

**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 BENCH MEMORANDUM REGARDING INADMISSIBILITY OF
DOCUMENTS RELEVANT ONLY TO ALLEGATIONS OF INEQUITABLE CONDUCT
THAT WERE NOT PLED BY ROCHE**

On Sunday September 9, 2007, Roche informed Amgen that it intends to use two documents in the current validity phase of trial: exhibits for identification OYF and PUY.

Both documents relate to one of Roche’s inequitable conduct allegations that was not pled and is thus out of the case. Specifically, both documents relate to Roche’s contention, first raised in its proposed Second Amended Answer lodged on May 23, 2007, that Amgen, during prosecution of the patents-in-suit, failed to disclose to the Patent Office prior art describing the use of human serum albumin (HSA) or bovine serum albumin (BSA) in combination with erythropoietin for therapeutic use.¹ Roche’s unpled contention concerns ‘422 Claim 2, which is not asserted in this case. In fact, both exhibits OYF and PUY are specifically referenced in

¹ Docket No. 445, Roche’s Motion for Leave to Amend its Answer to Amplify Allegations of Inequitable Conduct, attaching Proposed Second Amended Answer, paragraphs 148 through 172.

Roche's May 23, 2007 proposed Second Amended Answer.²

Twice, Roche belatedly sought to amend its pleadings to add these allegations,³ and twice this Court denied Roche's attempts.⁴ The last of these denials occurred on July 18, 2007.

Notwithstanding these orders, Roche persists in attempting to introduce evidence of its unpled allegations. Roche should be barred from seeking to argue or present evidence of allegations of inequitable conduct that were never previously pled, and for which leave to amend has twice been denied. Rule 9(b) of the Federal Rules of Civil Procedure requires that allegations of inequitable conduct be pled with particularity. This means that "[A]t a minimum, Rule 9(b) requires allegations of the particulars of who, what, when, where, and how of the alleged fraud."⁵ The assertion of unpled allegations in support of inequitable conduct claims violates Rule 9 (b) and should not be permitted.⁶

For the same reason, documents, including exhibits OYF and PUY, that would be relevant only in support of unpled allegations of inequitable conduct, are not admissible. Nor

² Docket No. 445, Roche's Motion for Leave to Amend its Answer to Amplify Allegations of Inequitable Conduct, attaching Proposed Second Amended Answer, paragraph 151 (referencing exhibit PUY) and paragraph 153 (referencing exhibit OYF).

³ See Docket No. 445 (Roche's Motion for Leave to Amend its Answer to Amplify Allegations of Inequitable Conduct); Docket No. 631 (Roche's Motion for Leave to Amend its Pleadings to Conform With the Evidence).

⁴ See 6/7/07 Court Order Denying Motion to Amend Its [Roche's] Answer To Amplify Allegations Of Amgen's Inequitable Conduct And To Define Relevant Markets For Purposes Of Antitrust Counterclaims; 7/18/07 Court Order No. 91.

⁵ *Computer Acceleration Corp. v. Microsoft Corp.*, 481 F. Supp. 2d 620, 627 (E.D. Tex. 2007) (internal citations omitted).

⁶ Inequitable conduct must be pled with particularity as required by Federal Rule of Civil Procedure 9(b). See *Cent. Admixture Pharm. Servs. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1356 (Fed. Cir. 2007). A claim of inequitable conduct is not particularly pled if it "failed to identify with particularity facts showing that the alleged omissions were material or that [applicant's] omission was done with intent to deceive." *Reid-Ashman Mfg. v. Swanson Semiconductor Serv., L.L.C.*, 2007 U.S. Dist. LEXIS 37665, at *19 (N.D. Cal. 2007). Nor can discovery responses be used to cure deficient pleadings or to add new claims entirely. *Goss International Americas, Inc. v. MAN Roland, Inc.*, 2006 U.S. Dist. LEXIS 36386, at 14-17 (D.N.H. June 6, 2006); see also *Nichols Motorcycle Supply, Inc. v. Dunlop tire Corp.*, 1994 U.S. Dist. LEXIS 3790, 2-3 (1994).

can Roche contend that exhibits OYF and PUY are somehow relevant to their invalidity allegations. The allegations regarding HSA and BSA pertain to Roche's theory of inequitable conduct concerning Claim 2 of the '422 patent, which is not one of the claims that Amgen asserts in this action.

Dated: September 11, 2007

AMGEN INC.,
By its attorneys,

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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 on-registered participants.

/s/Michael R. Gottfried

Michael R. Gottfried