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 *IN LIMINE* NO. 13 (DN 856): EXCLUDE EVIDENCE AND ARGUMENT REGARDING ROCHE'S FDA FILINGS AND COMMUNICATIONS WITHHELD THROUGHOUT FACT DISCOVERY

INTRODUCTION

This Court has consistently accepted Roche's position that incomplete clinical studies and associated data, and ongoing exchanges with the FDA after Roche filed the BLA for MIRCERA® are not relevant to the issues to be considered by this jury, and are therefore outside the scope of proper fact discovery for the jury phase of the trial. In fact, the Court rejected no fewer than four separate Amgen motions that sought to compel the production of those documents.

Amgen then employed a novel fifth strategy: it submitted expert reports questioning the safety of MIRCERA® based on surmise, conjecture, and inaccurate and misleading interpretation of data. Roche maintains that issues of "safety" are unrelated to jury issues and has filed its own motion *in limine* to exclude the irrelevant and highly prejudicial statements made in Amgen's flawed expert reports. Confronted with these reports, however, Roche was

forced to rebut Amgen's faulty expert opinions. Accordingly, Roche served its own expert reports based, in part, on two safety updates that included interim data from ongoing clinical studies, and a report created as part of Roche's ongoing communications with the FDA of a panel of independent experts analyzing data, including interim data obtained in those studies. At the same time, Roche produced these documents to Amgen. Although Roche's expert testimony and the underlying documents were properly disclosed during the expert discovery period, Amgen now seeks to exclude them while maintaining its ability to use its own experts to question MIRCERA®'s safety.

As Amgen well knows, there are no safety issues with MIRCERA® at the FDA, and once the FDA approves MIRCERA®, there will be no question of MIRCERA®'s safety and efficacy. While MIRCERA® is awaiting approval, however, Amgen intends to prejudice Roche and MIRCERA® by making frivolous and unfounded accusations. Roche has filed its own motion *in limine* to preclude Amgen from making these false and prejudicial statements, but, at the very least, Roche should be allowed to rebut Amgen's evidence, and thus, Amgen's motion should be denied.[1]

Amgen accuses Roche of "cherry-picking" the documents it has produced. But Roche has fully complied with this Court's orders and directives, as well as its discovery obligations, and the documents targeted by Amgen's motion offer a complete, not partial, picture of the safety issues that Amgen has chosen to introduce in these proceedings. Amgen's accusations

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[1] Amgen's motion also seeks to exclude unidentified evidence and arguments relating to "the potential FDA approved label and uses for [MIRCERA]." Amgen nowhere identifies any information allegedly withheld on this issue, however, or offers any justification for its exclusion. In any event, Roche is entitled to offer evidence of its negotiations with the FDA relating to the approval of the label and uses for MIRCERA in order to rebut Amgen's experts' poorly substantiated attacks on MIRCERA's safety and proposed dosing.

ring hollow in light of its own attempt to clutter the record with highly prejudicial information that casts a false shadow on the safety of MIRCERA®, while precluding Roche from offering evidence that shows the product is, in fact, safe. Amgen's attempt to distort the record and to prejudice the jury should not be indulged.

BACKGROUND

Beginning in December 2006, and continuing for many months, Amgen filed a series of motions to compel Roche to produce all its post-BLA-submission discussions with the FDA, including discussions about partially completed clinical studies — documents that are irrelevant to any issue to be presented to this jury, and highly sensitive.[2] In opposing Amgen's motions, Roche asked the Court to deny Amgen's requests seeking these documents. Dating back to December 29, 2006, the Court denied Amgen's motion to compel and thereafter repeatedly upheld that earlier ruling. Roche later produced—in addition to the hundreds of thousands of pages it had already produced relating to its BLA and Investigational New Drug ("IND") Application for MIRCERA®—documents concerning completed studies, consistent with the compromise position adopted by the Court. Amgen attempted to re-litigate the Court's denial of its motion on three separate occasions, each of which was unsuccessful.[3]

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[2] Roche briefed the relevance issue at length in its Opposition to Amgen's Motion for Clarification of the Court's December 29, 2006 Order (DN 246) and its Opposition to Amgen's Motion to Compel the Production of Documents (DN 199).

[3] *See* Amgen's Motion for Clarification of the Court's December 20, 2006 Order, Jan. 12, 2007 (Docket No. 235) *denied on* Jan. 22, 2007; Amgen's Motion to Enforce the Court's December 29, 2006 Order and to Compel the Further Production of Documents, Feb. 15, 2007 (Docket No. 281) *denied on* Mar. 2, 2007; 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 32 U.S.C. § 271(e)(1), Apr. 13, 2007 (Docket No. 377) *denied on* Apr. 30, 2007.

Amgen then contrived relevance of the discovery it sought by submitting expert reports in April 2007, of John Lubina and Glenn Chertow, both of whom opined on MIRCERA® safety. Their opinions were based on conjecture, as well as incomplete and flawed interpretation of data. Notably, Amgen failed to explain the purported legal significance of its experts' safety opinions, underscoring that the issues were not relevant to the case.

Notwithstanding their lack of relevance, Roche could not allow the misleading Chertow and Lubina opinions to stand without rebuttal. Roche maintained its objections to this information, but left with no recourse from Amgen's bad faith efforts to reveal sensitive and Court-protected BLA information, was compelled to address certain documents that were outside the scope of discoverable documents under the Court's December 29th Order. Roche promptly disclosed the interim data generated by ongoing studies.[4] At the same time, Amgen again moved for this information from the Court, and the Court again rebuffed Amgen's efforts. As the Court held in its Order on March 2, 2007, when it once again rebuffed Amgen's tactics:

"**Motion DENIED Hoffman-La Roche's Position Is Correct.**" (emphasis added).

As Amgen learned, these documents actually undercut, rather than supported, the opinions of Chertow and Lubina and belied any suggestion of safety issues with MIRCERA. Amgen does not even do this Court the courtesy of explaining that fact. Instead of being satisfied at obtaining documents related to ongoing FDA communications and ongoing clinical trials as it had been seeking, Amgen changed course and began laying the groundwork for the present motion that, if granted, will ensure that the jury hears only Amgen's inaccurate side of the story. In the very letter Amgen cites in its motion, counsel for Amgen stated that "Amgen

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[4] *See* Exh. A, Declaration of Krishnan Viswanadhan, at ¶ 3.

will not ask any questions of Roche's experts concerning these previously withheld documents."[5] However, at the same time it wrote this, 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.[6] Moreover, Amgen sought discovery related to safety analyses from other Roche experts including Dr. Fishbane, Dr. Lieberman and Mr. Vollmar. Knowing its position had no basis, Amgen showed the documents it now seeks to exclude to its expert Glenn Chertow in his preparation for deposition,[7] but because it doesn't like what they say, it now wants to preclude their further use.

Roche has complied with both the letter and spirit of the Court's Order and with its ongoing discovery obligations, and nothing in Amgen's allegations indicates otherwise. Amgen's suggestion that Roche somehow violated the December 29th order, by producing, during expert discovery, documents it calls "supplemental safety studies" submitted to the FDA in September and December 2006, is baseless. In fact, those "studies" were merely interim status reports relating to clinical trials that have not yet closed,[8] and therefore are beyond the scope of the Court's Order. In sum, Roche has fully complied with its discovery obligations with respect to all of the items at issue.

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[5] *See* Exh. 6 to Declaration of Deborah E. Fishman, DN 858.

[6] Deposition of Jeffrey S. Borer, dated 5/22/07, at 49:6-51:14; 54:3-56:23; 58:9-59:4.

[7] Deposition of Glenn M. Chertow, dated 6/8/07, at 213:22-214:4; 216:10-217:21. Roche has not filed excerpts of the deposition testimony of Borer or Chertow due to their highly confidential nature, and because Roche does not believe that it is necessary for the Court to review them to decide the present motion. If the Court deems these documents necessary to decide the motion, however, Roche stands ready to submit them to the Court for in camera review and will present a motion to accept them for filing under seal in accordance with the procedures previously ordered by the Court.

[8] *See* Exh. A, Declaration of Krishnan Viswanadhan, at ¶3.

ARGUMENT

Roche Appropriately Disclosed Its Communications With The FDA And Is Entitled to Rely Upon Them At Trial

When Amgen invokes the sanctions provided under Rule 37(c)(1), it fails to establish any of the elements required for exclusion of evidence. Rule 37(c)(1) provides that "a party that without substantial justification fails to disclose information required by Rule 26(a) or 26(e)(1) shall not, unless such failure is harmless, be permitted to use as evidence at trial…any witness or information not so disclosed." Fed.R.Civ.P. 37(c)(1) (emphasis added). But here, there has been no failure on Roche's part to disclose information pursuant to Rule 26.

Amgen should be precluded from discussing or raising with the jury any "apparition" concerning safety issues with MIRCERA®. Once the FDA approves MIRCERA®, the issues of safety and efficacy will, like an apparition, vanish. Amgen's goal is to invoke prejudice and damage to Roche, knowing that this Court has denied Amgen this discovery no less than four separate times in discovery.

Given the Court's repeated rejections of Amgen's motions to compel, Amgen has no basis for arguing that Roche failed to live up to the requirements of Rule 26 or any Order of the Court. Roche ultimately produced the disputed items not because it was obligated to do so, but rather because Amgen newly put at issue the safety of MIRCERA® as shown by clinical trial data, and Roche needed to respond to these issues. Thus, the threshold requirement for excluding evidence under Rule 37(c)(1)—that the putative evidence had been withheld in violation of Rule 26—is not met. Amgen would have sanctions against Roche under Rule 37(c)(1) for complying with the Court's many orders on this topic, not failing to comply.

Furthermore, Amgen cannot claim (and, in fact, does not allege) that it has suffered any harm as a result of the timing or scope of Roche's disclosure of the items it seeks to exclude. In

fact, if Amgen believed, after seeing the documents and testimony in question, that further discovery relating to the specific safety issues addressed was necessary, it was free to broaden the scope of its examination of Roche's experts and to probe the basis for their opinions. Amgen asked the expert who attached these documents to his report, Dr. Borer, about the very documents they now seek to preclude. In addition, they questioned other Roche experts such as Fishbane, Lieberman and Vollmar about MIRCERA® safety issues, and then prepared their own expert whose report made the production of the documents presented here necessary, Glenn Chertow, to answer questions regarding the documents at his deposition. Amgen acknowledged that it had the opportunity to conduct further discovery, but it declined to do so.

Amgen bears responsibility for the resulting consequences of pursuing its chosen litigation strategy. Here the Court multiple times rejected Amgen's efforts to get this protected information. Notwithstanding the Court's clear instructions, Amgen refused to take no for an answer. Now, Amgen seeks to punish Roche for complying with this Court's orders. *See McCarthy v. Option One Mortgage Corp.* 362 F.3d 1008, 1012 (7th Cir. 2004) (affirming denial of exclusion under 37(c)(1) where party seeking exclusion failed to pursue further discovery relating to disputed items). In *McCarthy*, the Court rejected the gambit of the party seeking to exclude evidence that was properly produced for the first time after the close of fact discovery in response to an issue newly contrived by the party seeking to exclude.

Amgen should be precluded from offering any evidence of so-called "safety" issues with MIRCERA® as it knows none exist, and to respond to such meritless allegations would force Roche to disclose information this Court has seen appropriate to protect. Roche agrees with this Court's rulings that such evidence is not relevant to the jury phase of the trial, and Amgen should not be permitted to use the shield granted by the Court as a sword to damage and prejudice

Roche in front of the jury. *See Sherrod v. Lingle*, 223 F.3d 605, 613 (7th Cir. 2000) ("drastic" sanction of exclusion inappropriate).

CONCLUSION

For all of the foregoing reasons, Amgen's motion *in limine* should be denied.

Dated: September 3, 2007

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,
ROCHE DIAGNOSTICS GMBH, and
HOFFMANN-LA ROCHE INC.

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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 will be delivered to Amgen's trial counsel by electronic mail in the manner requested in the August 29, 2007, letter of Renee DuBord Brown to Thomas F. Fleming. Paper copies will be sent to those indicated as non registered participants on September 4, 2007.

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