

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No.: 05-12237 WGY
)	
F. HOFFMANN-LAROCHE)	
LTD., a Swiss Company, ROCHE)	
DIAGNOSTICS GmbH, a German)	
Company and HOFFMANN LAROCHE)	
INC., a New Jersey Corporation,)	
)	
Defendants.)	
_____)	

**AMGEN’S MEMORANDUM IN OPPOSITION TO ROCHE’S MOTION FOR LEAVE
TO AMEND ITS ANSWER**

I. INTRODUCTION

On May 23, 2007, seven and a half weeks after the April 2 close of fact discovery, Roche moved to amend its answer by, among other things, asserting new allegations of inequitable conduct. Roche's attempt to amend its complaint with new factual allegations so late in the litigation, with no legitimate justification for delay, would prejudice Amgen, further burden the Court, and should not be permitted.

Amgen opposes Roche's motion to amend to the extent that it seeks to add allegations of inequitable conduct submitted for the first time after the close of fact discovery on April 2, 2007.

Roche's motion to amend is the most recent in a series of attempts to proliferate issues in the case, and particularly to add more and more claims of inequitable conduct in a manner inconsistent with the Court's schedule. Roche first asserted inequitable conduct in its original Answer on November 6, 2006, almost a year to the date after the Complaint had been filed and months after discovery had been provided by Amgen through the parallel ITC proceedings. When Amgen moved to strike Roche's original Answer and Counterclaims on the grounds of lack of particularity, Roche cross-moved for leave to amend its answer on December 8, 2006. After further proceedings, Roche ultimately filed an amended answer and counterclaims on March 30, 2007, adding further allegations of inequitable conduct.

Roche had ample opportunity to disclose its allegations of inequitable conduct within the discovery period. Indeed, Roche first responded to Amgen's interrogatories seeking the bases for Roche's claims of inequitable conduct on March 14, 2007. Then, on April 2, 2007, the last day of fact discovery, it filed a supplemental response adding numerous new allegations of inequitable conduct.

This conduct on Roche's part of asserting multiple new claims at the very end of the discovery process was bad enough. But then, on May 1, 2007, fully one month after the close of fact discovery, Roche served yet another supplemental response to Amgen's interrogatories

regarding inequitable conduct, adding additional brand new charges of inequitable conduct.

Roche now seeks to amend its answer to add the allegations of inequitable conduct set forth in its interrogatory responses, including the allegations made for the first time more than a month after the close of fact discovery. Having to address such new allegations asserted so late in the process is plainly prejudicial to Amgen, and Amgen opposes Roche's motion to the extent it includes such post-discovery allegations.

As discussed below, information concerning the vast majority of the new, post-discovery allegations of inequitable conduct has been in Roche's hands for months, if not years. Roche's proposed amendment reflects a tactic of back-end loading the inequitable conduct claims, thus preventing full discovery as to them and requiring Amgen to address them, including by way of supplemental expert reports and depositions, during the period reserved for other activities, including preparing and responding to dispositive motions.

Roche's motion to amend its answer at this late date, in order to add inequitable conduct allegations that never surfaced prior to the close of fact discovery, should be denied.

II. ARGUMENT

A. ROCHE'S SEEKS TO AMEND ITS ANSWER TO ADD ALLEGATIONS NOT DISCLOSED BEFORE THE END OF FACT DISCOVERY

Roche's proposed amended answer includes seven inequitable conduct allegations that were never raised until Roche submitted its May 1 Second Supplemental Response to Interrogatory No. 26, after the close of fact discovery.¹ In addition, Roche's proposed amendment seeks to add at least one new claim of inequitable conduct that has *never* before been raised by Roche in any context until now. Specifically, in its proposed amendment, Roche

¹ See Declaration of Mario Moore in Support of Plaintiff Amgen Inc.'s Opposition to Roche's Motion for Leave to Amend Its Answer (hereafter "Moore Decl.," Exh. 1 (5/1/07 Defendant's Second Supplemental Responses and Objections to Amgen Inc.'s Third Set of Interrogatories to Defendants (No. 26), pp. 4-90)).

alleges what it calls “Inventive Contribution Regarding Use of Probes,”² a claim never before made.

Appendix A to this opposition contains a list of Roche’s new post-discovery allegations, the list of documents cited by Roche in support of those allegations, and when those documents were produced to Roche.

As a result, Roche has now submitted eight new claims of inequitable conduct against Amgen since the end of fact discovery yet, as discussed below, it provides no legitimate reason for its unreasonable and prejudicial delay.

B. ROCHE OFFERS NO JUSTIFICATION FOR ITS DELAY IN ASSERTING THE POST-DISCOVERY CLAIMS OF INEQUITABLE CONDUCT

Roche argues that the delay in its current proposed amendment is due to Amgen producing important information late in the discovery period.³ But Roche fails to cite any particular, late-discovered facts that could not have been added to earlier pleadings or discovery responses.

To the contrary, Roche’s new, post-discovery allegations are primarily based on information that it has had for months – and in some instances, years - prior to the close of discovery.⁴ The documents cited in Roche’s May 1 Supplemental Expert Report of Sofocleous and the May 1 Supplemental Interrogatory Response consist of the file histories of the Lin patents, publicly available prior art, deposition testimony from 1997 and early March 2007, and documents produced to Roche in the ITC litigation in June of 2006.⁵ Roche has had this material

² Docket No. 445, Exh. A (5/23/07 Defendants’ Proposed Second Amended Answer and Counterclaims to Plaintiff’s Complaint, ¶ 189).

³ Docket No. 446 (5/23/07 Roche’s Memorandum in Support of Motion for Leave to Amend Its Answer to Amplify Allegations of Amgen’s Inequitable Conduct and to Define Relevant Markets for Purposes of Antitrust Counterclaims, pg. 8).

⁴ See Appendix A, showing that the documents relied upon by Roche in support of its new, post-discovery allegations were, with two exceptions, all produced to Roche in 2006.

⁵ Moore Decl., Exh. 2 (5/1/07 Supplemental Expert Report of Michael Sofocleous, ¶¶ 6-40).

since well before the close of discovery; none of it was produced belatedly by Amgen. In addition, Roche has studied the Lin patents and file histories and prior litigation files since at least 1999. In fact, its privilege log demonstrates many instances in which Roche prepared work product in anticipation of litigation brought by Amgen as far back as seven years ago.⁶ Roche offers no reason why its post-discovery allegations of inequitable conduct could not have been disclosed, and included in pleadings, long before the end of discovery.

Roche, in its proposed amended pleading, cites two facts that it says were revealed late in the discovery process: a citation to the Deposition of Lin, which occurred on March 27, 2007;⁷ and the other a citation to a letter dated March 27, 2007.⁸ But Roche uses those two items to justify the late disclosure of a number of inequitable conduct-related allegations that are not based on either of the referenced items. Notably, in its May 1 interrogatory responses, submitted 33 days after the March 27 deposition and letter, Roche failed to include reference to either the

⁶ Moore Decl., Exh. 3 (Defendants' Privilege Log - Volume 9, April 17, 2007, p. 28, RB00325058-RB00325063, 07/28/1999 Confidential memo reflecting legal advice re: CERA patent issues. AC; WP); Moore Decl., Exh. 3 (Roche's Defendants' Privilege Log - Volume 9, April 17, 2007, p. 67, RB00326390-RB00326391, 08/16/1999 Confidential letter reflecting legal advice re: CERA patent issues. AC; WP; from Leora B. Ami to George W. Johnston); Moore Decl., Exh. 3 (Roche's Defendants' Privilege Log - Volume 9, April 17, 2007, p. 238, RB00598354-RB00598356, 06/14/2000 Confidential communication reflecting legal advice of counsel re: CERA patent litigation, AC, WP, from Leora Ben-Ami*, Pat Carson* to George Johnston*); Moore Decl., Exh. 4 (Defendants' Privilege Log - Volume 5, April 2, 2007, p. 3527, RNE07535143-201, 10/20/2000 Draft document reflecting legal advice re: CERA patent litigation. AC; WP); Moore Decl., Exh. 4 (Defendants' Privilege Log - Volume 5, April 2, 2007, p. 160, RBED 07699009-010, 02/08/2001 Confidential meeting minutes reflecting legal advice re: Amgen patent lawsuit prepared in anticipation of litigation. AC; WP); Moore Decl., Exh. 4 (Defendants' Privilege Log - Volume 5, April 2, 2007, p. 10, RBED 07687678-718, (03/30/2001 Draft document reflecting legal advice re: CERA patent litigation prepared in anticipation of litigation. AC; WP)). Notably, Roche's more than 40,000 pages of privilege log include at least 75 entries from 1999 claiming work product and therefore contending anticipation of litigation, as well over 67 such entries in 2000, and 163 such entries in 2001. *Anderson v. Sotheby's Severance Plan*, 2005 WL 2583715 (S.D.N.Y. 2005) (if a party asserts work product as of a given date, then, by definition, the party anticipated litigation as of that date). *See also* Moore Decl., Exh. 5 (Letter from M. Pomerantz to M. Moore dated April 27, 2007 (noting that Roche anticipated litigation at least as early as 2001)).

⁷ Docket No. 445, Exh. A (5/23/07 Defendants' Proposed Second Amended Answer and Counterclaims to Plaintiff's Complaint, ¶ 185).

⁸ Docket No. 445, Exh. A (5/23/07 Defendants' Proposed Second Amended Answer and

March 27 deposition or the March 27 letter. Moreover, to the extent that Roche was relying on information learned on March 27 in support of new claims of inequitable conduct, those new claims could have been disclosed in its April 2 interrogatory response. There was no need, other than tactical, to wait until nearly a month after the close of discovery.⁹

Roche's argument regarding late discovery is an excuse that it raises to justify advancing more and more new allegations of inequitable conduct that Amgen has to deal with as it prepares for trial. That tactic should not be allowed.

C. AMGEN IS PREJUDICED BY ROCHE'S UNDUE DELAY

Roche's contention that its proposed amended answer and counterclaims are not the product of undue delay cannot be credited. In *Stepanishcen v. Merchants Despatch Transp. Corp.*, 722 F.2d 922, 933 (1st Cir. 1983) the First Circuit said that "Where, as here, considerable time has elapsed between the filing of the complaint and the motion to amend, the movant has the burden of showing some valid reason for his neglect and delay."¹⁰ Roche has not and cannot provide any legitimate reason for its late disclosure of allegations of inequitable conduct and its late proposed amended pleading. That delay, along with the prejudice to Amgen, warrants denial of Roche's motion for leave to amend, at least to the extent that it includes allegations of inequitable conduct that were not revealed until after the April 2 close of fact discovery.

The District Court for the District of Massachusetts, in *Espinosa v. Sisters of Providence*

Counterclaims to Plaintiff's Complaint, ¶ 115).

⁹ Roche's claims that its new inequitable conduct allegation regarding use of probes was only discovered when it read expert testimony in the current case that it claims is inconsistent with positions taken by Amgen before the PTO in 1983. See Docket No. 445, Exh. A (5/23/07 Defendants' Proposed Second Amended Answer and Counterclaims to Plaintiff's Complaint, ¶ 189). Since the inequitable conduct issue would be whether individuals intentionally deceived the patent office during prosecution in 1983, citing evidence of a 2007 deposition of an expert not involved in the prosecution does not warrant Roche's belated assertion of such a claim.

¹⁰ *Stepanischen v. Merchants Despatch Transp. Corp.*, 722 F.2d 922, 933 (1st Cir. 1983) (internal citations omitted).

Health Sys.,¹¹ in addressing a motion to amend the pleadings, stated “it is well established that such a motion should be made as soon as the necessity for altering the pleading becomes apparent.”¹² That was not done here.

The prejudice to Amgen from Roche’s undue delay in disclosing allegations of inequitable conduct is significant. Since the allegations at issue were all revealed after the close of fact discovery, Amgen had no opportunity to conduct discovery as to them, particularly in order to ascertain all the facts, circumstances, and rationales that Roche claims support the allegations. In addition, the delayed disclosure of such allegations in its May 1 interrogatory answers and its unauthorized May 1 expert report has required Amgen to prepare its own supplemental expert report to respond to the new issues, and to conduct and defend the resulting depositions.

In *Espinosa* the Court noted that, though the trial was not imminent, “there is little doubt that the proposed amendment would require Plaintiffs to undertake further discovery with respect to a defense the existence of which was not even hinted at in prior proceedings.”¹³ Roche’s untimely motion constitutes undue delay, and prejudices Amgen by requiring Amgen to address these new allegations without the benefit of complete discovery and during the period that it is fully engaged in preparing and responding to dispositive motions and otherwise preparing for trial.

¹¹ *Espinosa v. Sisters of Providence Health Sys.*, 227 F.R.D. 24, (Mass. 2005)

¹² *Id.* at 27.

¹³ *Id.*

III. CONCLUSION

For the foregoing reasons, Amgen requests that the Roche's motion to amend its answer be denied to the extent that it seeks to add allegations of inequitable conduct that were not disclosed by Roche prior to the close of fact discovery on April 2, 2007.

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 and paper copies will be sent to those indicated as non-registered participants.

/s/ Patricia R. Rich

Patricia R. Rich