

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

AMGEN INC.,)	
)	
Plaintiff,)	
v.)	Civil Action No.: 05 Civ. 12237 WGY
)	
F. HOFFMANN-LA ROCHE LTD, ROCHE)	
DIAGNOSTICS GmbH, and HOFFMANN-)	
LA ROCHE INC.,)	
Defendants.)	
)	
)	

**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 COUNTER CLAIMS**

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May 23, 2007

I. INTRODUCTION

In 51 paragraphs of its first amended answer, Roche alleged many facts in support of its affirmative defense that Amgen acted inequitably in prosecuting the asserted patents. Significant additional facts emerged in discovery including issues raised in Amgen's expert reports, and Roche included those facts and theories in its supplemented interrogatory responses and other discovery. In addition, Roche addressed those facts and theories in its own expert reports. Amgen filed a motion complaining that those allegations in Roche's discovery responses and expert reports were not as fully detailed in the then-existing Roche pleading (D.I. 385). Amgen has since withdrawn that motion and the Court has terminated Amgen's motion. (Docket, May 1, 2007).

To address Amgen's administrative objection, as expert discovery is still ongoing, Roche respectfully seeks leave to amend its answer to further satisfy its Rule 9(b) duty to plead inequitable conduct with particularity. Amgen has already submitted no less than two separate patent law experts' reports amounting to almost 300 pages addressing these issues. Roche's proposed Second Amended Answer appears as Exhibit A, in which the amended material is redlined. Roche seeks to more fully develop its contentions regarding Amgen's intentional misrepresentations and omissions before the Patent Office.

Abundant case law supports the amendment of pleadings where, as here, deposition testimony, expert reports and other discovery lend fresh support to the kind of averment—fraud, inequitable conduct, etc.—which Rule 9(b) requires be stated with particularity. Amendment will work no prejudice to Amgen for at least two reasons. First, Roche disclosed to Amgen in stark detail during discovery and expert reports the theories and facts that it proposes to add to its amended answer and seeks only to support its inequitable conduct defense with greater

particularity. No less significant, the facts underlying the proposed amendment are drawn from Amgen's own records and are based on Amgen's own acts and omissions. As a result, the amendment will necessitate no further fact discovery.

In addition, Roche seeks leave to make very limited clarifying amendments to its antitrust counterclaims to: 1) conform to the evidence those pleadings regarding the market for Erythropoiesis Stimulating Agent ("ESA") drugs sold for use by patients with chronic kidney disease not on dialysis (the "CKD ESA" market), 2) plead, in the alternative, an all-ESA market in which Amgen possesses monopoly power, and 3) define the market for white blood cell stimulators (the WBC Stimulator Market) and to plead Amgen's power in that market. These amendments reflect facts fully explored in discovery and in expert reports, and do not prejudice Amgen in any way.

Incidentally, Roche also seeks leave to amend its Walker Process antitrust counterclaims to rely on the additional inequitable conduct allegations described above as further evidence that the patents-in-suit were procured through fraud on the patent office.

II. RELEVANT BACKGROUND

Roche's articulation of its bases for inequitable conduct has been developed through evidence learned in discovery and set forth in appropriate disclosures to Amgen.. On November 6, 2006, Roche answered Amgen's amended complaint by denying infringement of the patents-in-suit and asserting affirmative defenses based upon the invalidity and unenforceability of those patents, including the defense of inequitable conduct. Soon thereafter, Amgen moved to strike several of Roche's affirmative defenses. Amgen argued that Roche's inequitable conduct defense, for one, was defective for lack of particularity.

While opposing Amgen's motion to strike, Roche cross-moved on December 8, 2006 for leave to amend its answer and attached its proposed first amended answer to its filing. That pleading profusely expanded the factual allegations supporting Roche's inequitable conduct defense. On December 20, the Court denied in part Amgen's motion to strike, enabling Roche to maintain, among others, the defense of inequitable conduct. On January 19, Roche filed a free-standing motion for leave to amend its pleading and attached its proposed first amended answer to that motion as well.

On March 14, 2007, Roche responded to Amgen's Interrogatory No. 26 relating to inequitable conduct with a 52-page answer providing extensive detail regarding Amgen's material misrepresentations and omissions before the Patent Office committed with the intent to deceive the Patent Office and procure issuance of the asserted patents. On March 30, soon after the Court granted Roche leave to amend its answer, Roche formally filed its pleading, setting forth additional defenses and, as noted, supplementing its existing inequitable conduct defense. On April 2, although it was still gathering relevant information in discovery,¹ Roche further elaborated on its inequitable conduct contentions in a 70-page supplemental response to Interrogatory No. 26.

In the waning days of the fact discovery period, Roche gathered many of the facts underlying the inequitable conduct allegations that it seeks to include in a further amended pleading. This circumstance resulted largely from Amgen's withholding key fact witnesses until the last week of depositions. These included the named inventor, Dr. Lin, contributing scientists

¹ On April 2, the last day of fact discovery, Roche took the deposition of Amgen prosecuting attorney Steven Odre.

Joan Egrie, Thomas Boone, Daniel Vapnek and Graham Molineaux, as well as prosecuting attorneys Stuart Watt and Steven Odre.²

Notwithstanding this chronology, Roche's expert Michael Sofocleous offered his opinion, supporting Roche's case for inequitable conduct, in a report dated April 6, 2007—just four days after the close of fact discovery. His report relies on previously known facts, as well as those uncovered in discovery, including at the depositions held in the final days of discovery. Following the submission of opening expert reports, Amgen filed a motion to strike on the basis that the allegations in Mr. Sofocleous's report and Roche's interrogatory responses were not sufficiently pled. Amgen then withdrew the motion and it was terminated by the Court when the parties agreed to additional time to exchange expert reports. Amgen's technical complaint was only that not all the theories and facts set forth in Roche's discovery responses and expert reports were as detailed in Roche's pleading. To ameliorate that concern, Roche respectfully files this motion.

Amgen has addressed Roche's inequitable conduct allegations in at least two written expert reports from patent attorneys, totaling almost 300 pages. Mr. Sofocleous also submitted a brief supplemental report on May 1, 2007, ten days before Amgen was to submit its rebuttal expert reports. Also on May 1, 2007, Roche served on Amgen a second supplemental interrogatory response regarding inequitable conduct which addressed the same issues and facts set forth in Mr. Sofocleous's supplemental report.

The facts supporting certain inequitable conduct allegations that appear in Mr. Sofocleous's reports, and with which Roche now seeks to supplement its affirmative defense,

² It is further noted that at the April 17, 2007 hearing, the Court granted in part Roche's Motion to Compel the Production of Documents Improperly Withheld on Grounds of Privilege (Docket No. 366). Specifically, the Court held that Roche is entitled to resume the deposition of Michael Borun to question him regarding certain of Roche's inequitable conduct defenses. This deposition has yet to take place.

could therefore not have been pled earlier. Although Roche fully informed Amgen of these facts when it learned of them, *e.g.*, in its first amended answer and in expansive responses to Amgen's Interrogatory No. 26, Roche seeks to further amend its answer to include the inequitable conduct information that was developed throughout the course of discovery. Furthermore, some of the issues Roche seeks to incorporate in its amended pleading did not arise until after Roche received Amgen's expert reports on April 6 and May 11, 2007. Since expert discovery is still in progress, Amgen has ample time to test Roche's allegations, as is evident by the reports already submitted by Amgen's experts.³

Roche seeks to more fully develop its contentions regarding the following intentional misrepresentations and omissions by Amgen before the Patent Office:

- Amgen's failure to disclose critical clinical trials involving uEPO, including those of Baron-Goldwasser, and the known obviousness of its claimed pharmaceutical compositions;
- Dr. Strickland's inventive contribution to the claimed pharmaceutical compositions;
- The inventive contribution of individuals other than Dr. Lin and the novelty of sequencing human EPO fragments, the use of probes, and the selection of CHO cells;
- Differences in apparent molecular weight between r-EPO and u-EPO, and specifically r-EPO expressed in COS cells as compared to u-EPO;
- The standard used in radioimmunoassay for testing its rEPO;
- Amgen's work with the 1411 cell line as a source of mRNA;
- Amgen's attempts to overcome double patenting rejections based on U.S. Patent. No. 4,667,016 (Lai *et al.*);

³ Roche took several fact depositions surrounding its allegations of inequitable conduct, including Mr. Borun, Mr. Watt, Mr. Odre, Dr. Lin, Dr. Egrie and others associated with the prosecution of the patents-in-suit. Amgen resisted this discovery, as evidenced by the motions to compel Roche was forced to make.

- Prior art regarding recombinant processes and purported “PEG-EPO” prior art.

Significantly, Roche’s inequitable conduct defense is based upon Amgen’s own acts and omissions during the prosecution of its patents and on documents and information taken from Amgen’s own records and witnesses.

III. ARGUMENT

A. Since Roche Seeks to Amplify an Affirmative Defense (Inequitable Conduct) that Requires Particularity, Leave to Amend Should be Granted

This Court has already found Roche’s pleadings to be adequately pled. In pleading inequitable conduct, Rule 9(b) is satisfied by the “specification of the time, place, and content of an alleged false representation.” *Davidson v. Cao*, 211 F. Supp. 2d 264, 286 (D. Mass. 2002) (Bowler, M.J.). Roche has consistently aimed to satisfy these requirements throughout this litigation, stating in its initial answer, and elaborating in its first amended answer, the who, what, when, where and how of Amgen’s inequitable conduct. In the interest of providing the Court, and Amgen, with a more detailed pleading and to maximize compliance with Rule 9(b), Roche requests leave to amend its answer further to incorporate the facts that were developed during discovery and earlier disclosed in its interrogatory responses and expert reports.⁴

“The clearest cases for leave to amend are correction of an insufficient claim or defense and *amplification of previously alleged claims and defenses.*” *Strachan v. Ashe*, 548 F. Supp. 1193, 1205 (D. Mass. 1982) (Freedman, J.) (emphasis added) (quoting 3 Moore’s Fed. Practice ¶ 15.08(3) at 15-55). Even where initial pleadings lack the requisite factual specificity for a particular cause of action, which is not the case here, courts routinely allow amendment. *See*

⁴ The main purpose of Rule 9(b) is to give adversaries notice of the allegations brought against them. *See, e.g., In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig.*, 433 F. Supp. 2d 172, 185 (D. Mass. 2006) (Saris, J.); *New England Data Servs., Inc. v. Becher*, 829 F.2d 286, 289 (1st Cir. 1987). Amgen has already received ample notice of the particulars of these allegations, and Roche seeks to amend its answer to further advance the rule’s purpose.

Boston Int'l Music, Inc. v. Austin, 2003 WL 22119228, *2 (D. Mass. Sept. 12, 2003) (O'Toole, J.) (granting leave to amend complaint to allege facts sufficient to demonstrate standing to assert copyright infringement claim); *MacNeill Eng'g Co., Inc. v. Trisport, Ltd.*, 73 F. Supp. 2d 73, 74 (D. Mass. 1991) (Young, J.) (granting leave to amend complaint where amendment provided factual allegations in support of contributory patent infringement claim).⁵

Applying similar considerations to a motion, parallel to Roche's, for leave to amend in order to expand upon an inequitable conduct pleading, one court has held: "Learning of a factual basis for a defense after the pleading stage and during discovery provides a perfectly permissible reason" for granting leave to amend. *ResQNET.Com, Inc. v. Lansa, Inc.*, 382 F. Supp. 2d 424, 450 (S.D.N.Y. 2005) (allowing amendment of inequitable conduct pleading almost three years after original pleading when it appeared that "expert reports and testimony rendered yielded details relevant to the proposed counterclaim, including the expert's opinion as to the materiality of certain purportedly prior art references to the claims").

Another court has ruled, similarly, that "[a]llegations of inequitable conduct are serious and we cannot fault [an infringement defendant] for waiting for further evidence before filing such an affirmative defense." *Douglas Press, Inc. v. Tabco Inc.*, 2004 U.S. Dist. LEXIS 8921, *3-4 (N.D. Ill. May 17, 2004). The court allowed the amendment where defendant had never previously pled inequitable conduct, even though it possessed some earlier knowledge of facts that supported the defense. *Id.* In this litigation, by contrast, Roche duly pled as many facts as it

⁵ See similarly *Lunkenheimer Co. v. Fed. Depos. Ins. Corp.*, 1993 WL 207750, *6 n.4 (D. Mass. June 3, 1993) (Zobel, J.) (granting leave to amend complaint to plead factual allegations supporting claim despite fact that original claim only provided a broad outline of the claim); *Wilkes v. Heritage Barcorp. Inc.*, 767 F. Supp. 1166, 1176 (D. Mass. 1991) (Freedman, J.) (adopting magistrate's recommendation that claimant have opportunity to particularize by amendment the fraudulence of statements allegedly violating federal securities law).

had when it filed its answer and first amended answer. Roche seeks merely to conform its pleading to subsequently discovered facts.

B. Amgen Cannot Show Any of the Factors That Might Discourage the Allowance of Roche's Amendment

Leave to amend pleadings “shall be freely given when justice so requires.” Fed. R. Civ. P. 15(a). Accordingly, a motion to amend must be granted “unless there appears to be an adequate reason for the denial, such as undue delay, bad faith, dilatory motive on the part of the movant, or futility of the amendment.” *Carmona v. Toledo*, 215 F.3d 124, 136 (1st Cir. 2000) (reversing a trial court’s denial of leave to amend); *similarly, Gonzalez-Perez v. Hosp. Interamericano de Medicina Avanzada*, 355 F.3d 1, 5-6 (1st Cir. 2004) (adding “undue prejudice” to the above factors). The rule’s default in favor of granting leave burdens Amgen with establishing one or more of the above grounds for denial, none of which is apparent here.

1. Roche Seeks to Amend in Good Faith and Without Undue Delay

Roche raised the defense of inequitable conduct in both its answer and its first amended answer, each time mustering the facts then available to it. The purpose of the proposed amendment is to continue Roche’s adherence to Rule 9(b)’s requirement of pleading fraud-related averments with particularity. The added allegations are of course also meant to bolster Roche’s defenses. The good faith of Roche’s request cannot fairly be impugned.

Having assembled additional supporting facts right through the end of the fact discovery period, Roche promptly seeks to amend. The proposed amendment contains, for example, facts that were gathered from deposing the several witnesses whom Amgen produced only in the last week of fact discovery. Roche has informed Amgen—through initial and supplemental

interrogatory responses, and expert reports—of the relevant information as soon as Roche developed it.⁶ This motion is likewise brought without undue delay.

2. Roche’s Proposed Amendment is Not Futile

As this Court has held, in weighing a motion to amend, “the court must first consider whether the proposed new claims are futile, that is, whether they would be subject to dismissal for failure to state a claim.” *MacNeill*, 59 F. Supp. 2d at 201 (cite omitted); *Glassman v. Computervision Corp.*, 90 F.3d 617, 623 (1st Cir. 1996) (“In reviewing for ‘futility,’ the district court applies the same standard of legal sufficiency as applies to a Rule 12(b)(6) motion”).

Roche, of course, proposes not to assert a new claim but to bolster an existing affirmative defense with new factual allegations. For an affirmative defense, the equivalent to Rule 12(b)(6) is Rule 12(f), which allows a party to move to strike a defense as insufficient. “In the case of an amendment to add a new defense, futility ought technically turn on the proposed defense’s legal sufficiency and whether it is subject to a motion to strike under Fed.R.Civ.P. 12(f).” *Credit Suisse First Boston, LLC v. Intershop Communications AG*, 407 F. Supp. 2d 541, 546 (S.D.N.Y. 2006) (adding that “the standard by which 12(f) and 12(b)(6) motions are evaluated are ‘mirror images’”) (cites omitted).

Here, the Court need not long ponder the sufficiency of Roche’s inequitable conduct defense, because the Court has already done so. Amgen moved in November 2006 to strike several of Roche’s affirmative defenses, targeting the one asserting inequitable conduct for lack of particularity. In its opposition, Roche explained why its proposed first amendment was not

⁶ The only allegation not explicitly disclosed by Roche in interrogatory responses and expert reports to date—the inventive contribution of individuals other than Dr. Lin regarding the use of tryptic fragments—could not have been made prior to Roche receiving Amgen’s recent rebuttal reports on May 11, 2007. Amgen’s expert Dr. Orkin argues in his report that the selection and use of tryptic fragments was not obvious. Amgen had previously maintained during prosecution and related interference proceedings that the work of its scientist Por Lai regarding tryptic fragments was routine. Thus, Roche was only put on notice of this contradiction on May 11 and timely includes this point as a basis for inequitable conduct in its attached proposed amended pleading.

futile and, especially regarding the inequitable conduct defense, represented a “textbook case of pleading with particularity.” Docket No. 161 at 11-14.

The Court evidently agreed with Roche, since it denied, at the December 20, 2006 hearing, Amgen’s motion to strike as it related, *inter alia*, to this defense. The Court subsequently allowed Roche’s (first) motion for leave to amend its answer, whereupon Roche amended its inequitable conduct defense by adding numerous new factual allegations gleaned during discovery.

Since the Court implicitly held that the initial amendment of the inequitable conduct defense was not futile, it follows that the present one--which seeks merely to amplify that defense with allegations based on later-acquired and developed facts--is likewise not futile.

3. No Undue Prejudice Would Result from the Sought Amendment

“Absent a showing of futility, leave should only be denied if the amendment would be overly prejudicial.” *MacNeill*, 59 F.Supp.2d at 201. Given that Roche’s allegations were disclosed during discovery, and before Amgen’s experts reports, and long before Roche’s experts are to be deposed, Amgen cannot claim unfair surprise or prejudice. *See In re Mercedes-Benz*, 2006 WL 2129100, *5-6 (D.N.J. July 26, 2006) (denying motion *in limine* to exclude consideration of particularized allegations in summary judgment because no prejudice where non-moving party relied on facts well-known to the movant and where defensive theory was generally articulated in interrogatory responses); *Wilson v. Sundstrand Corp.*, 2003 WL 259139, *6 (N.D. Ill. Feb. 3, 2003) (finding no prejudice in allowing motion to amend complaint where plaintiffs were essentially conforming their complaint to expert’s report, and defendants accordingly had notice); *Enzo Life Sciences v. Digense Corp.*, 270 F. Supp. 2d 484, 486-88 (D.

Del. 2003) (finding no prejudice to plaintiff in permitting alleged infringer to amend its answer after a deposition adduced support for an unenforceability defense).

The sought amendment causes Amgen no prejudice, as the information underlying Roche's inequitable conduct defenses is derived from Amgen's own prosecution of its patents and information previously known to Amgen. *See Rhone-Poulenc Agro S.A. v. Monsanto Co.*, 73 F. Supp. 2d 537, 539 (M.D.N.C. 1999) (finding that a patentee is not prejudiced by amendment where an "inequitable conduct defense is based entirely upon [its own] acts and omissions ... during the prosecution of its patents and [defendant] has provided [patentee] with a detailed analysis of the technical facts underlying its inequitable conduct defense."); *see also Frank M. McDermott, Ltd. v. Moretz*, 898 F.2d 418, 421 (4th Cir.1990) (amendment granted where "the claim of fraud as a defense was based entirely on documents taken from plaintiff's own records, and no additional discovery would have been necessary, nor would additional third-party witnesses have been required to testify on the issue"). As Amgen will suffer no prejudice from Roche's amplifying its inequitable conduct defense with additional facts, Roche should be allowed to amend.

Roche should not be penalized for acquiring, when it did, facts relevant to its proposed amendment. A party "determin[ing] an additional basis for its invalidity and unenforceability arguments at the very end of the fact discovery process does not tender it in violation of the applicable discovery rules." *Cytoc Corp. v. TriPath Imaging, Inc.*, 2005 WL 1527883, *4 (D. Mass. June 21, 2005) (Woodlock, J.). The court in *Cytoc* held that "wholesale exclusion of the defense" would be a "draconian remedy unwarranted in these circumstances [of belatedly uncovering an additional basis for an invalidity defense]." *Id.* Similarly, Roche should be

allowed to add allegations that it developed in the late stages of discovery, especially where this resulted largely from Amgen's belated production of relevant witnesses.

C. Roche Should Be Permitted to Make Limited Clarifying Amendments to Its Antitrust Counterclaims

Roche seeks to make three modest amendments regarding relevant markets, which would conform the antitrust counterclaims to the evidence and expert reports. In the first such amendment, Roche proposes to clarify that its definition of the CKD ESA market can alternatively be termed the non-End Stage Renal Disease ESA market (the "non-ESRD Market"). Roche has set forth in numerous court filings and letters that the CKD ESA market can be so designated. Underscoring the absence of any prejudice from this amendment, Amgen's own antitrust expert agrees that under conventional antitrust analysis the two relevant markets for the sale of ESAs are the ESRD and non-ESRD markets (*See* Expert Report of David J. Teece, Ph.D, dated May 11, 2007 ("Teece Report"), ¶70).

Roche seeks also to plead, in the alternative, an "all-ESA" market in which Amgen possesses monopoly power. Roche long ago put Amgen on notice that it was considering an amendment to more formally define this relevant market. (Roche's Memorandum in Opposition to Amgen's Motion to Dismiss Roche's Counterclaim Counts I-IX and XII, dated December 8, 2006, Docket No. 162, at p. 14, n. 15). One of Amgen's experts analyzes this market, so no surprise or prejudice will result from this conforming amendment. Teece Report ¶60.

Roche's amendment regarding the WBC Stimulator market is similarly formal in nature. In its original pleading, Roche alleged that Amgen used its monopoly power over drugs it sells in the WBC Stimulator market to further its antitrust violations in the two relevant ESA markets. In the proposed amendment, Roche simply defines the WBC Stimulator market. Again, Amgen's expert generally agrees with Roche's definition of the WBC Stimulator market and

agrees that Amgen has monopoly power within it. *See Teece Report* ¶¶58, 72, 90. Amgen is not prejudiced in any way.⁷

IV. CONCLUSION

Based on the foregoing reasons and authorities, Roche requests that the Court grant it leave to amend its pleadings to add allegations of inequitable conduct and make limited clarifying amendments to the antitrust counterclaims.

Dated: May 23, 2007
Boston, Massachusetts

Respectfully submitted,

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⁷ Roche seeks also leave to amend its Walker Process antitrust counterclaims to reflect their reliance on all of Roche's inequitable conduct allegations, including those described above as evidence of Amgen's fraud on the patent office. This amendment merely incorporates the inequitable conduct allegations and for the same reasons described above will not prejudice Amgen.

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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
Keith E. Toms

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