

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

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

**MEMORANDUM IN SUPPORT OF AMGEN INC.'S MOTION TO
STRIKE ROCHE'S AFFIRMATIVE DEFENSES NOS. 2, 7, 8, 10, AND 12**

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I. INTRODUCTION

Amgen Inc. moves to strike the 2nd, 7th, 8th, 10th, and 12th Affirmative Defenses of Defendants F. Hoffmann-La Roche Ltd., Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (“Roche”).

Roche’s 2nd, 7th, and 8th Affirmative Defenses for patent misuse, inequitable conduct, and unclean hands, is respectively, are founded in whole or in part upon the charge that each of Amgen’s patents-in-suit are unenforceable due to inequitable conduct. To make such a charge, Roche was obligated to comply with FED. R. CIV. P. 9(b). Rule 9(b) ensures that “allegations of fraud are specific enough to give [the party] notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong.”¹ It also serves to prevent discovery “fishing expeditions,”² unwarranted waste of resources,³ and harm to reputation.⁴

Throughout its Answer, Roche conclusorily alleges that agents of Amgen “misrepresented and/or withheld material information” from the PTO. But Roche never pleads *with particularity*:

- What information was allegedly withheld or misrepresented
- When and where such acts allegedly occurred
- Who allegedly made such misrepresentations and omissions

¹ *Neubronner v. Milken*, 6 F.3d 666, 671-72 (9th Cir. 1993) (quoting *Semegen v. Weidner*, 780 F.2d 727, 731 (9th Cir. 1985)).

² *Semegen v. Weidner*, 780 F.2d 727, 731 (9th Cir. 1985); *see also Kowal v. MCI Commc’ns Corp.*, 16 F.3d 1271, 1279 n.3 (D.C. Cir. 1994).

³ *Chiron Corp. v. Abbott Labs.*, 156 F.R.D. 219, 221 (N.D. Cal. 1994).

⁴ *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988) (discussing “absolute plague” of inequitable conduct assertions in patent cases and negative effect of unsupported accusations on attorney reputations); *see also Chiron*, 156 F.R.D. at 221 (“The reputations of respectable clients, eminent experts, and honest patent examiners may all be impugned by careless or malicious accusations of ‘fraud on the Patent Office.’”).

- What, if anything, was allegedly false or deceptive about Amgen’s purported communications
- How such misrepresentations and omissions were material to the patentability of the patents-in-suit.

At most, Roche vaguely asserts that inequitable conduct arises from “statements and information regarding the molecular weights and carbohydrate compositions of r-EPO and u-EPO.”⁵ This vague allegation not only fails to meet the particularity standard under Rule 9(b), but the same allegation was extensively litigated in *Amgen Inc. v. Hoechst Marion Roussel, Inc.* (“the *TKT* case”) and found to be meritless: “[T]he Court finds that Amgen complied with its duty of candor with respect to data regarding glycosylation differences.”⁶

Roche will ultimately bear the burden of persuading this Court that there is a material distinction between its claim and that rejected in *TKT*.⁷ For this reason, it was incumbent upon Roche to plead its inequitable conduct allegations with particularity to identify whether there are any such differences. But Roche’s vague allegations assert no material facts different from those rejected in *TKT*. Unless Roche’s inequitable conduct allegations are stricken, or at a minimum, it is ordered to plead them with particularity, Amgen will be denied a fair opportunity to prepare its

⁵ Roche’s 11/6/06 Answer to Am. Compl. and Countercls., Answer at ¶ 44, Docket No. 140 [hereinafter “Answer” or “Counterclaims”].

⁶ 126 F. Supp. 2d 69, 141-45 (D. Mass. 2001), *aff’d in pertinent part*, 7-58 (Fed. Cir. 2003). Roche’s other allegations of time (“in the course of the foreign patent proceedings”), place (“before the FDA”), and content (“statements and information regarding the molecular weights and carbohydrate compositions of r-EPO and u-EPO”) are woefully deficient. *See, e.g., Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc.*, 1996 U.S. Dist. LEXIS 11700, at *17 (N.D. Cal. July 24, 1996).

⁷ *Stevenson v. Sears, Roebuck & Co.*, 713 F.2d 705, 711 n.5 (Fed. Cir. 1983) (“If [] the record in the second suit is substantively identical to the record produced in the first suit, then it is extremely likely that the court will give its prior holding *stare decisis* effect.”); *Am. Photocopy Equip. Co. v. Rovico, Inc.*, 384 F.2d 813, 816 (7th Cir. 1967) (discussing defendant’s burden when patents-at-issue were declared not invalid in a previous case).

response to Roche's accusations; the parameters of discovery will not be reasonably bounded; and many resources will be wasted.

Roche's 10th Affirmative Defense, entitled "Amgen is estopped from seeking damages," is legally insufficient as a matter of law and should be stricken pursuant to FED. R. CIV. P. 12(f). Amgen's Amended Complaint seeks a declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202,⁸ and "such other and further relief as the Court deems proper."⁹ These sections of the statute authorize further or new relief based on the declaratory judgment. Such "further relief" may subsequently include money damages in the event that Roche sells infringing product in the United States or otherwise causes compensable damage to Amgen. Any additional facts that might be necessary to support such relief can be proved in a post-judgment hearing. Further pleading in the Amended Complaint is not a prerequisite for the grant of such relief. Moreover, it is disingenuous for Roche to insist that Amgen should have pled damages for sales which Roche asserts have yet to be made.¹⁰ Because Roche fails to allege any facts sufficient to override the statutory provisions of 28 U.S.C. § 2202 or otherwise support any "estoppel" against Amgen, its 10th Affirmative Defense should be stricken.

Nor does Roche plead the necessary elements of its 12th Affirmative Defense, entitled "Equitable Estoppel." Roche does not plead any misleading act, communication, or silence of Amgen to Roche. Nor does Roche plead any facts establishing that it relied to its prejudice on any act, omission, or communication of Amgen. Rather, the facts as alleged in Roche's

⁸ Amgen's 4/25/06 Am. Compl. For Declaratory J. of Infringement ¶¶ 7, 32, Docket No. 52 [hereinafter "Amended Complaint"].

⁹ *Id.* at Prayer for Relief ¶ d.

¹⁰ Roche's 4/11/06 Mem. In Support of Its Mot. To Dismiss for Lack of Subject Matter Jurisdiction and Failure to State a Claim for Which Relief May be Granted at 15 ("Until FDA approval, there can be no sales of CERA."), Docket No. 45 [hereinafter "Roche's Motion to Dismiss"].

Counterclaims establish just the opposite. Because there is no possible state of facts that could support Roche's 12th Affirmative Defense, it should be stricken.¹¹

“[T]he purpose of pleading is to facilitate a proper decision on the merits.”¹² Roche's deficiently pled affirmative defenses defeat this purpose. They deny Amgen a fair opportunity to defend against such bald accusations, threaten needless uncertainty in discovery, undermine proper preparation of the case for trial, and engender undue delay and cost. All of this is yet further exacerbated by the tight pretrial schedule, especially given that all fact discovery is to be completed in less than four months. Thus, “to secure the just, speedy, and inexpensive determination” of this action,¹³ Roche's deficiently pled defenses should be stricken.

II. ARGUMENT

A. BECAUSE ROCHE'S 7TH DEFENSE — INEQUITABLE CONDUCT — IS NOT PLED WITH PARTICULARITY, IT SHOULD BE STRICKEN.

1. FED. R. CIV. P. 9(b) requires that inequitable conduct be pled with particularity.

To establish inequitable conduct, a defendant must prove that the patentee withheld material information from the patent examiner or submitted false material information, with the intent to deceive or mislead the examiner into allowing the patent.¹⁴ Thus, allegations of inequitable conduct are a form of fraud,¹⁵ and are subject to the requirements of Rule 9(b).¹⁶

¹¹ FED. R. CIV. P. 12(f); *see also United States SEC v. Nothorn*, 400 F. Supp. 2d 362, 364 (D. Mass. 2005) (quoting *FDIC v. Gladstone*, 44 F. Supp. 2d 81, 85 (D. Mass. 1999)).

¹² *Conley v. Gibson*, 355 U.S. 41, 48 (1957); *Foman v. Davis*, 371 U.S. 178, 181-82 (1962).

¹³ FED. R. CIV. P. 1.

¹⁴ *Upjohn Co. v. MOVA Pharm. Corp.*, 225 F.3d 1306, 1312 (Fed. Cir. 2000) (citing *Kingsdown Med. Consultants Ltd. v. Hollister Inc.*, 863 F.2d 867, 872 (Fed. Cir. 1988)).

¹⁵ *See Systemation, Inc. v. Engel Indus., Inc.*, 183 F.R.D. 49, 50 (D. Mass. 1998); *see also, e.g., Samsung Elecs. Co. v. Texas Instruments Inc.*, 39 U.S.P.Q.2d 1673, 1675 (N.D. Tex. 1996) (citing *Burlington*, 849 F.2d at 1422).

¹⁶ *See Ferguson Beauregard/Logic Controls, Division of Dover Res., Inc. v. Mega Sys., LLC*,

Rule 9(b) requires more than mere notice pleading — it requires particularity: “In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity.”¹⁷ “Rule 9(b) requires that the ‘particular times, dates, places or other details of [the] alleged fraudulent involvement of the actors be alleged.’”¹⁸ Importantly, the party pleading inequitable conduct must identify the *precise* content of the alleged fraudulent representations or omissions.¹⁹ For example, in *Chiron Corp. v. Abbott Labs.*, defendant’s characterization of a seven-page expert declaration as “deceptive and misleading” was insufficient to meet the particularity requirement because it failed to point out the exact statements within the document which were purportedly deceptive and misleading and to explain why.²⁰ In sum, an averment of “the who, what, when, where, and how” of the allegedly false or fraudulent representation or omission is required.²¹

2. Roche has failed to plead inequitable conduct with particularity.

350 F.3d 1327, 1344 (Fed. Cir. 2003); *Davidson v. Yihai Cao*, 211 F. Supp. 2d 264, 285 (D. Mass. 2002).

¹⁷ FED. R. CIV. P. 9(b).

¹⁸ *Swartz v. Schering-Plough Corp.*, 53 F. Supp. 2d 95, 104 (D. Mass. 1999) (quoting *Serabian v. Amoskeag Bank Shares, Inc.*, 24 F.3d 357, 361 (1st Cir. 1994)); *Systemation*, 183 F.R.D. at 50; *In re Papst Licensing, GmbH, Patent Litig.*, 174 F. Supp. 2d 446, 449 (E.D. La. 2001) (citing *Laitram Corp. v. OKI Elec. Indus. Co.*, 1994 U.S. Dist. LEXIS 1284, at *9 (E.D. La. Feb. 7, 1994)) (“allegations of inequitable conduct should identify four elements: (1) the particular statements, misrepresentations, or omissions made; (2) when the complained of acts or omissions occurred; (3) the reason why those acts or omissions were inequitable; and (4) the basis for that belief”); *Sun-Flex Co. v. Softview Computer Prods. Corp.*, 750 F. Supp. 962, 963 (N.D. Ill. 1990) (“defendants must specify the time, place, and content of any alleged misrepresentations that plaintiffs made to the PTO”).

¹⁹ *Sun-Flex*, 750 F. Supp. at 963-64 (“The amended answer does not identify the precise content of the alleged fraudulent representations and omissions. Moreover, defendants have not disclosed the time frame during which the inequitable conduct occurred.”).

²⁰ *Chiron*, 156 F.R.D. at 222-23.

²¹ See FED. R. CIV. P. 9(b); *Alternative Sys. Concepts, Inc. v. Synopsys, Inc.*, 374 F.3d 23, 29 (1st Cir. 2004) (In cases alleging fraud, “the pleader usually is expected to specify the who, what, where, and when of the allegedly false or fraudulent representation.”).

Roche pleads its inequitable conduct defense at paragraphs 38-45 of its Answer. It begins by vacuously accusing Amgen of “repeated instances of inequitable conduct.”²² To the extent it makes any effort to describe such conduct, it does so in paragraphs 41-44. But, at most, these paragraphs only vaguely allege unspecified omissions or misrepresentations concerning differences between r-EPO and u-EPO — a subject much litigated in the *TKT* case and held to be devoid of inequitable conduct.²³ Roche then compounds the ambiguity of its pleading by asserting that the acts alleged are merely “*among*” other unstated acts.²⁴ Roche’s allegations are therefore deficient because they fail to specify: (1) “the who, what, when, where, and how” of the alleged misrepresentations and omissions; (2) all acts upon which it bases its defense; and (3) the material differences, if any, between its current allegations and those of the *TKT* case.

First, paragraphs 41-44 of Roche’s Answer fail to plead the requisite “who, what, when, where, and how” of the alleged misrepresentations and omissions. Paragraph 41 alleges:

41. Among the acts of inequitable conduct that Amgen, and those substantively involved in the prosecution of the patents-in-suit acting on its behalf, made misleading and erroneous statements to the PTO regarding the differences between recombinant erythropoietin (“r-EPO”) and urinary erythropoietin (“u-EPO”), while in other arenas Amgen employees made statements that were inconsistent with the statements made to the PTO.

This allegation is deficient because it fails to specify:

- What specific statements to the PTO were “misleading or erroneous”?
- What was allegedly “misleading or erroneous” about the statements?
- Who made the allegedly “misleading or erroneous statements”?
- When was each such statement made?

²² Answer at ¶ 39.

²³ *Amgen*, 126 F. Supp. 2d at 144, *aff’d in pertinent part*, 314 F.3d 1313, 1357-58 (Fed. Cir. 2003).

²⁴ Answer at ¶ 41.

- What specific statements made in “other arenas” were allegedly “inconsistent”?
- What were the “other arenas”?
- Who made these allegedly “inconsistent” statements?
- How was the PTO purportedly misled?

Paragraph 42 alleges:

42. Amgen and its employees, including the named inventor of the patents-in-suit, also made numerous statements that directly contradicted statements made to the PTO during the prosecution of the patents-in-suit relating to r-EPO.

This allegation is deficient because it fails to specify:

- What “statements ... directly contradicted statements made to the PTO during the prosecution of the patents-in-suit relating to r-EPO”?
- Who, besides Lin, made these statements and which statements did they make?
- What were the specific “statements made to the PTO”?
- When was each such statement made?
- Whether, and if so how, the PTO was purportedly misled?

Paragraph 43 alleges:

43. The acts of inequitable conduct include that material references and information were not listed as a reference in Amgen’s Information Disclosure Statement (“IDS”) filings nor submitted to, nor considered by, the Examiner in connection with the prosecution of the patents-in-suit.

This allegation is essentially identical to the allegation rejected in *Systemation* which caused the court to conclude that the defendant there “failed to identify any particular prior art it claims should have been disclosed to the Patent and Trademark Office.”²⁵ Roche’s paragraph 43 is similarly deficient because it fails to specify:

²⁵ *Systemation*, 183 F.R.D. at 50 (rejecting as deficiently pled: “The ‘880 and ‘944 patents are unenforceable because during prosecution of the ‘880 and ‘944 patents, the applicant willfully or with gross negligence committed certain inequitable acts that misled the Patent and Trademark Office. In particular, the applicant, having knowledge of certain prior art willfully refrained from disclosing such prior art to the Patent and Trademark Office and, therefore, violated his duty of disclosure.”).

- What “references” were allegedly omitted?
- What “information” was allegedly omitted?
- What rendered each such reference or information material?
- What basis exists to believe that such references or information were known to those prosecuting the patent at the time?
- How was the PTO purportedly misled?

Paragraph 44 alleges:

44. In addition, Amgen and its representatives, in the course of the foreign patent proceedings and before the FDA, relied on statements and information regarding the molecular weights and carbohydrate compositions of r-EPO and u-EPO that were inconsistent, and refuted the positions Amgen took during prosecution of its patents before the PTO, and in *Fritsch et al. v. Lin* patent interference No. 102,334. For example, Amgen submitted arguments and supporting declarations during European opposition proceedings involving EP 411 678 and EP 209 539 indicating that r-EPO had the same molecular weight and carbohydrate composition as u-EPO. In contrast, to argue that its EPO was patentable, Amgen represented to the PTO that r-EPO differed from u-EPO in molecular weight and carbohydrate composition.

This allegation is deficient because it fails to specify:

- What specific “foreign patent proceedings and before the FDA” are at issue?
- What specific “positions Amgen took during prosecution of its patents before the PTO”?
- What specific “statements” were allegedly made in the course of such proceedings?
- What specific “information” was allegedly provided in the course of such proceedings?
- Who made the alleged statements to the European Patent Office?
- What specific statements made to the PTO are allegedly contradictory?
- How the PTO was allegedly misled?

Second, Roche must specify *all* of the acts which it contends constitute inequitable conduct. A party must identify the precise content of the alleged fraudulent representations and omissions.²⁶ Without sufficient notice of the precise content of *each* alleged fraudulent

²⁶ See *Sun-Flex*, 750 F. Supp. at 963 (granting motion to strike where “amended answer does not identify the precise content of the alleged fraudulent misrepresentations and omissions”).

representation or omission, Amgen cannot adequately respond to those allegations. Plainly, Roche's use of such open-ended terms as "among," "including," and "include"²⁷ directly violates its obligation to specify the *precise content* of the alleged inequitable conduct and should be stricken.²⁸

Third, the very subject which Roche now alleges to be the gravamen of its of inequitable conduct defense — i.e., differences between r-EPO and u-EPO — was previously litigated and held by this Court and the Federal Circuit to provide no basis for inequitable conduct.²⁹ Thus, it was incumbent upon Roche to plead its inequitable conduct allegations with sufficient particularity to afford Amgen an opportunity to assess whether Roche's allegations are materially different from those of the *TKT* case. Roche's current allegations, however, utterly fail in this regard.

3. Striking Roche's inequitable conduct defense is an appropriate remedy under Rule 12(f).

Rule 12(f) permits the Court to strike "any insufficient defense" from pleadings.³⁰ Because Roche's inequitable conduct allegations are insufficient as a matter of law under Rule 9(b), they should be stricken. Should the Court allow Roche to amend its Answer, however, Amgen respectfully requests that it order Roche to: (1) specify "the who, what, when, where,

²⁷ Answer at ¶¶ 41, 42, 43.

²⁸ *Astra Aktiebolag v. Genpharm Inc.*, 2000 U.S. Dist. LEXIS 2513, at *4 (S.D.N.Y. Feb. 21, 2000) ("To the extent that Astra argues that this gives them notice of one specific piece of prior art but is insufficient to place them on notice of any other allegedly material omissions they are correct. Accordingly, the phrase 'includes at least' in paragraphs 69 and 157 is stricken.").

²⁹ *Amgen*, 126 F. Supp. 2d at 141 ("Amgen complied with its duty of candor . . . regarding glycosylation differences."), *aff'd in pertinent part*, 314 F.3d 1313, 1357 (Fed. Cir. 2003) ("The district court found that TKT has not proven inequitable conduct by clear and convincing evidence, and we have not been persuaded on appeal that a contrary result is compelled.").

³⁰ FED. R. CIV. P. 12(f); *see also Chiron*, 156 F.R.D. at 220 (quoting *Kaiser Aluminum & Chem. Sales, Inc. v. Avondale Shipyards, Inc.*, 677 F.2d 1045, 1057 (5th Cir. 1982), *cert. denied*, 459 U.S. 1105 (1983)).

and how” of the alleged misrepresentations and omissions in the manner discussed above; (2) identify *all* specific acts upon which Roche bases its inequitable conduct defense; and (3) specify all relevant differences, if any, between its current allegations and those of the *TKT* case.

B. BECAUSE ROCHE’S 2ND AND 8TH DEFENSES — PATENT MISUSE AND UNCLEAN HANDS — ARE NOT PLED WITH PARTICULARITY, THEY SHOULD BE STRICKEN.

Roche’s 2nd and 8th Affirmative Defenses respectively read in their entirety:

33. The patents-in-suit are not enforceable, in whole or in part, due to the wrongful and improper conduct by Amgen which constitutes patent misuse.

46. The asserted patents are unenforceable due to Amgen’s unclean hands.

Conduct of a patentee rises to the level of patent misuse only when “the patentee has impermissibly broadened the scope of the patent grant with anticompetitive effect.”³¹ “To assert a defense of unclean hands, [defendant] must plead that [plaintiff] acted in a way that amounts to fraud, misconduct or bad faith.”³² If either of these defenses is based on inequitable conduct, Rule 9(b) requires that they be pled with particularity: “To the extent that defendant’s affirmative defense for unclean hands and patent misuse rests on allegations of inequitable conduct before the PTO, defendant must plead these defenses with the specificity required under Rule 9(b).”³³

³¹ *Monsanto Co. v. McFarling*, 363 F.3d 1336, 1341 (Fed. Cir. 2004) (quoting *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1372 (Fed. Cir. 1998)).

³² *Global Poly Inc. v. Fred’s Inc.*, 2004 U.S. Dist. LEXIS 3880, at *17 (N.D. Ill. Mar. 10, 2004); see also *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814-15 (1945) (Those who pursue justice in a court of equity “shall have acted fairly and without fraud or deceit as to the controversy at issue.”); *Castle v. Cohen*, 676 F. Supp. 620, 627 (E.D. Pa. 1987) (“The clean hands doctrine is applicable when 1) a party seeking affirmative relief 2) is guilty of conduct involving fraud, deceit, unconscionability, or bad faith 3) directly related to the matter in issue 4) that injures the other party 5) and affects the balance of equities between the litigants.”).

³³ *Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc.*, 1996 U.S. Dist. LEXIS 11696, at *40

Roche alleges no specific facts supporting either affirmative defense. Roche's Answer and Counterclaims make no other reference to "unclean hands." Although not cross-referenced to these defenses in any way, paragraph 62 of Roche's Counterclaims suggests that Roche bases its misuse defense at least in part on unspecified inequitable conduct:

Amgen's anticompetitive, strong arm tactics with customers, its sham litigation before the ITC, and its knowing attempt to enforce in this Court *patents obtained through fraud on the PTO* threaten to maintain Amgen's monopoly over the ESRD ESA market, and to help Amgen achieve monopoly power in the CKD ESA market. At the very least, Amgen's conduct will hinder the introduction of additional competition into the highly concentrated CKD and ESRD ESA markets. Amgen's course of conduct also amounts to misuse of its patents.³⁴

Roche's current unclean hands and misuse allegations plainly fail the requirement that these defenses be pled with particularity under Rule 9(b). If Roche's unclean hands and misuse defenses are not based upon inequitable conduct, Roche should have so pled and should not be permitted to exploit this ambiguity to subsequently assert inadequately pled defenses.³⁵

Roche's failure to plead its 2nd and 8th Affirmative Defenses with particularity prejudices Amgen by denying it adequate notice to enable preparation of its response, exposing it to needless discovery, and wasting resources.³⁶ Accordingly, they should be stricken under Rule 12(f).³⁷ Should Roche be permitted to amend its Answer and Counterclaims, however, it should be ordered to: (1) identify all factual allegations supporting the elements of these equitable defenses; and (2) plead all allegations of inequitable conduct with the particularity identified

(N.D. Cal. July 24, 1996).

³⁴ Counterclaims at ¶ 62 (emphasis added).

³⁵ See *Chase Med., LP v. CHF Techs., Inc.*, 2005 U.S. Dist. LEXIS 13731 (N.D. Tex. July 11, 2005).

³⁶ See *Semegen*, 780 F.2d at 731.

³⁷ *Advanced Cardiovascular*, 1996 U.S. Dist. LEXIS 11696, at *40-41.

above. If its unclean hands and misuse defenses are not based upon inequitable conduct, Roche should be required to state so.

C. BECAUSE ROCHE’S 10TH DEFENSE — DAMAGES ESTOPPEL — IS LEGALLY INSUFFICIENT, IT SHOULD BE STRICKEN.

Roche’s 10th Affirmative Defense is entitled “Amgen is estopped from seeking damages.” It claims that Amgen has “waive[d] any damages, compensatory or otherwise” and is “estopped and precluded from seeking, asserting or maintaining a claim for damages, compensatory or otherwise, for any damages, whether past, current or future, in the event that Amgen is successful on its claims and the Court determines that a permanent injunction is not warranted in this case.”³⁸ But Roche fails to assert any legally cognizable doctrine of waiver or estoppel under which such a defense may be asserted.

Rule 12(f) permits this Court to strike from a pleading “any insufficient defense.”³⁹ A defense is insufficient where “it clearly appears that the plaintiff would succeed despite any state of facts which could be proved in support of [the] defense.”⁴⁰ A motion to strike will be granted where: (1) the insufficiency of the defense is clearly apparent; (2) there is an absence of factual issues that require a hearing on the merits; and (3) the moving party would be prejudiced if the defense is permitted to remain in the pleadings.⁴¹ Motions to strike serve to narrow the issues by eliminating defenses which can have no bearing on the outcome: “[I]t is useful to consider the legal sufficiency of the defenses at this early stage in order to narrow the issues so as to avoid the

³⁸ Answer at ¶ 53.

³⁹ FED. R. CIV. P. 12(f).

⁴⁰ *Nothern*, 400 F. Supp. 2d at 364 (quoting *Gladstone*, 44 F. Supp. 2d at 85).

⁴¹ *See id.*

needless expense involved in preparing and litigating issues which can have no bearing on the outcome.”⁴²

Amgen’s Amended Complaint seeks a declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202.⁴³ § 2202 states:

Further relief. Further necessary or proper relief based on a declaratory judgment or decree may be granted, after reasonable notice and hearing, against any adverse party whose rights have been determined by such judgment.

Amgen’s Complaint also requests “such other and further relief as the Court deems proper.”⁴⁴ Such “further relief” may include money damages in the event that Roche sells infringing product in the United States or otherwise causes compensable damage to Amgen.

The legal insufficiency of Roche’s “estoppel” defense is clearly illustrated in *Edward B. Marks Music Corp. v. Charles K. Harris Music Publishing Co., Inc.* (“*Marks Music*”).⁴⁵ In *Marks Music*, the plaintiff, sole owner of a number of copyrights, instituted an action for a declaratory judgment and requested an injunction restraining defendant from infringing its copyrights. The court ruled in plaintiff’s favor and granted injunctive relief. As further relief, plaintiff then moved for an accounting. On appeal, the plaintiff’s right to seek further monetary relief was confirmed notwithstanding the absence of any prior claim for damages:

We come, then, to plaintiff’s appeal from the denial of its motion for an adjudication of infringement and for an accounting. ***If plaintiff is not barred by laches this relief is proper.*** 28 U.S.C. § 2202 specifically provides that: ‘Further necessary or proper relief based on a declaratory judgment or decree may be granted, after reasonable notice and hearing, against any adverse party whose rights have been determined by such judgment.’ We take this to mean that the ***further relief sought — here monetary recompense — need not have been demanded, or even proved, in the original action for declaratory relief.*** The

⁴² *FDIC v. Gaziano*, 1998 U.S. Dist. LEXIS 2150, at *6 (D. Mass. Jan. 29, 1998).

⁴³ Amended Complaint at ¶¶ 7, 32.

⁴⁴ *Id.* at Prayer for Relief ¶ d.

⁴⁵ 255 F.2d 518 (2d Cir. 1958).

section authorizes further or new relief based on the declaratory judgment, and any additional facts which might be necessary to support such relief can be proved on the hearing provided in the section or in an ancillary proceeding if that is necessary. Cf. *Security Ins. Co. of New Haven v. White*, 10 Cir., 236 F.2d 215. Here the further demand for relief is based on the declaration of plaintiff's ownership of the songs at issue and, unless otherwise barred, is proper under the statute.

...

First, the defendant claims that plaintiff waived such additional relief by failing in its complaint to allege infringement and consequent damages. But obviously this argument is specious. If plaintiff had proved infringement on the trial it would have been entitled to damages under *F.R.Civ.Proc.*, rule 54(c); but under the declaratory judgment statute it was not compelled to take this course. Hence defendant was not entitled to assume from the absence of a plea for damages that plaintiff would not seek them at trial. ***Likewise defendant was not entitled to assume that plaintiff would not seek damages after trial and entry of the declaratory judgment because plaintiff's complaint ended with the prayer 'that upon application therefor, plaintiff be granted such further relief based on said declaratory judgment as may be necessary or proper' — the very procedure provided by 28 U.S.C. § 2202.*** The course plaintiff adopted was thus not unusual.⁴⁶

The only possible defense the appeals court considered in *Marks Music* was laches in bringing the claim for damages, which Roche has not asserted and which in any event would not be applicable in the current factual situation. Thus, Roche's "damages estoppel" defense ignores both the explicit statutory language of § 2202 and existing legal precedent, and is wholly insufficient in law.

Moreover, it is disingenuous for Roche to insist that Amgen should have pled a claim for damages for sales where Roche contends that it cannot and is not selling any accused product in the United States.⁴⁷ Nothing in Amgen's claim for declaratory relief under 28 U.S.C. § 2202

⁴⁶ *Marks Music*, 255 F.2d at 522-23 (emphasis added); see also *United Teacher Ass'n Ins. Co. v. United Labor Life Ins. Co.*, 414 F.3d 558 (5th Cir. 2005); *Fred Ahlert Music Corp. v. Warner/Chappell Music, Inc.*, 155 F.3d 17 (2d Cir. 1998).

⁴⁷ Roche's Motion to Dismiss at 15.

bars a later request by Amgen for damages, and Roche alleges no facts to support any “estoppel” against Amgen or otherwise override the statutory provisions of § 2202.

Rule 12(f) permits this Court to eliminate defenses that are fatally flawed in their legal premises and destined to fail, and thereby spare litigants the burden of unnecessary pretrial and trial activity.⁴⁸ Because the insufficiency of Roche’s 10th Affirmative Defense is clearly apparent and because it implicates no factual issues, it should be stricken. Moreover, Amgen will be prejudiced if this alleged defense is not stricken. How can Amgen be estopped from asserting a claim for damages arising from sales that Roche contends it has not and cannot yet make? If Roche attempts to take discovery relating to this legally insufficient defense, time and litigation resources will be wasted on meritless issues. “Weeding out legally insufficient defenses at an early stage of a complicated law suit may be extremely valuable to all concerned ‘in order to avoid the needless expenditures of time and money,’ in litigating issues which can be foreseen to have no bearing on the outcome.”⁴⁹

D. BECAUSE ROCHE DOES NOT PLEAD AND CANNOT ESTABLISH THE NECESSARY ELEMENTS OF ITS 12TH DEFENSE — EQUITABLE ESTOPPEL — IT SHOULD BE STRICKEN.

Roche’s 12th Affirmative Defense states: “Amgen’s claims for infringement of the ‘868, ‘933, ‘698, ‘080, ‘349 and ‘422 patents are barred by equitable estoppel.”⁵⁰ To establish equitable estoppel in a patent case, an accused infringer must prove three essential elements: (1) misleading conduct by the patentee; (2) reliance thereon by the alleged infringer; and (3) material

⁴⁸ See *Advanced Cardiovascular Sys., Inc. v. SciMed Life Sys., Inc.*, 988 F.2d 1157, 1160 (Fed. Cir. 1993).

⁴⁹ *Narragansett Tribe of Indians v. So. R.I. Land Dev.*, 418 F. Supp. 798, 801 (D.R.I. 1976) (citing *Purex Corp. v. Gen. Foods Corp.*, 318 F. Supp 322, 323 (C.D. Cal. 1970)); see also *FDIC v. Gaziano*, 1998 U.S. Dist. LEXIS 2150, at *6.

⁵⁰ Answer at ¶ 55.

prejudice to the alleged infringer.⁵¹ The defendant bears the burden of proving each element of equitable estoppel using “competent evidence” to bar a patentee’s suit for patent infringement.⁵² Because Roche cannot assert any state of facts to meet each element of equitable estoppel, its 12th Affirmative Defense is legally insufficient and should be stricken.⁵³

First, Roche’s Answer alleges no facts describing or supporting any misleading communication (or silence) from Amgen to Roche. Nor does Roche plead any facts establishing its reliance on any communication by Amgen to its prejudice. Because misleading conduct, reliance, and prejudice are each necessary elements required to prove equitable estoppel, Roche’s 12th Affirmative Defense is insufficient as a matter of law.⁵⁴

Second, Roche’s equitable estoppel defense is at odds with its antitrust counterclaims. Those counterclaims are based on the factual allegation that Amgen’s vigilant enforcement of its EPO patent rights results in high barriers to entry into the EPO market: “Amgen has vigorously enforced its patent portfolio against other companies for the past twenty years.”⁵⁵ From its own

⁵¹ *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1028 (Fed. Cir. 1992) (“Three elements must be established to bar a patentee’s suit by reason of equitable estoppel: a. The patentee, through misleading conduct, leads the alleged infringer to reasonably infer that the patentee does not intend to enforce its patent against the alleged infringer. ‘Conduct’ may include specific statements, action, inaction, or silence where there was an obligation to speak. b. The alleged infringer relies on that conduct. c. Due to its reliance, the alleged infringer will be materially prejudiced if the patentee is allowed to proceed with its claim.”).

⁵² *Giese v. Pierce Chem. Co.*, 29 F. Supp. 2d 33, 43 (D. Mass. 1998) (“Defendant must prove each element using competent evidence.”).

⁵³ FED. R. CIV. P. 12(f); *see also Nothern*, 400 F. Supp. 2d at 364 (quoting *Gladstone*, 44 F. Supp. 2d at 85).

⁵⁴ Similarly deficient is Roche’s 13th Affirmative Defense, which it entitles “Prosecution Laches Estoppel” but then describes as “prosecution laches and estoppel.” Roche fails to provide any further explanation or facts regarding this defense, particularly failing to explain how it differs from its 11th Affirmative defense (“File Wrapper Estoppel) or its 12th Affirmative Defense (“Equitable Estoppel”). To the extent that this defense purports to raise an issue of equitable estoppel, it should be stricken for the reasons its 12th Affirmative Defense should be stricken.

⁵⁵ Counterclaims at ¶¶ 27, 36; *see also Amgen*, 126 F. Supp. 2d at 76 (“As one would expect, Amgen

first-hand experience, Roche knew this long before it started developing peg-EPO — Amgen successfully asserted Lin’s ‘008 patent in this Court against Roche’s subsidiary Chugai, and its licensor Genetics Institute.⁵⁶ Thus, Roche cannot claim for purposes of equitable estoppel that it was lulled into a sense of security⁵⁷ that Amgen would not assert its patents against peg-EPO, while at the same time for antitrust purposes rely on the fact that Amgen has diligently (and successfully) asserted its patents against competitors.

Third, as to Roche’s peg-EPO product in particular, the patents-in-suit issued and were being asserted against Hoechst Marion Roussel and Transkaryotic Therapies long before Roche filed its first Investigational New Drug Application to administer peg-EPO to humans in 2001.⁵⁸ Moreover, the issue of Roche’s notice of Amgen’s intent to enforce the Lin patents against Roche’s peg-EPO already has been litigated in this action. In response to Roche’s motion to dismiss Amgen’s Declaratory Judgment of Infringement claim under FED. R. CIV. P. 12(b)(1) and 12(b)(6), Amgen set forth its public warnings to Roche in detail. Roche, did not contest any of these facts in reply, but instead argued that such statements were irrelevant to its motion.⁵⁹

has sought to preserve its commercial success through a cluster of related patents that it has defended with skill and perseverance.”).

⁵⁶ *Amgen Inc. v. Chugai Pharm. Co.*, 1989 U.S. Dist. LEXIS 16110 (D. Mass. Dec. 11, 1989), *aff’d*, 927 F.2d 1200 (Fed. Cir. 1991).

⁵⁷ *A.C. Aukerman*, 960 F.2d at 1043 (“To show reliance, the infringer must have had a relationship or communication with the plaintiff which lulls the infringer into a sense of security in going ahead [with its planned action].”).

⁵⁸ The ‘868, ‘933, ‘698, ‘349, and ‘422 patents issued in 1995, 1996, 1997, 1998, and 1999, respectively. Amgen filed its Complaint against HMR/TKT in 1997. Roche’s first Investigational New Drug Application was filed on 12/4/2001. 4/11/06 Decl. of Kingma-Johnson in Support of Defs.’ Mot. To Dismiss for Lack of Subject Matter Jurisdiction and Failure to State a Claim for Which Relief May Be Granted ¶ 7, Docket No. 46 [hereinafter “Kingma-Johnson Decl.”].

⁵⁹ Roche’s 5/1/06 Reply Mem. In Further Support of its Mot. To Dismiss for Lack of Subject Matter Jurisdiction and Failure to State a Claim for Which Relief May Be Granted at 2 (“Amgen’s self-serving threats by its executives against Roche in the media are irrelevant to this

Although not necessary to grant Amgen's instant motion, a brief summary of the facts establishing Roche's knowledge of Amgen's intentions follows:

As early as 2003 — three years before Roche's filing of its Biologics License Application for peg-EPO — Amgen warned Roche of its intent to enforce its patent rights. Amgen's CEO and CFO publicly stated that Amgen would vigorously defend its patents against peg-EPO:

Q: "Did I hear you correctly that Roche's SERRA [sic.] compound may infringe on your issued patent?" (Joel Sendek)

A: "We're quite certain it does." (Amgen's response)⁶⁰

"[W]e're confident in our patents. We'll defend them vigorously . . . As we wrap up TKT, we'll get ready for these guys, if that's what it takes. . . ."⁶¹

Foreclosing *any* possibility that Roche could prove reliance, the head of Roche's Global Pharmaceuticals division stated, as early as 2003, that **Roche "should expect that [Amgen] will take us to court."**⁶² Even with this recognition of Amgen's intent to enforce its patents against it, Roche refused to discontinue development of peg-EPO, and proceeded with Phase III Clinical Trials in 2004.⁶³ Amgen filed this lawsuit in November 2005.

How could Roche have been misled into believing Amgen would not enforce its EPO patents when Amgen's public commitment to defend its EPO patent estate has never wavered? Since Roche cannot present any state of facts to prove that it was misled by Amgen into believing that Amgen would not assert its patent rights against Roche, and since Amgen will be

issue."), Docket No. 62.

⁶⁰ 4/25/06 Decl. of Michael R. Gottfried In Support of Amgen Inc.'s Opp'n to Defs.' Mot. To Dismiss for Lack of Subject Matter Jurisdiction and Failure to State a Claim for Which Relief May Be Granted, Ex. 14 at 12, Docket No. 54.

⁶¹ *Id.*, Ex. 14 at 6.

⁶² *Id.*, Ex. 19.

⁶³ Kingma-Johnson Decl. at ¶ 9.

prejudiced by an unjustified expansion of the scope of discovery and an unnecessary expenditure of time and litigation resources if Roche's equitable estoppel defense remains in the pleadings, Roche's 12th Affirmative Defense of equitable estoppel should be stricken.

III. CONCLUSION

For the foregoing reasons, Amgen respectfully requests that:

1. Roche's 2nd, 7th, 8th, 10th, and 12th Affirmative Defenses be stricken; and
2. Should Roche be permitted an opportunity to amend its Answer, Amgen respectfully requests that Roche be ordered to:
 - (a) specify "the who, what, when, where, and how" of all alleged misrepresentations and omissions in the manner discussed above;
 - (b) identify all specific acts upon which Roche bases its inequitable conduct defense;
 - (c) identify all relevant differences, if any, between its current inequitable conduct allegations and those of the *TKT* case;
 - (d) identify all factual allegations supporting the elements of its unclean hands and patent misuse defenses; and
 - (e) state whether, and if so how, its unclean hands and misuse defenses are based on inequitable conduct.

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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 on November 27, 2006.

/s/ Michael R. Gottfried
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