

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,
Plaintiff,
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.
Civil Action No.: 05-12237 WGY

AMGEN'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO
STRIKE ROCHE'S AFFIRMATIVE DEFENSES NOS. 2, 7, 8, 10, AND 12
AND MEMORANDUM IN OPPOSITION TO ROCHE'S
MOTION FOR LEAVE TO AMEND ITS ANSWER

Amgen Inc. ("Amgen") respectfully submits this reply brief (i) in support of its motion to
strike the 2nd, 7th, 8th, 10th, and 12th Affirmative Defenses in the Answer filed by Defendants F.
Hoffmann-La Roche Ltd., Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively
"Roche") and (ii) in opposition to Roche's motion for leave to amend its Answer.

1. Roche's Inequitable Conduct defense should be stricken and Roche
should not be permitted to amend its Answer in the form proposed.

Roche's original inequitable conduct allegations suffer from a glaring lack of
particularity, as its motion to amend tacitly acknowledges by adding 51 new paragraphs of

inequitable conduct allegations.¹ Betrayed by the proposed amendment, Roche's defense as originally pled should be stricken.² There being no reason to belabor the deficiencies of Roche's original pleading, Amgen will focus its reply on the failure of Roche to rectify those deficiencies in its proposed amendment.

Roche's original inequitable conduct allegations suffered from two glaring deficiencies: (1) the failure to plead *with particularity* the "who, what, when, where, how" of *each* alleged instance of inequitable conduct, and (2) the improper use of open-ended allegations to leave *unspecified* the *set of all* acts, omissions, or misrepresentations that allegedly comprise its inequitable conduct defense. Because Roche's proposed amended Answer perpetuates both deficiencies, Roche should not be permitted to amend its Answer in the form Roche proposes.

As the following examples demonstrate, Roche's proposed amended Answer improperly casts its allegations in opened-ended terms and, in so doing, creates uncertainty and ambiguity about the set of acts, omissions, or misrepresentations that allegedly comprise its defense:

- "The patents-in-suit are unenforceable because individuals *including, but not limited to*, Michael Borun, Steven Odre and Stuart Watt" (¶ 43) [*Who else?*]
- "*As exemplified below, on numerous occasions* during the prosecution of these co-pending lines of applications, the examiner in one line of co-pending applications issued *rejections* to claims" (¶ 55) [*Who, what, when, where, and how as to "exemplified below, on numerous occasions"? Who, what, when, where, and how as to "rejections"?*]
- "Amgen's intent to deceive the patent office is further evidenced by the fact that *at least* Amgen's attorneys Steven Odre and Michael Borun" (¶ 57) [*Who else?*]
- "*Amgen, and those acting on its behalf* who were substantively involved in the prosecution of the patents-in-suit" (¶ 74) [*Who acted on Amgen's behalf?*]

¹ Roche's 12/8/06 Mem. in Opp'n to Amgen's Mot. to Strike, Ex. A at ¶¶ 38-88, Docket No. 161 [hereinafter "Roche's Br."].

² Although Roche asserts that striking its defective allegations is not a proper remedy, the law is plain that it is. *See Systemation v. Engel Indus., Inc.*, 183 F.R.D. 49, 51-52 (D. Mass. 1998).

- “*Amgen and its representatives*, in the course of foreign patent proceedings and before the FDA, relied on *statements and information . . .*” (§ 76) [*Who are “its representatives”? What, when, where, and how as to “statements and information”?*]
- “Amgen’s knowing and intentional failure to disclose material information from Amgen’s European opposition proceedings is *evidenced at least* by the direct involvement of Amgen attorneys Steven Odre and Stuart Watt in those proceedings . . .” (§ 83) [*Who else? What else?*]
- “In addition to the contradictory statements made by Amgen in the 1992 and 1994 Strickland declarations, *Amgen and its employees, including* even the named inventor of the Amgen EPO patents, have made *numerous statements*, in publications and to the FDA . . .” (§ 84) [*Who are “its employees”? What, when, where, and how as to the “numerous statements”?*]
- “*Additional internal documents* from Dr. Egrie provide evidence regarding glycosylation inconsistent with *the positions* that Amgen took during prosecution of its patents. (See AM-ITC 00828987-88).” (§ 87) [*What, when, where, and how as to the “additional internal documents”? What, when, where, and how as to “the positions”?*]
- “Additionally, in order to receive approval for its r-EPO drug, Amgen made *statements to the FDA* that directly contradict *the positions* Amgen took in arguing patentability of its EPO claims to the PTO.” (§ 88) [*What, when, where, and how as to the “statements to the FDA”? What, when, where, and how as to “the positions”?*]

Roche’s use of such vague, open-ended language defeats the requirement that it state with particularity both the substantive content of and all bases for its allegations. Such open-ended allegations of inequitable conduct have been rejected in other patent cases. For example, in *Astra Aktiebolag v. Genpharm Inc.*, the defendant had identified the prior art allegedly withheld to include “*at least* European Patent No. 124,495, Omeprazole Salts.”³ Plaintiff moved to strike defendant’s inequitable conduct defense. The *Astra* court held that the open-ended phrase “*includes at least*” did not sufficiently place plaintiff on notice of *any other* allegedly material omissions and ordered that phrase stricken.⁴

³ 2000 U.S. Dist. LEXIS 2513, at *4 (S.D.N.Y. Feb. 21, 2000) (emphasis added).

⁴ *Id.* at *4, 7.

Roche's repeated use of open-ended language defies both the letter and spirit of Rule 9(b)'s heightened pleading requirement. It wrongly implies that there are additional unstated bases for its inequitable conduct defense without ever pleading with particularity what those bases are. Such an artifice wrongly seeks to leave the door open for Roche to make a series of further, as yet unspecified allegations.⁵ Roche, once and for all, must provide full and fair notice to this Court and Amgen as to *all* of its theories and allegations underlying its inequitable conduct defense. Amgen should not be forced to guess as to the basis of Roche's defense nor forced to investigate through discovery what other unstated and unarticulated bases Roche seeks to assert.

Accordingly, Roche's 7th Affirmative Defense for inequitable conduct in its original Answer should be stricken, and Roche should not be permitted leave to amend its Answer to contain the various offending open-ended terms and ill-defined allegations shown in Exhibit A submitted herewith.⁶

2. Roche's Patent Misuse and Unclean Hands defenses should be stricken.

Roche's Opposition notwithstanding, its original and proposed amended Answers at most allege nothing other than inequitable conduct as a basis for its patent misuse and unclean hands defenses. To the extent that Roche's 2nd and 8th Affirmative Defenses are based on inequitable conduct, they too must be pled with particularity under Rule 9(b). Roche has not done so, as discussed above, and these defenses should therefore be stricken.

⁵ See *Stowe Woodward, LLC v. Sensor Prods., Inc.*, 230 F.R.D. 463, 468 (W.D. Va. 2005) ("Parties may not draw in a series of unspecified allegations on the coattails of a single particularized allegation.").

⁶ Submitted herewith as Exhibit A are pages of Roche's proposed amended Answer red-lined to identify instances of defective pleading of inequitable conduct.

3. Roche's Damages Estoppel defense should be stricken.

Roche premises its damages estoppel defense upon the false dilemma that Amgen was required to bring a claim for damages along with its claim for declaratory and injunctive relief, or else forfeit any and all rights to damages. Yet, elsewhere, Roche contends it cannot infringe Lin's Patents — and hence can cause no damages — unless and until the FDA approves the sale of peg-EPO.⁷ Even if Roche were to come forward and concede that it is currently infringing Lin's Patents — and is thus liable for damages — it cites no authority that required Amgen to bring its damages claim simultaneously with its declaratory and injunctive relief claim. To the contrary, as held in *Edward B. Marks Music Corp. v. Charles K. Harris Music Publishing Co., Inc.*, 28 U.S.C. § 2202 permits a declaratory relief claimant to seek further relief — including damages — *after* declaratory judgment has been entered.⁸

Significantly, Roche neither addresses 28 U.S.C. § 2202 nor distinguishes Amgen's authorities. It instead argues that a statement by Amgen's counsel constituted an express waiver of Amgen's right to damages.⁹ But that statement, a response to the Court's question as to whether this is a "jury case," merely clarified that Amgen's current claim for declaratory and injunctive relief should be resolved by this Court — not a jury: "As the claim is *currently* framed, it's an *equitable* case, it doesn't require a jury. There's no damage claim."¹⁰ Nothing in this statement waived Amgen's right under § 2202 to seek "further relief" — including damages — after declaratory judgment has been entered. Amgen has never said that there *will never* be a

⁷ See Roche's 4/11/06 Mem. in Supp. of its Mot. to Dismiss for Lack of Subject Matter Jurisdiction and Failure to State a Claim for which Relief May Be Granted at 11, Docket No. 45.

⁸ 255 F.2d 518, 522-23 (2d Cir. 1958); see also Amgen's 11/27/06 Mem. in Supp. of its Mot. to Strike at 13, Docket No. 154 [hereinafter "Amgen's Opening Br."].

⁹ Roche's Br. at 18.

¹⁰ 5/10/06 Mot. Hr'g Tr. at 33:22-23, Docket No. 82 (emphasis added).

claim for damages. If anything, by using the present tense and specifying “as currently framed,” this statement serves to preserve Amgen’s right to subsequently seek damages, a position underscored by the express allegations in Amgen’s Amended Complaint, which request “further relief” and relief under “§§ 2201 and 2202.”¹¹

Because Roche does not and cannot raise any legal or factual basis that estops Amgen from seeking damages, its 10th Affirmative Defense should be stricken.

4. Roche’s Equitable Estoppel Defense should be stricken.

In its Opposition, Roche mischaracterizes Amgen’s argument as asserting that Roche’s equitable estoppel defense must be pled with particularity. As Amgen explained in its motion, however, the defect in Roche’s equitable estoppel defense lies in Roche’s failure *and* inability to plead any facts sufficient to sustain it. The defense of equitable estoppel requires proof of three essential elements: (1) misleading conduct by the patentee, (2) reliance thereon by the alleged infringer, and (3) material prejudice to the alleged infringer.¹² Nowhere does Roche allege any specific act or statement of Amgen on which it reasonably relied to its detriment in bringing peg-EPO to market. Indeed, as Roche publicly admitted in 2003, it “should expect that [Amgen] will take us to court.”¹³ The failure of Roche’s Opposition to address this admission is dispositive. Because Roche cannot possibly contend that it reasonably relied to its detriment upon any act or statement by Amgen, its equitable estoppel defense should be stricken.

¹¹ Amgen’s 4/25/06 Am. Compl. For Declaratory J. of Infringement Prayer for Relief at ¶ d, ¶ 7, Docket No. 52. Notably, Roche itself seeks this form of relief in its own counterclaims against Amgen. Roche’s 12/8/06 Mem. in Opp’n to Amgen’s Mot. to Dismiss Roche’s Countercls. at 3, Docket No. 162.

¹² *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1028 (Fed. Cir. 1992).

¹³ 4/25/06 Decl. of Michael R. Gottfried, Ex. 19, Docket No. 54.

Seeking to divert attention away from its admission, Roche instead proffers the red herring that the 1998 Ortho/Aranesp[®] arbitration and 2001 settlement negotiations somehow misled it to believe that Amgen would not sue Roche as to its infringing peg-EPO activities. Setting aside for now Roche's misrepresentation of these events, they both occurred long *before*, and plainly had no effect upon, Roche's clear expectation in 2003 that Amgen would sue it for infringement of the Lin Patents. Notably, neither Roche's original Answer nor its proposed amended Answer incorporates its characterization of these events into its equitable estoppel defense.

Roche cannot have it both ways: it cannot complain that Amgen "has vigorously enforced its patent portfolio against other companies for the past twenty years,"¹⁴ *including Roche's licensor and subsidiary*,¹⁵ state publicly that it expected to get sued by Amgen, and then claim surprise at having been sued. As no interest is served by requiring the parties to address such an absurd and fruitless defense, Roche's 12th Affirmative Defense should be stricken.

For the foregoing reasons, Amgen respectfully requests that:

1. The Court strike Roche's 2nd (patent misuse), 7th (inequitable conduct), 8th (unclean hands), 10th (damages estoppel), and 12th (equitable estoppel) Affirmative Defenses; and
2. Should Roche be permitted an opportunity to amend its Answer, it should not be permitted leave to amend in the form proposed. Amgen respectfully requests that Roche be ordered to:
 - (a) specify "the who, what, when, where, and how" of all alleged misrepresentations and omissions;
 - (b) eliminate all instances of open-ended language and unspecified allegations in the manner set forth in Exhibit A submitted herewith; and

¹⁴ Roche's 11/6/06 Counterclaims at ¶ 27, Docket No. 140.

¹⁵ Amgen's Opening Br. at 17.

(c) plead with particularity the factual bases for its misuse and unclean hands defenses to the extent that they are based on allegations of inequitable conduct.

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Respectfully Submitted,
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CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of electronic filing and paper copies will be sent to those indicated as non-registered participants on December 15, 2006.

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