the identical question that the Court has three times resolved against Amgen.

III. Roche Properly Instructed Third Parties DaVita and Fresenius to Comply with Amgen's Subpoenas in Accordance with the Court's Previous Orders

Just as the documents and deposition testimony Amgen seeks from Roche relating to its ongoing clinical trials are inconsistent with the Court's Orders, so are similar requests that Amgen

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[4] The CMC section describes the relevant structure, properties, function and method of manufacturing of Roche's proposed product awaiting approval.

[5] Roche has briefed the relevance issue at length in its Opposition to Amgen's Motion for Clarification of the Court's December 29, 2006 Order (Docket No. 246) and its Opposition to Amgen's Motion to Compel the Production of Documents (Docket No. 199).

served on third parties DaVita and Fresenius. Accordingly, it was proper for Roche to inform independent counsel for DaVita and Fresenius of the Court's Orders and advise that their production of documents related to Roche's ongoing clinical trials comply with those Orders. Roche also acted on the belief that deposition testimony should conform to the Court's definition of the scope of discovery.

Several of Amgen's discovery requests to DaVita and Fresenius, which were served after this Court's Order of December 29, 2006, were wholly inconsistent with that Order. The discovery requests underlying Roche's instructions to DaVita and Fresenius not to produce certain information are reproduced below:

> **Document Request No. 12**: Documents and things sufficient to identify and describe DaVita's participation, or potential participation, in any trial, research, or other study sponsored or conducted by or on behalf of ROCHE, *scheduled to commence after April 18, 2006*. *See* Moore Declaration, Docket No. 379, at Ex. 1, Amgen's Subpoena of DaVita, Inc. dated Jan. 12, 2007, at 10.
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> **Deposition Topic No. 6**: DaVita's actual or planned participation in any trial, research, or other study sponsored or conducted by or on behalf of ROCHE, *scheduled to commence after April 18, 2006*. *See* Moore Declaration, Docket No. 379, at Ex. 2, Amgen's Subpoena of DaVita, Inc. dated March 9, 2007, at 8.
>
> **Deposition Topic No. 6**: FRESENIUS'S actual or planned participation in any trial, research, or other study sponsored or conducted by or on behalf of ROCHE, *scheduled to commence after April 18, 2006*. *See* Moore Declaration, Docket No. 379, at Ex. 3, Amgen's Subpoena of Fresenius, dated March 27, 2007, at 8.

(Emphasis added.)

It is apparent on the face of these requests that Amgen seeks documents and testimony from DaVita and Fresenius that are clearly beyond the scope of the Court's Order excluding

discovery related to post-April 18, 2006 clinical trials.[6] Thus, it was entirely appropriate for Roche to advise counsel for DaVita and Fresenius that the Court had determined that the Court excluded certain information sought by Amgen from the scope of discovery. *See* Exhibit A, 3/26/07 and 3/28/07 emails from D. Cousineau to B. Mathie and M. Hebert, counsel for Fresenius and DaVita respectively, attaching Court's 3/2/07 Order and Roche's related brief. Amgen's subpoena to third parties for this information is an attempt to circumvent the Court's Orders.

In keeping with the Orders, Roche informed counsel for DaVita and Fresenius that Roche would not waive their confidentiality obligations related to ongoing tests. As in the past, however, Roche did not object to DaVita's and Fresenius's production of information related to completed tests. *See* Exhibit B, Cousineau emails of 3/27/07 and 3/29/07 to B. Mathie and D. Fishman, counsel for DaVita and Amgen, respectively, regarding approved production of completed tests. DaVita and Fresenius in fact produced responsive information related to the completed clinical tests. Amgen received all the information that this Court deemed appropriate.

IV. Amgen's Motion Is Untimely and Therefore Improper

In addition to being wholly inconsistent with the compromise position ordered by the Court, Amgen's motion improperly seeks to compel documents and testimony after the discovery deadline. While Amgen has attempted to disguise this motion as a "Motion to Preclude Interference," its second prayer for relief – "ordering Roche to produce all documents concerning protocol numbers ML20336, ML20337, ML20338" – reveals Amgen's purpose. *See* Amgen's memorandum (Docket No. 378) at 11. Likewise, the lengthy title of Amgen's motion discloses that it is, essentially, a motion "to compel production of documents and deposition testimony."

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[6] Amgen makes the insulting accusation that Roche violated Model Rule of Professional Conduct 3.4(f) in requesting that DaVita and Fresenius not produce certain documents. *See* Amgen's memorandum, at 10. It cannot be a breach of that rule to inform attorneys representing third parties of Court rulings that govern the scope of discovery.

But the close of discovery was April 2, 2007, and Amgen filed this motion on April 13. Amgen acknowledges in its motion that "the deadline for discovery has now passed." *Id.* at 2.

Amgen's disregard for the Court's discovery deadlines and the interests of expeditiously advancing this case should not be tolerated. Because Amgen's motion to compel is untimely and completely inappropriate at this stage in the litigation, it should be denied.

Although Amgen is the party ignoring the Court-imposed definition of the scope of discovery, its motion seeks the extreme sanction of striking one of Roche's defenses. Amgen fails to show that Roche's actions are egregious enough to warrant this penalty. To warrant a sanction against Roche, Amgen must demonstrate that Roche's actions were not "substantially justified." Fed R. Civ. P. 37(a)(4)(A). Roche was substantially justified in objecting to Amgen's attempts to ignore the Court's prior Orders. Both the Advisory Committee Notes and the Supreme Court define "substantially justification" to mean that the dispute is genuine or that reasonable people could differ as to the outcome. Advisory Committee Note to 1970 Amendments to Federal Rule of Civil Procedure 37(a)(4), *reprinted* at 48 F.R.D. 487, 540; *Pierce v. Underwood*, 487 U.S. 552, 565 (1988).

As described above, Roche based its response to Amgen's third party subpoenas for information relating to ongoing clinical trials on its understanding of the Court's Orders. Roche objected only to testimony and production of documents related to post-April 18, 2006 data relating to ongoing clinical trials. It did not object to discovery on any other topics. Amgen does not, indeed cannot, demonstrate that Roche's actions were not substantially justified. Roche's actions were based on not one, but three, Court Orders placing the sought information beyond the scope of discovery. Roche was following the Court's directions.

V. Conclusion

For all of the foregoing reasons, Roche requests that the Court deny the relief sought in Amgen's motion.

Dated: April 27, 2007
Boston, Massachusetts

Respectfully submitted,

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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.

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