UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, vs. F. HOFFMANN-LA ROCHE LTD; ROCHE DIAGNOSTICS GmbH; and HOFFMANN-LA ROCHE INC. Defendants.	CIVIL ACTION No.: 05-CV-12237WGY

MEMORANDUM OF COUNTERCLAIM-PLAINTIFF ROCHE IN SUPPORT OF ITS MOTION TO AMEND ITS COUNTERCLAIMS AND AFFIRMATIVE DEFENSES

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I. INTRODUCTION AND SUMMARY OF AMENDED SHAM LITIGATION AND EQUITABLE ESTOPPEL ALLEGATIONS

Counterclaim-plaintiffs F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche"), respectfully submit this memorandum of law in support of its motion to amend the counterclaims asserted against Amgen, Inc. ("Amgen"), to charge that Amgen has brought sham litigation against Roche in violation of the antitrust laws, and to add the affirmative defense of equitable estoppel.

As set forth in detail in Roche's [Proposed] First Amended Answer and Counterclaims ("Am. Cclaims")[1], Amgen has engaged in a comprehensive scheme to squelch the competitive threat posed by Roche's CERA (short for Continuous Erythropoiesis Receptor Activator) drug and maintain Amgen's monopoly power. Amgen's anticompetitive conduct includes contractual practices and threats designed to foreclose Roche from potential CERA customers and enforcement of fraudulently-obtained patents before this Court.

Importantly, and the subject of these amendments, including to Count II, Amgen also has engaged and continues to engage in sham litigation, illegal conduct that anticompetitively hinders Roche and facilitates Amgen's continued dominance of the relevant markets. As detailed in the amended counterclaims (Am. Cclaims ¶¶ 45-60, 92-95), Amgen sued Roche before the International Trade Commission ("ITC") without an objective basis for obtaining relief and solely for the purpose of harming Roche and competition through the litigation process, rather than its outcome. As Amgen knew, its ITC action was doomed from the start because Amgen lacked evidence that Roche was

[1] Roche's Proposed Amended Pleading is attached as Exhibit A to its motion for leave. Exhibit B is a redlined version of that document.

actually importing or had contracted to import CERA into the United States for a use outside 35 U.S.C. §271(e)'s safe harbor, which exempts from the statutory definition of infringement uses of a product reasonably related to the process for obtaining Food and Drug Administration ("FDA") approval (Am. Cclaims ¶ 47).

An infringing importation, or commercial sale for importation of infringing product, is a prerequisite for obtaining relief from the ITC. Thus, in contrast to this Court, which can award declaratory or injunctive relief concerning future infringement, the ITC has never granted relief when neither an infringing importation nor contract for commercial sale was demonstrated (Am. Cclaims ¶ 49). Moreover, although this Court had to take Amgen's allegations of present infringement as true here, the sham litigation doctrine tests whether there was a basis for the allegations in the first place. These two critical distinctions between this case and the now-dismissed ITC action explain why Amgen's ITC action was a sham even though Amgen, this Court has ruled, sufficiently pled patent claims here.

Despite knowing that it lacked a basis for seeking ITC relief, Amgen put Roche through the wringer of a costly ITC proceeding until the Administrative Law Judge ("ALJ") dismissed the case on summary judgment, concluding that Amgen – after intensive, expensive, and wasteful discovery – adduced no evidence of any infringing importation, or commercial sale for importation, by Roche. Amgen pressed its baseless ITC action, as the counterclaims explain, solely to impose costs on Roche, to attempt to disrupt Roche's ability to secure FDA approval and CERA customers, and to thereby facilitate Amgen's continued dominance in the relevant ESA markets – classic sham litigation in violation of the antitrust laws (Am. Cclaims ¶ 57).

Amgen achieved its anticompetitive aim. Amgen's sham ITC case imposed enormous costs on Roche, required Roche to produce 16 employees for deposition in Europe and the United States, taking them away from company duties, including business related to CERA's FDA approval and launch, and harassed potential CERA customers with subpoenas (Am. Cclaims ¶¶ 58-60). Meanwhile, not a single Amgen employee was deposed in the ITC proceeding by the time the ALJ put an end to it. Amgen's conduct raised already high entry barriers by increasing the cost to Roche of competing against Amgen's ESA products and harmed competition and consumers (Am. Cclaims ¶¶ 57-60, 78, 81).

Amgen has repeated in this case its tactic of pursuing baseless claims solely to harass Roche and anticompetitively raise its costs (Am. Cclaims ¶¶ 61-66, 95-96). Specifically, the Federal Circuit in August 2006 held that the claims of Amgen's '080 patents do not cover a glycoprotein with a 165 amino acid sequence. Amgen nonetheless continues to press three '080 patent infringement claims even though Amgen knows (from Roche's BLA For CERA, in Amgen's possession since June 2006 (ITC-R-BLA-000042029)) that CERA's EPO starting material consists of 165 amino acids (Am. Cclaims ¶ 64). Moreover, this Court held that claim 9 of the '933 was invalid for lack of definiteness. *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 165 (D. Mass. 2001), *aff'd in part*, 314 F.3d 1313, 1342 (Fed. Cir. 2003). The Federal Circuit in its August 2006 opinion reiterated this holding that claim 9 of the '933 patent was invalid. *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1299 n.5 (Fed. Cir. 2006) Although Roche anticipated that Amgen would drop the '080 claims and claim 9 of the '933 patent following the Federal Circuit's rulings, Amgen continues to

wield them to demand onerous discovery even though Amgen admits it has no basis for doing so (Am. Cclaims ¶ 66). Amgen's maintenance of its '080 infringement claims and claim 9 of the '933 patent without any prospect of obtaining relief can only be explained as intended to raise Roche's costs and thereby anticompetitively raise already high barriers to entry (Am. Cclaims ¶ 67).

This Court should permit Roche's proposed amendment. The Court dismissed Roche's sham litigation claim *without* prejudice and granted Roche leave to replead. Roche has done so in great detail in the accompanying proposed amended counterclaims. Roche's amended allegations state claims upon which relief can be granted and thus, contrary to what Roche anticipates Amgen will argue, are not futile. Moreover, Amgen could not possibly claim prejudice from the amendment. This case is still early in discovery, which the Court only recently ordered to "go forward hammer and tongs" (Hearing Tr. at 20 (Dec. 20, 2006, Docket No. 196)).

Finally, this Court also dismissed Roche's proposed 12th affirmative defense of equitable estoppel *without* prejudice and invited Roche with the opportunity to "articulate" the defense in a more detail. *Id.* Roche has done so in its proposed pleading by demonstrating a course of conduct by Amgen beginning in 1991 which led Roche to the reasonable expectation that Amgen would not enforce the patents-in-suit against Roche's MIRCERA™ product. *See* Amended Affirmative Defense ("Am. Affdef.") No. 12, at ¶ 98.

II. ARGUMENT

A. Standards for Granting the Proposed Amendment

Rule 15(a) of the Federal Rules of Civil Procedure provides that leave to amend pleadings "shall be freely given when justice so requires." As the First Circuit instructs,

a court should liberally allow an amendment to the pleadings if prejudice does not result. *See, e.g.*, *Maddalone v. Okada Shosen, KK*, 756 F.2d 886, 887 (1st Cir. 1985). The Court should grant the proposed amendment here because Roche's sham litigation claims are not futile and because Amgen will suffer no prejudice.

B. Roche's Sham Litigation Claims are Sufficiently Plead and Not Futile

Roche's amended sham litigation claims sufficiently plead each element of the offenses of monopolization and attempted monopolization under Section 2 of the Sherman Act. Amgen's illegal litigations are not immune from antitrust scrutiny under *Noerr-Pennington*, because Roche alleges (Am. Cclaims ¶¶ 45-56, 66-67) that each is (i) objectively baseless; and (ii) subjectively intended by Amgen to harm Roche "through the use of the governmental *process* – as opposed to the *outcome* of that process – as an anticompetitive weapon." *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc. (PRE)*, 508 U.S. 49, 60-61 (1993). Roche further alleges the elements of Amgen's monopoly power and/or a dangerous probability of its achievement, harm to competition in the relevant markets from Amgen's anticompetitive acts, antitrust injury, and damages to Roche from Amgen's conduct (Am. Cclaims ¶¶ 23, 35, 58-59, 67, 78-82, 92-98). Although no heightened pleading standard applies to sham litigation claims (*see* Roche Mem. in Opposition to Amgen's Motion to Dismiss at 15 (Dec. 8, 2006, Docket No. 162) ("Roche Op.")), Roche's allegations undoubtedly would meet one.

Amgen nonetheless has in prior briefing advanced a number of arguments why Roche's sham litigation claims are nonetheless legally deficient. Those arguments are without merit.

1. Amgen's ITC Action was Objectively Baseless Because Amgen Had No Basis for Seeking Relief under Any Theory

The Proposed Amended Counterclaims explain that Amgen's ITC action was objectively baseless for two reasons. *First*, Amgen had no basis to assert any Roche importation of CERA that fell outside of § 271(e)(1)'s safe harbor, which by statute defines non-infringing activities, and the ITC's ability to grant relief based on actual importation is limited to importation, or sale for importations, of "articles that infringe" a patent. 19 U.S.C. § 1337(a)(1)(B) (Am. Cclaims ¶¶ 47-48). *See Enercon v. ITC*, 151 F.3d 1376, 1380 (Fed. Cir. 1998); *see also In re Certain Mech. Lumbar Supports & Prods. Containing Same*, Inv. No. 337-TA-415, 1999 ITC LEXIS 229, at *101-02 (U.S.I.T.C. June 29, 1999); *In re Certain Fluidized Bed Combustion Sys.*, Inv. No. 337-TA-213, 1985 ITC LEXIS 80, at *13 (U.S.I.T.C. March 21, 1985) (where plaintiff unable to prove infringing importation "[t]he Commission lacks the authority to issue a declaratory judgment before the product in issue has been imported").

Second, Amgen had no basis to seek ITC relief based on a theory of "imminent" infringement because the ITC has never awarded such relief absent a commercial "sale for importation," *In re Certain Variable Speed Wind Turbines & Components Thereof*, Inv. No. 337-TA-376, 1996 ITC LEXIS 251, at *31 (U.S.I.T.C. May 30, 1996), which Amgen could not validly claim. Moreover, Amgen could not objectively assert that Roche's activities met a narrow circumstance *Wind Turbines* speculated in dicta might permit imminence relief absent a commercial sale for importation. Tellingly, both the ALJ and ITC summarily rejected Amgen's baseless imminence argument. Unlike this Court's broad discretion to award relief directed to future infringement, the ITC's ability

to grant relief is constrained by the statute it enforces, which requires either a commercial sale for importation or importation of infringing articles (Am. Cclaims ¶¶ 50-54).

Amgen's response on actual infringing importation is that "the facts show[ed]," and the ITC found, a basis to believe Roche activities fell outside § 271(e)(1) (Amgen Reply in Support of Motion to Dismiss at 12 (Dec. 18, 2006, Docket No. 182) ("Amgen Rep.")). This is both false and misconceived. The argument is false because none of the activities Amgen cites are infringing activities – which is precisely what the ITC recognized when, after wasteful discovery, it summarily rejected Amgen's case. And as the ITC explained in *In re Certain Radios & Components Thereof*, 2002 ITC LEXIS 696 (U.S.I.T.C. Nov. 8, 2002), opening an investigation does not establish probable cause or "make[] the complaint per se not objectively baseless." *Id.* at *14. The argument is misconceived because Amgen confuses the standard for ***pleading*** a violation with a ***sham***. That a case is sufficiently pled ***or even survives summary judgment*** is insufficient to defeat allegations that the action was a sham, because the issue for sham is the ***basis*** for the allegations pled or the facts asserted. *See In re Relafen Antitrust Litig.*, 360 F. Supp. 2d 166, 182 (D. Mass. 2005) (Young, CJ.) (rejecting defendant's "assertion that its survival of summary judgment, without more, compelled the conclusion that its claim was not objectively baseless"); *El Cajon Cinemas, Inc. v. Am. Multi-Cinemas, Inc.*, 832 F. Supp. 1395, 1398 (S.D. Cal. 1993) (same).

This explains why Amgen's ITC case was a sham even though this Court has upheld Amgen's allegations of present infringement as sufficiently pled. This Court reasoned that it had to accept Amgen's allegations of present infringement as true (Order Denying Roche's Motion to Dismiss at 3, 9-10, 15 n.6 (Oct. 20, 2006, Docket No. 121)).

By contrast, Roche's sham litigation allegation, which also must be taken as true, is that Amgen's ITC allegations ***lacked a basis when made***.

Amgen's argument that it had a basis for seeking "imminence" relief is similarly unavailing. As the ALJ observed in rejecting Amgen's imminence argument (which the ITC summarily affirmed), the ITC has ***never*** ordered imminence relief absent a commercial "sale for importation," a circumstance Amgen had no basis to contend existed. Grasping at straws, Amgen has pointed to dicta in *Wind Turbines*, which speculated that "there could be an imminent importation without a sale," *id.* at *31. This dicta, Amgen suggests, supports a contention that its lack of a right to relief from the ITC was "unsettled" (Amgen Rep. at 12-13).

Amgen's argument is factually and legally flawed. It is factually flawed because Roche's allegations, which must be taken as true, include (Am. Cclaims ¶ 50) that Amgen had no objective basis for asserting any facts remotely like the situation *Wind Turbines* suggested – where the suspected infringer has a "stockpile" overseas it is about to import. *Wind Turbines*, 1996 ITC LEXIS 251, at *31. Roche's allegations that Amgen could not meet even the *Wind Turbines* dicta is ***alone*** sufficient to reject Amgen's *Wind Turbine* argument and find its imminence argument baseless. Amgen's argument that it had a basis for expanding the relief available from the ITC is also legally flawed. As *Wind Turbine* itself observed, ***no*** ITC case has granted relief absent a commercial "sale for importation," a circumstance Congress enshrined in the ITC's statute in 1988. *Id.* The absence of such authority negates any objective basis for Amgen to argue that the ITC ***broadly*** could order "imminence" relief in a manner similar to this Court (*i.e.*, without a commercial sale). Although Congress may not have intended to limit the

remedies available to the ITC when in 1988 it added "sale for importation" to the ITC's statute (Section 337; 19 U.S.C. § 1337(a)(1)(B)), the language Congress selected does not evidence an intent to ***broaden*** available remedies. At the ***very*** least, there is no objective basis for Amgen to have sought imminence relief ***beyond*** the narrow *Wind Turbine* dicta. The ITC recognized these fatal legal and factual defects when it summarily ordered the ALJ to focus on the § 271(e)(1) issue "at an early date," ignored Amgen's imminence argument, and affirmed the ALJ's rejection of Amgen's imminence argument.

2. Amgen's Collection of Other Objections to Roche's ITC Sham Claim are Baseless

The other objections Amgen has advanced to Roche's straightforward sham litigation claim are equally baseless.

a. ***Harm to Competition***. Amgen's suggestion that Roche fails to allege competitive harm from Amgen's sham litigation (Amgen Rep. at 13) is flatly wrong. The Amended Complaint sets forth in detail how Amgen's sham ITC action imposed unjustifiable obstacles upon, and raised the entry costs of, an entrant (Roche) uniquely situated to dissipate Amgen's monopoly and near-monopoly power in the relevant ESA markets (Am. Cclaims ¶¶ 57-60, 78, 81). The Amended Complaint explains how Amgen thereby harmed competition and consumers by raising already high entry barriers and hindering CERA's entry. It is settled that allegations of baseless, cost-raising litigation by an actual or would-be monopolist that burdens rivals, whether they are new entrants, see *Novo Nordisk of N. Am., Inc. v. Genentech, Inc.*, 885 F. Supp. 522, 525 (S.D.N.Y. 1995), or present competitors, *see, e.g.*, *Handgards, Inc. v. Ethicon, Inc.*, 601 F.2d 986, 996-97 (9th Cir. 1979); *Kearny & Trecker Corp. v. Cincinnati Milacron Inc.*, 562 F.2d 365, 374 (6th Cir. 1977), sufficiently avers competitive harm, even if the sham litigation

does not preclude entry. A rule requiring complete preclusion of rivals to harm competition would be perverse and, not surprisingly, finds no support in the cases. *See, e.g.*, *United States v. Microsoft Corp.*, 253 F.3d 34, 69, 78-80 (D.C. Cir. 2001) (en banc) (*per curiam*); *Handgards*, 601 F.2d at 966-97; *Kearny*, 562 F.2d at 374. The counterclaims here, moreover, further allege that Amgen's baseless ITC action raised already high entry barriers in the relevant markets and hindered Roche's ability to dissipate Amgen's monopoly power (Am. Cclaims ¶¶ 57-60, 78, 81). Such allegations, too, aver harm to the competitive process and not merely harm to a competitor. *See* Roche's Surreply to Amgen's Reply Brief in Support of its Motion to Dismiss at 4 (Dec. 27, 2006, Docket No. 198) ("Roche Surreply") (citing *inter alia* Areeda).

b. ***Standing***. Roche has previously explained why it has standing to seek declaratory and injunctive relief for all its claims, including sham litigation, and sufficiently alleges antitrust injury. *See* Roche Op. 4-10; Roche Surreply at 1-5. Amgen's further arguments against Roche's standing, made in its opposition to Roche's Surreply, are meritless. As just explained, there is no basis for Amgen's assertion (Amgen's Opposition to Roche's Motion for Leave to File a Surreply at 7 (Dec. 26, 2006, Docket No. 197-1) ("Amgen Sur. Op.")) that litigation costs flowing from sham litigation must ***preclude*** entry to establish harm to competition or provide a basis for standing to seek damages. *See Novo Nordisk*, 885 F. Supp. at 525.

Moreover, Roche independently can establish standing to seek damages based on its allegations that Amgen's baseless litigation has hindered CERA's entry. Amgen's argument that FDA approval is an absolute prerequisite for seeking such damages (Amgen Sur. Op. at 1) is flawed. That argument, premised on Amgen's contention that

the "intent and preparedness" test applies ***only*** to claims for injunctive or declaratory relief and not claims seeking damages (*id.*), is refuted by numerous cases applying the test to determine the standing of not-yet-entered plaintiffs to seek non-speculative damages.[2] Indeed, "[t]he whole purpose of the 'intention and preparedness' test is to allow recovery of ***damages*** in cases where the plaintiff has not entered the business in which he is seeking lost profits." *JamSports & Entm't, LLC v. Paradama Prods., Inc.*, 2004 WL 2966947, at * 5 (N.D. Ill. Nov. 24, 2004) (emphasis added).

The "intent and preparedness" test thus applies when damages hinge on future FDA approval. *See, e.g., Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 806-08 (D.C. Cir. 2001) (applying "intent and preparedness" test to determine whether Biovail "can sufficiently plead ***an injury or*** a threatened injury" including damages and explaining test requires that FDA approval be probable (emphasis added)); *XeChem, Inc. v. Bristol Myers-Squibb Co.*, 274 F. Supp. 2d 937, 943-44 (N.D. Ill. 2003) (applying *Andrx* to require timely and likely FDA approval and upholding standing to assert damages claim), *rev'd on other grounds*, 372 F.3d 899 (7th Cir. 2004) (sustaining

[2] *See, e.g., Amtrol, Inc. v. Vent-Rite Valve Corp.*, 646 F. Supp. 1168, 1177-78 (D. Mass. 1986) (finding standing to assert damages claim based on "intent and preparedness" to enter relevant market) (Young, J.); *Hecht v. Pro-Football, Inc.*, 570 F.2d 982, 987 (D.C. Cir. 1977) (same); *Bourns v. Raychem Corp.*, 331 F.3d 704, 711-12 (9th Cir. 2003) (reversing damages claim because of ***lack*** of intent and preparedness). Amgen's implicit premise that a hindered new entrant can seek damages only if ***all*** conditions for entry, save those denied by the defendant's conduct, have been satisfied is refuted by this line of cases. *See, e.g., JamSports & Entm't, LLC v. Paradama Prods., Inc.*, 2004 WL 2966947, at *5 (N.D. Ill. Nov. 24, 2004) (rejecting a "full financing" requirement). Finally, in *Novo Nordisk*, the plaintiff chose to seek as damages only litigation costs and not damages that presupposed FDA approval and eventual entry. *See* 885 F. Supp. at 525.

damages claim).[3] Because Roche's allegations sufficiently aver that FDA approval is likely in a reasonable period, Roche easily meets the intent and preparedness test (Roche Surreply at 2) and thus has standing to seek damages and declaratory relief even apart from the past injury associated with the costs of defending against Amgen's baseless action.

Contrary to Amgen's suggestion, *Andrx* and *XeChem*, which held the "intent and preparedness" test can be met, and thus standing to seek damages satisfied, by allegations of probable FDA approval, cannot be distinguished as involving conduct that precluded such approval. For one thing, the conduct in *XeChem* allegedly merely *discouraged* the plaintiff from entering (including seeking FDA approval) but did not bar FDA approval. *See* 274 F. Supp. at 943-44. For another, the "intent and preparedness" test concerns the ***causal link*** between the defendant's bad acts (some of which included conduct that delayed FDA approval) and the alleged harm (lost profits from delayed or impeded future entry). *See, e.g.*, *Andrx*, 256 F.3d at 806 (analyzing intent and preparedness under causation). So too here, if FDA approval of CERA is likely, then the damages presupposing such approval flow from Amgen's acts. That the entry-hindering acts here (including sham litigation and attendant intimidation of Roche's partners and potential customers) are different from those in *Andrx* and *XeChem* is simply a distinction without difference.

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[3] Amgen mis-describes *Andrx* in asserting that the court limited its application of the "intent and preparedness" doctrine – including its ruling that the test could be met by allegations of probable FDA approval – to Biovail's claim for injunctive relief. The court reversed the dismissal with prejudice as to damages as well. *See Andrx*, 256 F.3d at 808, 815 (explaining that Biovail's entitlement to damages too required demonstrating "intent and preparedness" to enter). *XeChem* thus correctly read *Andrx* to hold that FDA approval is not a prerequisite for seeking damages. 274 F. Supp. at 943 n.2.

c. ***Affirmative Defense***. Amgen argues that its ITC claim of actual infringement was not baseless because § 271(e)(1) is an affirmative defense (Amgen Rep. at 12). But it is settled that a sham litigation claim can be based on the defendant-in-suit having a valid defense that the plaintiff has no objective basis to contest. *See, e.g.*, *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408, 426-27 (D. Del. 2006) (invoking *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1070 (Fed. Cir. 1998) to hold that a sham litigation claim may be based on the patentee's pursuit of an infringement claim with knowledge that the defendant possesses a good inequitable conduct defense); *Int'l Motor Contest Ass'n, Inc v. Staley*, 434 F. Supp. 2d 650, 679 (N.D. Iowa 2006) (sham litigation claim based in part on copyright holder seeking infringement outside statute of limitations period). This makes perfect sense because, as explained, sham litigation concerns the basis for the litigation, not whether the plaintiff has pled all elements of its *prima facie* case.

d. ***"Intervening" Governmental Action***. Finally, Amgen contends that any harm to Roche flows from discretionary ITC decisions (such as allowing discovery) and not Amgen's illegal litigation. This contention is entirely misconceived. The "ministerial" act doctrine pertains to whether *Noerr* immunity applies in the first place; not whether that immunity is lifted because the suit is a "sham." *See* Roche Op. at 17. Moreover, as *Certain Radios* teaches, *see supra* p.6, the opening of an ITC investigation is a ministerial act and does not reflect a finding of probable cause. Finally, Amgen's argument that the ITC staff's discretion to permit certain discovery eliminates harm suffered from enduring the litigation process turns the sham litigation doctrine on its head. The sham litigation offense, after all, concerns harm flowing from forcing a

defendant to endure the costs of the "litigation process." *PRE*, 508 U.S. at 60-61. That Amgen's baseless allegations induced the ITC to grant discovery – which proved those allegations wanting – is precisely the harm that the sham litigation doctrine antitrust offense designed to guard against. It is no wonder that Amgen can cite no authority for its perverse argument.

3. Amgen's Infringement Claims based on the '080 patent and claim 9 of the '933 patent are a Sham

Roche's amendments add allegations that Amgen's three claims of infringement of the '080 patent and claim 9 of the '933 patent are a sham because Amgen is pressing those claims even though the Federal Circuit removed the legal basis for those claims and even though Amgen can articulate no basis for those claims (Am. Cclaims ¶¶ 61-67, 96-97). Specifically, Amgen's three '080 infringement claims presuppose a 166 amino-acid sequence molecule, as the Federal Circuit confirmed in *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1308 (Fed Cir. 2006). Yet Roche disclosed in its CERA BLA, which Amgen has had since June 2006, that CERA's EPO starting material contains 165 amino acids (ITC-R-BLA-00004029).

In addition, claim 9 of the '933 has already been held invalid for lack of definiteness by this Court and the Federal Circuit. *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 165 (D. Mass. 2001), *aff'd in part*, 314 F.3d 1313, 1342 (Fed. Cir. 2003); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1299 n.5 (Fed. Cir. 2006) ("As noted above, in *Amgen II*, we affirmed the ruling of the district court in *Amgen I* that claims 1, 2, and 9 of the '933 patent are invalid. *Amgen II*, 314 F.3d at 1342.").

There was no reason for Amgen to bring, and certain now no reason to ***press***, the '080 claims and claim 9 of the '933 patent except anticompetitively to hinder Roche and impede CERA's entry through baseless litigation.

Roche did not include these detailed allegations in its original Answer and Counterclaims because Roche assumed that Amgen would withdraw these claims in light of the Federal Circuit's August 2006 decision, which confirmed their lack of legal basis.[4] But rather than withdraw these claims, Amgen continues to ***press*** them. In its interrogatory responses, which post-date briefing on Amgen's motion to dismiss, Amgen defends doing so by arguing that the Federal Circuit's decision is "not final" and that Amgen needs discovery to "fully characterize" CERA (Amgen Response to Defendant's First Set of Interrogatories 3-4 (Jan. 9, 2007) (Attached hereto as Ex. C)).

In other words, Amgen now admits that it has ***no*** basis for maintaining the '080 claims and claim 9 of the '933 patent and merely wants to employ them as a harassing discovery tool. This conduct – which seeks to harm Roche, competition, and consumers through the litigation *process* rather than through a reasonable prospect of a favorable *outcome* – is the paradigm of sham litigation. As Amgen has only further demonstrated its anticompetitive intent by maintaining the infringement claims of the '080 patent and claim 9 of the '933 patent rather than withdrawing them, Roche was constrained to add the sham litigation claim of the '080 and '933 patents in its amended counterclaims.

Roche anticipates that Amgen will advance some or all the arguments discussed above in connection with Roche's ITC sham litigation claim to argue that the claim based

[4] Roche did allege that Amgen "not only engaged in sham litigation before the ITC, but also persists in doing so in this Court" (Roche Answer and Counterclaims ¶ 49 (Nov. 6, 2006, Docket No. 140)) in anticipation of possibly adding these further allegations if Amgen continued to press the '080 claims, which it has.

on the '080 patent is futile. Those arguments would be baseless for the reasons identified above. Moreover, the allegations relating to the '080 patent evidence Amgen's subjective intent to harm Roche through the litigation process. Accordingly, the sham litigation allegations relating to the '080 patent comprise further support for Roche's allegation that Amgen, in bringing the ITC action against Roche, subjectively intended to harm Roche through the litigation process and without legitimate basis.

C. Roche's Equitable Estoppel Defense Is Sufficiently Pled And Not Futile

In patent cases, the affirmative 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 . . . ."). Moreover, 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.

At the December 20, 2006 hearing, the Court dismissed Roche's proposed 12th affirmative defense of equitable estoppel, but invited Roche with the opportunity to replead the defense upon a better showing of facts. *See* (Hearing Tr. at 20 (Dec. 20, 2006, Docket No. 196)). Roche has done so in its proposed pleading by demonstrating a course of conduct by Amgen spanning several years which led Roche to the reasonable expectation that Amgen would not enforce the patents-in-suit against Roche's MIRCERA™ product. *See* Amended Affirmative Defense ("Am. Affdef.") No. 12, at ¶ 98.

Specifically, as early as 1991, Amgen knew that its patents could not claim generic products covering EPO analogs, i.e., derivatives. *See Amgen v. Chugai*, 927 F.2d 1200, 1214 (Fed. Cir. 1991) ("It is not sufficient, having made the gene and a handful of analogs whose activity has not been clearly ascertained, to claim all possible genetic sequences that have EPO-like activity. Under the circumstances, we find no error in the court's conclusion that the generic DNA sequence claims are invalid under Section 112."). By 1998, Amgen was telling the world during its arbitration with Johnson & Johnson that Amgen's derivative EPO product, Aranesp, was not EPO, and not part of the product license of the patents-in-suit. *See* Am. Affdef. No. 12 at ¶ 98. By 2001, Amgen and Roche entered into a global license agreement by which Roche was allowed to sell EPO in Europe and PEG-EPO was considered a derivative product. *Id.* By 2002, when Aranesp was launched in the U.S., it was marked with only one of the patents-in-suit, the process patent '698, thereby indicating that for the majority of the claims, this derivative product was not covered by the claims. *Id.* As late as December 2005, Amgen

attorney, Rusty Day stated at the Federal Circuit that Amgen was not allowed to get claims to EPO analogs, i.e. derivatives. *Id.*

Therefore, for a span of more than 10 years, Amgen consistently misled the public and Roche that the patents-in-suit would not cover a derivative product, such as Roche's MIRCERA™. Based on Amgen's misconduct, Roche had a reasonable expectation that the patents-in-suit would not be asserted against its third generation derivative product. As a result, Amgen should be equitably estopped from asserting these claims against Roche.

D. Allowing the Amendment Will Cause no Prejudice to Amgen

Granting the Motion and allowing the amended pleading will cause Amgen no prejudice. This Court granted Roche leave to replead; the discovery period is not yet closed; and Amgen and Roche have been negotiating discovery requests that include items relevant to Roche's sham litigation claims.

III. CONCLUSION

For the reasons set forth above, the Court should grant Roche's Motion to Amend.

Dated: January 19, 2007
Boston, Massachusetts

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and HOFFMANN-LA ROCHE INC.

By its Attorneys,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and, due to the federal holiday, paper copies will be sent to those indicated as non-registered participants on the above-referenced date.

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