

**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 OPPOSITION TO AMGEN’S MOTION TO
STRIKE ROCHE’S AFFIRMATIVE DEFENSES NOS. 2, 7, 8, 10 AND 12 AND IN
SUPPORT OF ROCHE’S MOTION FOR LEAVE TO AMEND ITS
ANSWER AND COUNTERCLAIMS**

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Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively “Roche”) submit this memorandum in opposition to the motion of Amgen Inc. (“Amgen”) to strike Roche’s 2nd, 7th, 8th, 10th, and 12th affirmative defenses, and in support of Roche’s motion for leave to amend its Answer and Counterclaims. For the reasons discussed below, Amgen’s motion to strike should be denied and Roche’s motion for leave to amend its pleading should be granted.

I. INTRODUCTION

Motions to strike under Rule 12(f) are generally disfavored by federal courts. They should only be granted when there is no doubt that the defendant cannot prevail on the defense in question. Indeed, even when technically appropriate and well founded, motions to strike are routinely denied in the absence of prejudice to the moving party. As discussed below, Amgen cannot satisfy these strict requirements of Rule 12(f) as its motion serves only to harass Roche and interfere with its defense of this action. Accordingly, Amgen’s motion should be denied.

Amgen’s motion is based almost entirely on its contention that Roche’s patent misuse, inequitable conduct and unclean hands defenses do not comply with the particularity requirement of Fed. R. Civ. P. 9(b). To read Amgen’s brief, however, one would think that Roche must *prove* that Amgen committed inequitable conduct in its Answer and Counterclaims. That is not the law. Rule 9(b) places no such burden on a defendant to come forward with evidence before discovery has even begun. Roche need only set out the time, place and content of the alleged misrepresentation or omission that forms the basis for its allegations of inequitable conduct.

Roche’s Answer and Counterclaims contain the information required by Rule 9(b). For example, Roche has identified the individuals who made the alleged

misrepresentations, including the inventor of the patents-in-suit, Dr. Lin, and those involved in the prosecution of those patents. There is no question that the alleged misrepresentations were made before the PTO. In addition, Roche's counterclaims specify that Amgen's misrepresentations are directly contradicted by statements it made in connection with the *Fritsch et al. v. Lin* patent interference No. 102,334. Accordingly, Roche's counterclaims identify the time and place of Amgen's inequitable conduct.

Roche has also identified the specific content of Amgen's inequitable conduct. For example, Roche detailed Amgen's failure to inform the Patent Office that the inventions claimed by the patents-in-suit were merely obvious variations over Amgen's now expired US Patent No. 4,703,008. Amgen also made erroneous statements to the Patent Office regarding alleged differences between recombinant erythropoietin ("r-EPO") and urinary erythropoietin ("u-EPO"), including misrepresentations concerning the carbohydrate composition and molecular weights of r-EPO and u-EPO. Thus, Roche's Answer and Counterclaims give Amgen more than adequate notice of the metes and bounds of Roche's inequitable conduct defense.

Even if this Court were to grant Amgen's motion, which it should not, the appropriate remedy is not to strike those allegations but to grant Roche leave to amend. Courts normally grant the non-moving party leave to amend unless its pleading could not possibly be cured by the allegation of other facts. That is clearly not the case here. Moreover, Roche's motion for leave is timely, coming only a month after Roche filed its original pleading and within the deadline agreed to by the parties and endorsed by the Court for such motions. Thus, whether this Court grants or denies Amgen's motion, Roche's motion for leave to amend its pleading should be granted.

Roche's proposed amended pleadings will eliminate any alleged doubt in Amgen's mind concerning Roche's inequitable conduct allegations. In an effort to address Amgen's groundless complaints, Roche laid out the time, place, and content of Amgen's inequitable conduct before the Patent Office in excruciating detail. These include Amgen's intentional misrepresentations to the Patent Office in order to overcome a double patenting rejection during the prosecution of the parent application of several of the patents-in-suit, as well as Amgen's failure to raise prior office action rejections to the Patent Office in related applications during the prosecution of the patents-in-suit.

Amgen attacks the unclean hands and patent misuse defenses on the same grounds as it does Roche's inequitable conduct defense. Those criticisms are flawed for the reasons discussed above. What is more, the common law defenses of patent misuse and unclean hands relate to much broader categories of conduct that need not be pled with particularity. Consequently, Amgen's cannot possibly succeed on its motion to strike these defenses.

Amgen also moves to strike Roche's 10th Affirmative Defense, which alleges that Amgen is estopped from seeking damages. In response to a Court inquiry related to whether this action would be tried before a jury, Amgen argued to this Court that it was not seeking damages against Roche. This was an express waiver of any claim it may have had for money damages. Roche's 10th Affirmative Defense aims to hold Amgen at its word. Simply put, Amgen cannot have it both ways. Consequently, Roche's 10th Affirmative Defense should stand.

Amgen posits that Roche's 12th Affirmative Defense ("Equitable Estoppel") should be stricken because it has not been pled with particularity and on the grounds that

“there is no possible state of facts that could support” this defense. (Memorandum in support of Amgen Inc.’s Motion to Strike Roche’s Affirmative Defenses Nos. 2, 7, 8, 10, and 12 (“Amgen Br.”) at 4). There is no support for Amgen’s demand that this defense be pled with particularity. Meanwhile, Amgen’s “no possible state of facts” defense is seemingly manufactured out of whole cloth. As detailed herein, this defense is amply supported by facts. Accordingly, there is no legitimate basis to strike Roche’s 12th Affirmative Defense.

II. ARGUMENT

A. Motions To Strike Are Disfavored By Federal Courts

Motions to strike are generally disfavored by federal courts. *See United States SEC v. Nothern*, 400 F. Supp. 2d 362, 364 (D. Mass. 2005) (“Motions to strike a defense as insufficient are not favored by the federal courts because of their somewhat dilatory and often harassing character.”). They should only be granted when there is no doubt that the defendant cannot prevail on the defense in question. *See Honeywell Consumer Prods. v. Windmere Corp.*, 993 F. Supp. 22, 24 (D. Mass. 1998); *FDIC v. Gladstone*, 44 F. Supp. 2d 81, 85 (D. Mass. 1999) (plaintiff may prevail on a Rule 12(f) motion only where “it clearly appears that the plaintiff would succeed despite any state of facts which could be proved in support of defense”). Indeed, “even when technically appropriate and well-founded, Rule 12(f) motions are not granted in the absence of a showing of prejudice to the moving party.” *Nothern*, 400 F. Supp. 2d at 364 (quoting 5C Wright & Miller, FED. PRAC. & PROC. § 1381, at 421-22 (3d ed. 2004)). As discussed below, Amgen cannot satisfy these strict requirements of Rule 12(f).

**B. Roche's Answer And Counterclaims
Satisfy The Requirements of Rule 9(b)**

Rule 9(b) requires that allegations of fraud be pled with particularity. Fed. R. Civ. P. 9(b). However, malice, intent and knowledge may be averred generally. *Id.* In the First Circuit, 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).¹ The main purpose of this rule 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); *New England Data Servs., Inc. v. Becher*, 829 F.2d 286, 289 (1st Cir. 1987). As discussed below, Roche's inequitable conduct allegations satisfy both the spirit and the letter of Rule 9(b).

Roche's Answer and Counterclaims plead that Amgen committed inequitable conduct when it failed to inform the Patent Office during the prosecution of the patents-in-suit that those inventions were only obvious variations over Amgen's prior issued U.S. Patent No. 4,703,008 (“the ‘008 patent”). (*See* Answer and Counterclaims ¶¶ 39, 40). Importantly, Roche's pleading states that were it not for these intentional material misrepresentations, the patents-in-suit would not have issued, *id.*, which suffices to allege the key elements of Roche's *Walker Process* claims.² Amgen's misconduct, as Roche's

¹ Amgen's reliance on *Chiron Corp. v. Abbott Labs.*, 156 F.R.D. 219 (N.D. Cal. 1994) is misplaced. The allegations were far more general in *Chiron*. They referred generally to a declaration filed during the prosecution of the patent-in-suit. The Court found that it was unclear whether defendant alleged that prior art was concealed or that an expert opinion was deliberately misstated. Roche's inequitable conduct allegations present no similar confusion.

² This brief also addresses Amgen's motion to dismiss Count I of Roche's counterclaims pursuant to *Walker Process Equipment, Inc. v. Food Machinery and Chem. Corp.*, 382 U.S. 172 (1965), alleging that Amgen has violated the antitrust laws by seeking to enforce fraudulently obtained patents; also addressed herein is Amgen's motion to dismiss Count XII of Roche's counterclaims for a declaratory judgment of unenforceability.

pleading describes, was fueled by its recognition that it needed to maintain its monopoly over EPO products beyond the expiration of the '008 patent by prosecuting patents that it knew were obvious from double patenting over the '008 patent. (*Id.*).

Roche's Answer and Counterclaims also detail misrepresentations relating to alleged differences between r-EPO and u-EPO. Specifically, Amgen made misrepresentations during the prosecution of applications related to the patents-in-suit concerning the carbohydrate composition and molecular weights of r-EPO and u-EPO. (*Id.* ¶¶ 41, 44). Accordingly, Roche's counterclaims specify the content of the alleged misrepresentations.

The Answer and Counterclaims also specify that misrepresentations occurred during the prosecution of the patents-in-suit before the PTO in direct contravention to statements Amgen made while a party in the *Fritsch et al. v. Lin* patent interference No. 102,334. (*Id.*). The Counterclaims therefore comply with Rule 9(b)'s requirements to specify the time and place of the inequitable conduct. *See Davidson*, 211 F. Supp. 2d at 286.

Roche's Answer and Counterclaims also serve the purpose of Rule 9(b). They provide Amgen more than adequate notice of Roche's inequitable conduct allegations. Amgen is keenly aware that it has impermissibly extended its patent monopoly by obtaining multiple patents to obvious variants of a single invention. In fact, even Amgen's current CEO, Mr. Sharer, was at a loss for words when asked why the patents-in-suit have lasted so long beyond their statutorily prescribed periods. He could only answer: "It's an obvious question; I've had it myself."³ Amgen also knows that during

³ Pollack, A., "Rivals Laying Siege to Amgen's Near Monopoly in Anemia Drugs," THE NEW YORK TIMES, Dec. 23, 2005, attached as Ex. C, at 2 ("Amgen received seven patents. All

the prosecution of the patents-in-suit, it faced rejections based on the presence of u-EPO in the prior art. Amgen is also intimately familiar with the misrepresentations made by the inventor, Amgen's attorneys, and others involved in the prosecution of the patents-in-suit concerning alleged differences between r-EPO and u-EPO. Indeed, no one knows more about the prosecution of the patents-in-suit than Amgen.

In light of the foregoing, Roche's inequitable conduct defense and related counterclaims, including *Walker Process*, satisfy the requirements of Rule 9(b). It also adequately serves the purpose behind that rule. Amgen has been given adequate notice of the allegations made against it to conduct discovery and prepare a response. Roche's allegations are also specific enough to demonstrate that Roche has a reasonable basis to pursue an inequitable conduct defense in this action. Given that Roche's inequitable conduct allegations comply with Rule 9(b), Amgen's request to strike that defense under Rule 12(f) should be denied.

C. The TKT Litigation Is A Red Herring

Amgen devotes pages of its brief to an issue that is completely irrelevant to the present motion — alleged similarities between the inequitable conduct allegations made against it in this case and those litigated in the *TKT* case. (Amgen Br. at 2, 6 and 9).

Amgen contends that Roche's inequitable allegations in this case must be "materially different" from the inequitable conduct defense litigated in the *TKT* case. (*Id.* at 9).

were based on the work done in the early 1980's by one of its scientists, Fu-Kuen Lin, who isolated the human gene for erythropoietin, or EPO, the protein that makes up the drugs. While the first of these patents expired late last year, the others were not granted until the mid-to-late 1990's and could preserve Amgen's monopoly until 2015 – well beyond the 17 or 20 years contemplated in patent law for an innovation Even Kevin W. Sharer, Amgen's chief executive, when asked why EPO's patent life lasted so long, replied, "It's an obvious question; I've had it myself.").

Noticeably absent from Amgen's brief, however, is any support for this proposition.

Indeed, no such support exists.

The inequitable conduct allegations in the *TKT* case are legally irrelevant here. Roche was not a party to the *TKT* action or any other case against Amgen related to the patents-in-suit. Roche is not precluded by collateral estoppel, *res judicata* or *stare decisis* from litigating its inequitable conduct defense in this action — even if it is identical to the defense litigated in the *TKT* case. As a matter of fact, the very case Amgen cited in support of its reliance on the *TKT* decision makes this crystal clear. *See Stevenson v. Sears, Roebuck & Co.*, 713 F.2d 705, 709 (Fed. Cir. 1983) (quoting *Boutell v. Volk*, 449 F.2d 673, 678 (10th Cir. 1971)) (“it is grossly inequitable to bind a party to a judgment of *validity* rendered in an action against some other party”) (Amgen Br. at 2 n.7). Thus, Roche simply cannot be bound by a decision in the *TKT* case when it was not a party to that case.⁴

In addition to being legally irrelevant, Amgen's *TKT* argument is also baseless. Roche's pleadings contain specific allegations of inequitable conduct related to Amgen's response to double patenting rejections made by the Patent Office. These allegations have never been raised or litigated in any prior Amgen litigation. As discussed below, Roche's proposed amended pleadings also contain specific allegations related to Amgen's failure to bring critical office action rejections to the Examiner's attention in co-pending applications and declarations offered on behalf of Amgen that were not uncovered in the

⁴ Amgen is undoubtedly well aware that its reference to the *TKT* decision is nothing more than a Red Herring. That is the only reasonable explanation for its decision not to try and strike/dismiss Roche's inequitable conduct allegations on issue/claim preclusion grounds.

TKT litigation. Thus, Roche’s original and amended pleadings contain a host of allegations that are “materially different” from those in the *TKT* case.

D. Roche Should Be Granted Leave To Amend

1. Legal Standard

The proper remedy on a Rule 9(b) motion is normally to allow the non-movant to amend its pleading.⁵ “[L]eave to amend should be granted if it appears at all possible that the plaintiff can correct the defect.” *Balistreri v. Pacifica Police Dep’t*, 901 F.2d 696, 701 (9th Cir. 1988) (internal quotation marks omitted) (alteration in original); *see also Bly-Magee v. California*, 236 F.3d 1014, 1019 (9th Cir. 2001) (“leave to amend should be granted unless the district court determines that the pleading could not possibly be cured by the allegation of other facts”) (internal quotation marks omitted); *Caputo v. Pfizer, Inc.*, 267 F.3d 181, 191 (2d Cir. 2001) (“in the event that the court is inclined to dismiss on Rule 9(b) grounds, the failure to grant leave to amend is an abuse of discretion unless the plaintiff has acted in bad faith or the amendment would be futile”); *Eminence Capital v. Aspeon, Inc.*, 316 F.3d 1048 (9th Cir. 2003).

Federal Rule of Civil Procedure Rule 15 permits parties to seek leave of court to amend pleadings and specifies that “leave shall be freely given when justice so requires.” Fed. R. Civ. P. 15(a). Thus, “permission is liberally granted where there is no prejudice.”

⁵ *See, e.g., Wilkes v. Heritage Bancorp, Inc.*, 767 F. Supp. 1166 (D. Mass. 1991) (granting plaintiffs leave to amend so as to comply with 9(b)); *Driscoll v. Landmark Bank for Savings*, 758 F. Supp. 48, 54 (D. Mass. 1991) (same); *Bio-Vita, Ltd. v. Rausch*, 759 F. Supp. 33, 38 (D. Mass. 1991) (granting defendants leave to amend their counterclaim so as to comply with Rule 9(b)); *Enterprise Fin. Leasing Co. v. Westford Regency Inn, Inc.*, 1990 WL 279512 at *1 (D. Mass. Oct. 26, 1990) (same); *Palace v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 1981 WL 1411, at *2 (D. Mass. Aug. 3, 1981) (“It would be unjust to preclude plaintiff from prosecuting his claim solely because of his failure to comply with Rule 9(b).”); *New England Data Servs., Inc. v. Becher*, 829 F.2d 286, 292 (1st Cir. 1987) (plaintiff may amend its complaint to comply with Rule 9(b)); *Barry v. St. Paul Fire & Marine Ins. Co.*, 555 F.2d 3, 13 (1st Cir. 1977) (same).

Eastern Food Servs., Inc. v. Pontifical Catholic Univ. Servs. Ass'n, 357 F.3d 1, 8 (1st Cir. 2004); *see also Fed. Deposit Ins. Corp. v. Consolidated Mortg. & Fin. Corp.*, 805 F.2d 14, 16 (1st Cir. 1986) (Rule 15 “requires that motions to amend be liberally granted in the absence of undue prejudice to the opposing party”). Indeed, as the Supreme Court has held:

In the absence of any apparent or declared reason – such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc. – the leave sought should, as the rules require, be “freely given.”

Foman v. Davis, 371 U.S. 178, 182 (1962); *accord Carmona v. Toledo*, 215 F.3d 124, 136 (1st Cir. 2000) (“we will not affirm the denial [of leave to amend] unless there appears to be an adequate reason . . . such as undue delay, bad faith, dilatory motive on the part of the movant, or futility of the amendment”).

2. There Are No Reasons To Deny Roche Leave To Amend

First, there was no undue delay or dilatory motive associated with filing the amendment. Roche submitted its motion within the December 8th deadline agreed to by the parties and endorsed by the Court. (*See* D.I. #143 at 2). Moreover, Roche has never before sought leave to amend its pleading, as it was only on November 6, 2006, one month ago, that Roche first answered the Complaint. The parties are at the nascent stages of fact discovery, having only served document requests and requests to admit. No depositions have been noticed by the parties, no interrogatory responses have been served, and the end of fact discovery is still five months away.

Second, there is no bad faith by Roche or prejudice to Amgen in granting the motion for leave to amend. Roche believed at the time of filing, and still does, that its

original pleadings were sufficiently particular. However, Roche is now faced with Amgen's motion to strike and the impending deadline to amend its pleadings. Roche's motion for leave comes in direct response to Amgen's request that the pleadings provide more detail. In complying with Amgen's wishes, the proposed amendments do not prejudice Amgen, but do the very opposite, by offering more notice to Amgen of Roche's defenses at this early stage of the case.⁶

Third, the proposed amendments are not futile. They include all the requisite factors making out Roche's various defenses. In particular, they address Amgen's allegations that the inequitable conduct defenses do not satisfy Rule 9(b)'s particularity requirements. As discussed below, Roche's inequitable conduct defenses are now pled with exacting detail. Accepting those allegations as true, Roche's defenses state a claim upon which relief may be granted under Rule 12(b)(6). *See Transwitch Corp. v. Galazar Networks, Inc.*, 377 F. Supp. 2d 284, 290 (D. Mass. 2004) ("Futility of a proposed amendment 'is gauged by reference to the liberal criteria of Federal Rule of Civil Procedure 12(b)(6).'" (quoting *Hatch v. Dep't for Children, Youth & Their Families*, 274 F.3d 12, 19 (1st Cir. 2001)); *One Beacon Ins. Co. v. Electrolux & Sears Roebuck & Co.*, 223 F.R.D. 21, 24 (D. Mass. 2004). Consequently, Amgen cannot establish futility under Rule 15.

3. Roche's Proposed Amendments To Its Inequitable Conduct Defense Are Exceedingly Particular

Roche's proposed amendments to its inequitable conduct allegations are a textbook case of pleading with particularity. Even Amgen cannot now complain about

⁶ Roche's First Proposed Amended Answer and Counterclaims to Plaintiff's Complaint ("Am. Answer") is attached hereto as Ex. A. A redline of Roche's proposed amendments is attached as Ex. B.

this heightened level of specificity since the proposed amendments respond to all of Amgen's outstanding inquiries regarding the "who, what, when, where, and how" of the inequitable conduct.

Specifically, with respect to Amgen's inequitable conduct regarding Amgen's double patenting rejection, Roche's proposed amendments identify specific misrepresentations made by Amgen's attorneys. These misrepresentations took place on at least two occasions during the prosecution of Application No. 113,179, which is the parent application to several of the patents-in-suit, including the '868 patent, the '698 patent, the '422 patent, and the '349 patent: (1) an office action interview, dated September 7, 1994, before Examiner Martinell, where Amgen was represented by its outside prosecuting attorney, Mr. Borun, and its in-house counsel, Mr. Odre and Mr. Watt; and (2) Applicant's Amendment and Remarks, dated October 7, 1994, executed by Mr. Borun. (Am. Answer ¶¶ 43-53). These misrepresentations included the fact that Amgen argued that the pending claims were not obvious for double patenting over the previously issued U.S. Patent No. 4,703,008 patent ("the '008 patent") because the pending claims and the prior patent were part of different interference proceedings. (*Id.*).

However, as Roche's proposed amendment makes clear, in actuality, Amgen argued during those interference proceedings that the subject matter of the interferences was one and the same, and thus intentionally deceived the Patent Office into thinking those proceedings were not related. (*Id.* ¶ 44-48). In particular, Amgen stated the following in the related interference proceedings:

While the count is directed to a process for preparing in vivo biologically active EPO using a mammalian host cell transfected or transformed with an isolated DNA sequence encoding human EPO [i.e., the process patent claims], and

the litigation was directed to the purified and isolated DNA sequence and host cells transfected or transformed thereby [i.e., the '008 DNA claims], **it is evident that these are only different manifestations of the same invention** as acknowledged by Fritsch et al in their Motion Q here (and in Motion G in Interference No. 102,096). Clearly, the whole purpose and intent of the purified and isolated DNA sequence encoding human EPO (and host cells transfected therewith) at issue in the litigation was to express in vivo biologically active human EPO.

(*See Id.* ¶ 47 (quoting Brief for the Senior Party Lin, *Fritsch v. Lin*, Interference No. 102,097, at 25-26 (emphasis added)). Thus, even though Amgen argued to the Board of Patent Interferences that the two interference proceedings were about the “same invention,” Amgen took a completely contradictory position during the prosecution of the patents-in-suit when it stated otherwise. (*Id.*).

As a result of this misrepresentation, the Patent Office withdrew its double patenting rejection, a withdrawal that ultimately led to the issuance of each of the patents-in-suit. **But for** Amgen’s intentional misrepresentation to the Patent Office of the interference proceedings and Amgen’s knowing failure to disclose crucial statements it made in those interference proceedings, Amgen’s patents would not have issued and could not have formed the basis of past and present patent infringement cases.⁷ As Roche’s proposed amendment reveals, Amgen’s misconduct was motivated by its desire to improperly extend the life of its EPO invention by maintaining and prosecuting patent

⁷ Here, as in its original pleading, Roche has pled that the Patent Office justifiably relied upon Amgen’s misrepresentation in issuing the patents-in-suit. But for Amgen’s misconduct, the patents would not have been granted and enforced against Roche and others. Thus, contrary to Amgen’s arguments in Support of its Motion To Dismiss Roche’s Counterclaims Nos. I-IX and XII (Amgen Memo at 10), Roche’s allegations of detrimental reliance fully support a *Walker Process* claim.

applications that were merely obvious extensions over its now expired '008 patent. (*Id.* ¶ 51).

Similarly, on Amgen's inequitable conduct with respect to its failure to raise critical office action rejections in related co-pending applications, Roche again provides exacting detail in its proposed amendment. (*Id.* ¶¶ 54-73). For example, the proposed pleading identifies the non-disclosed material as an August 3, 1988 Office Action by the Patent Office. (*Id.* ¶¶ 59-65). The amendment proceeds to identify numerous instances where Amgen's attorneys, including Mr. Odre and Mr. Borun, failed to disclose this office action in a related patent application that resulted in the '933 and '080 patents, both of which are asserted in this case, including a December 1, 1988 Amendment and Reply and a June 2, 1989 Amendment. (*Id.*). Moreover, Roche's proposed amendment explains the materiality of the withheld Office Action in relation to the prosecution of the related application. The Office Action stated that making a glycosylated recombinant EPO was obvious and unpatentable over the Yokota and Gething references. The related application had pending claims directed to the product of the process for making glycosylated recombinant EPO. Therefore, Amgen continued to argue the novelty of its product-by-process claims, even though it was directly inconsistent with the Office Action rejection in a related co-pending application. (*Id.* ¶¶ 64-72).

Importantly, these amended allegations of inequitable conduct ((1) double patenting and (2) failures to disclose Office Action) were never before raised in prior Amgen litigation. Moreover, while the issue of Amgen's inequitable conduct regarding differences between natural and recombinant EPO was raised in the prior *TKT* litigation, Roche's proposed amendment expands upon these allegations and identifies two new

material declarations by Dr. Strickland made on behalf of Amgen which demonstrate further inconsistencies before the Patent Office. (*Id.* ¶¶ 74-83).

E. Roche's Patent Misuse And Unclean Hands Defenses Do Not Have To Be Pled With Separate Particularity

Amgen moves to strike Roche's unclean hands and patent misuse defenses on the grounds that Roche's inequitable conduct defense is not pled with particularity. (Amgen Br. at 10).

Amgen's critiques of Roche's inequitable conduct defense are baseless for the reasons discussed above. Moreover, even the supposed deficiencies in those allegations identified by Amgen have been rectified by Roche's proposed amended pleading. Accordingly, Amgen's motion to strike Roche's patent misuse and unclean hands defenses should be denied for the reasons discussed above.

Moreover, the common law defenses of unclean hands and patent misuse are not limited to allegations of fraud or inequitable conduct. Rather, they relate to much broader categories of behavior. *See, e.g., Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 815 (1945) (the unclean hands doctrine "gives wide range to the equity court's use of discretion in refusing to aid the unclean litigant"); *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1372 (Fed. Cir. 1998) (patent misuse "relates generally to the use of patent rights to obtain or to coerce an unfair commercial advantage"). For example, Amgen's decision to use its patent monopoly to improperly interfere with competition and extend the scope of the patent grant, as detailed in Roche's counterclaims, is patent misuse. This includes conduct that is totally unrelated to Roche's allegations of inequitable conduct, such as interfering with customer relationships, anticompetitive contracting practices and sham litigation. (*See Answer and Counterclaims*, ¶¶ 45-56).

In light of the above, Roche need not plead its general misuse and unclean hands defense with particularity. *See, e.g., Matsushita Elec. Indus. Co. v. CMC Magnetics Corp.*, 2006 WL 3290413, at *2 (N.D. Cal. Nov. 13, 2006) (patent misuse is pled under the standard of Fed. R. Civ. P. 8(a)); *Ocean Atlantic Woodland Corp. v. DRH Cambridge Homes, Inc.*, 2003 WL 1720073, at *6 (N.D. Ill. Mar. 6, 2003) (“unclean hands is an equitable affirmative defense that need not be pled with particularity unless fraud is alleged invoking Rule 9(b)”). Accordingly, Amgen’s motion to strike Roche’s unclean hands and misuse defenses should be denied for this additional reason.

F. Amgen Waived Its Damages Claim

In order to succeed on its motion to strike Roche’s 10th Affirmative Defense, “the Court must be convinced that there are no questions of fact, that any questions of law are clear and not in dispute, and that under no set of circumstances could the defense succeed.” *Levin-Richmond Terminal Corp. v. Int’l Longshoremen’s & Warehousemen’s Union*, 751 F. Supp. 1373, 1375 (N.D. Cal. 1990) (citation omitted); *see also Mastrocchio v. Unnamed Supervisor Special Inv. Unit*, 152 F.R.D. 439, 441 (D.R.I. 1993) (“In order to grant a motion to strike an insufficient defense, there must be a finding that the defense is wholly insufficient in law and so unrelated to plaintiff’s claim as to be unworthy of any consideration as a defense.”); *Honeywell*, 993 F. Supp. at 24. As discussed below, Amgen cannot succeed on its motion to strike because Roche has pled a legally and factually cognizable claim of waiver and estoppel.

Amgen contends that Roche’s 10th Affirmative Defense should be stricken because it “fails to assert any legally cognizable doctrine of waiver or estoppel under which such a defense may be asserted.” (Amgen Br. at 12). It is hard to believe that authority need be cited to Amgen in support of one of the most well established principles of the law (and

life) — no party, not even Amgen, can have it both ways. *See, e.g., Palandjian v. Pahlavi*, 614 F. Supp. 1569, 1579 (D. Mass. 1985) (“Long and firmly established principles of common law provide that . . . a man should not be permitted ‘to blow hot and cold’ with reference to the same transaction, or insist, at different times, on the truth of each of two conflicting allegations”); 18B Wright, Miller, & Cooper, FED. PRAC. & PROC. § 4477 (“a party should not be allowed to gain an advantage by litigation on one theory, and then seek an inconsistent advantage by pursuing an incompatible theory”). Simple fairness requires that if Amgen makes a representation to Roche and this Court, as it has done in this case, Amgen will have to live with that statement. Amgen cannot flip-flop between positions to serve its whim, and in the hopes of someday recovering damages from Roche.

Not surprisingly, the law of waiver and estoppel also supports Roche’s Damages Estoppel defense. As the Supreme Court has explained:

Where a party assumes a certain position in a legal proceeding, and succeeds in maintaining that position, he may not thereafter, simply because his interests have changed, assume a contrary position, especially if it be to the prejudice of the party who has acquiesced in the position formerly taken by him. This rule, known as judicial estoppel, generally prevents a party from prevailing in one phase of a case on an argument and then relying on a contradictory argument to prevail in another phase.

New Hampshire v. Maine, 532 U.S. 742, 749-50 (2001) (internal citations omitted).

The circumstances under which judicial estoppel may arise are not sharply defined or reducible to any general formula. *Id.* at 750; *see also Thore v. Howe*, 466 F.3d 173 (1st Cir. 2006) (“The contours of the judicial estoppel doctrine are not sharply defined, and there is no mechanical test for determining its applicability.”). Several factors typically inform the decision whether to apply the doctrine in a particular case. These include two

questions: (1) whether a party should have succeeded in persuading a court to accept its earlier inconsistent position and (2) whether they derived an unfair advantage or imposed an unfair detriment on the opposing party. *Id.*

Amgen cannot argue that there exists no “set of circumstances” under which Roche can succeed on its 10th Affirmative Defense. On May 10, 2006, the Court held a hearing on Roche’s pending motions to dismiss. During that hearing, in response to a question from the Court concerning whether this action would be tried before a jury, Amgen argued against a jury trial on the grounds that it was not seeking damages from Roche. (*See* Transcript of May 10, 2006 Motion Hearing, attached as Ex. D, at 33:16–24). This was an express waiver of any claim it may have had for money damages. Roche’s 10th Affirmative defense simply asks that Amgen be held at its word, and judicially estopped from pursuing damages from Roche in the event it is successful in this action. These allegations fall squarely within the doctrine of judicial estoppel. Accordingly, Amgen’s motion to strike Roche’s 10th Affirmative Defense should be denied.

G. Roche’s 12th Defense – Equitable Estoppel – Should Not Be Stricken

Again, with respect to Roche’s 12th defense of equitable estoppel, Amgen conflates the standard of a Rule 12(f) motion for that of a motion to dismiss under Rule 12(b)(6) or for summary judgment on the merits. (Amgen Br. at 16). Amgen conspicuously fails to inform the Court that in patent cases, the defense of equitable estoppel does not have to be pled with particularity, because fraud is not a necessary element for the defense. *See Poly-America v. GSE Lining Tech., Inc.*, 1998 WL 355477, at *7 (N.D. Tex. June 29, 1998) (“Equitable estoppel is recognized as an equitable defense to a claim of patent infringement. . . . Like the affirmative defense of laches, the affirmative defense of estoppel is sufficiently pled in accordance with Rule 8 of the

Federal Rules of Civil Procedure.”); *Patel v. Holiday Hospitality Franchising, Inc.*, 172 F. Supp. 2d 821, 825 (N.D. Tex. 2001) (“Rule 9(b) does not apply to an action for promissory/equitable estoppel because fraud is not an element of this claim. Instead, notice pleading under Rule 8 is sufficient . . .”).⁸

While equitable estoppel does require misleading conduct on the part of Amgen, that conduct is very broad and can constitute “specific statements, action, inaction, or silence where there was an obligation to speak.” *See A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1028 (Fed. Cir. 1992). Courts have found that this misleading conduct does not rise to the level of fraud that would trigger the pleading with particularity requirement of Rule 9(b). *See Poly-America*, 1998 WL 355477, at *7; *Patel*, 172 F. Supp. 2d at 825.

Here, Roche’s equitable estoppel defense should be decided on the merits after discovery in this case has closed. Amgen’s remedy in seeking more details of this defense can be accomplished through a contention interrogatory, rather than seeking drastic relief through a motion to strike. In responding to such an interrogatory, Roche would include at least the following information that forms the basis of its defense. First, through highly visible and public patent disputes with Ortho Biotech Products, L.P. concerning the coverage of the patents-in-suit, Amgen made it explicitly clear that claims of those patents did not cover second generation Erythropoiesis Stimulating Agents (“ESAs”), such as Amgen’s Aranesp[®]. The accused drug in this case, CERA, is even more different from

⁸ Similarly, to the extent Amgen contends that Roche’s 13th Affirmative Defense is deficient (*see* Amgen Br. at 16 n.54), Amgen’s position is baseless, as prosecution laches need not be pled with particularity. *See Poly-America*, 1998 WL 355477, at *7 (“The affirmative defense of laches does not include elements of fraud and therefore does not require the heightened pleading requirements of Rule 9(b).”).

EPO than Aranesp[®], and therefore constitutes a third generation ESA. As a result, Roche relied upon this fact to its detriment that Amgen would not be seeking to enforce the patents-in-suit against CERA. Contributing to this was the fact that Roche and Amgen entered into a global settlement agreement in 2001 whereby certain worldwide territorial rights were reconfirmed. Roche was granted immunity from Amgen to sell EPO in certain European territories while Amgen maintained its monopoly of selling EPO in the U.S. Through the course of those negotiations and by virtue of that settlement agreement, Amgen never indicated that it would seek to enforce its EPO patents against second and third generation ESA products, such as CERA.

III. CONCLUSION

Amgen requested (and was granted) an expedited discovery schedule in this case. Now it wields that schedule and the present motion as a sword to cut off Roche's chosen defenses in this action. Amgen is a sophisticated company with capable counsel, and with nearly twenty years of experience litigating matters related to the patents-in-suit. Roche's pleadings give Amgen adequate notice of Roche's claims and defenses. Roche should be allowed to develop those claims and defenses during discovery. Roche's ability to do so should not be overridden by Amgen's hope for a speedy, inexpensive and favorable result.

For the foregoing reasons, Amgen's motion to strike Roche's 2nd, 7th, 8th, 10th, and 12th affirmative defenses should be denied, and Roche's motion for leave to amend its Answer and Counterclaims should be granted.

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Boston, Massachusetts

Respectfully submitted,

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