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 DISMISS ROCHE'S COUNTERCLAIMS COUNTS I-IX AND XII AND MEMORANDUM IN OPPOSITION TO ROCHE'S MOTION FOR LEAVE TO AMEND ITS COUNTERCLAIMS

Amgen respectfully submits this reply brief (i) in support of its motion to dismiss Counterclaims I-IX and XII of 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 Counterclaims.

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I. INTRODUCTION

Roche's Counterclaims I-IX and XII were deficient as originally pled, and Roche's proposed amendments fail to correct these pleading deficiencies.[1] Unable to sell peg-EPO without FDA approval — an absolute barrier to competitive entry unrelated to any act of Amgen — Roche lacks standing to seek damages for its antitrust-related Counterclaims I-IX. Notably, Roche persists in refusing to allege in its Amended Counterclaims that FDA approval is likely and imminent. Rather than correct this deficiency, Roche instead attempts to rely on statements made by Amgen — statements that Roche contests in its Answer and Counterclaims, and elsewhere. But the sufficiency of Roche's pleading must be measured by the allegations of its Answer and Counterclaims. Consequently, its allegations concerning sham litigation remain fundamentally flawed and Roche's proposed amendment does nothing to allege the additional geographical facts required to bring its state law antitrust counterclaims. Finally, while Roche's proposed amendments would add new allegations to bolster its inequitable conduct defense and *Walker Process* counterclaim, even its new allegations remain deficient, as more fully explained in Amgen's Reply Brief in Support of its Motion to Strike Roche's Affirmative Defenses.[2]

Because Roche's Proposed Amended Answer and Counterclaims do not address the pleading deficiencies in Roche's Counterclaims I-IX and XII, they should be dismissed and Roche should not be permitted leave to amend them in the form proposed.

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[1] Roche's proposed amendments to its counterclaims substantively add only two additional sentences to its *Walker Process* Counterclaim I. *See* Roche's 12/8/06 Mem. In Opp'n to Amgen's Mot. to Strike, Docket No. 161 [hereinafter "Roche's Strike Br."] and accompanying Ex. B [hereinafter "Roche's Proposed Am. Redlines"].

[2] *See* Amgen's 12/15/06 Reply Brief in Supp. of its Mot. to Strike at 1-4, Docket No. 171 [hereinafter "Amgen's Strike Reply Br."].

II. ARGUMENT

One undisputed fact is fatal to Roche's standing to seek antitrust damages: notwithstanding any act of Amgen, Roche is unable to compete in any alleged market due to its lack of FDA approval. Furthermore, Roche's potential standing to seek declaratory judgment relief is undermined by its stubborn refusal to allege that FDA approval is likely and imminent.

A. Roche Lacks Standing to Seek *Damages* for Counterclaims I-IX.

Roche offers two arguments why it has standing to seek antitrust damages, despite its regulatory exclusion from the alleged markets. First, Roche contends that litigation expenses related to its sham litigation and *Walker Process* claims confer standing to seek damages for ***all*** of its separate antitrust counterclaims.[3] This is wrong. At most, "litigation expenses" might confer standing to assert sham litigation or *Walker Process* claims, not the Sherman Act § 1 and § 2 claims Roche alleges in Counterclaims III, IV and V and its related state law antitrust counterclaims.[4] But even then, as more fully explained below, the litigation expenses Roche alleges are not the type of antitrust injury the law requires to bring sham litigation or *Walker Process* claims in circumstances such as these, because Roche is excluded from competing in the market by law, not by any act of Amgen.

Recognizing that litigation expenses alone cannot suffice to confer antitrust standing in this case, Roche offers a second argument, namely, that Roche's "intent and preparedness" to enter the alleged markets are sufficient to establish its antitrust standing for damages. But Roche

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[3] *See* Roche's 12/8/06 Mem. in Opp'n to Amgen's Mot. to Dismiss, Docket No. 162 [hereinafter "Roche's Br."] at 2, 5-6.

[4] *See CVD, Inc. v. Raytheon Co.*, 769 F.2d 842, 858 (1st Cir. 1985) (bad faith theory); *Handgards, Inc. v. Ethicon, Inc.*, 601 F.2d 986, 997 (9th Cir. 1979) (bad faith / sham litigation theories); *Kearney & Trecker Corp. v. Cincinnati Milacron, Inc.*, 562 F.2d 365, 372-74 (6th Cir. 1977) (*Walker Process* theory); *Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 90 F. Supp. 2d 540, 542-46 (D.N.J. 2000) (same); *Novo Nordisk of N. Am., Inc. v. Genentech, Inc.*, 885 F. Supp. 522, 524-27 (S.D.N.Y. 1995) (sham litigation and *Walker Process* theories).

mistakes the meaning of "preparedness," which requires that, but for some allegedly restraining act of the defendant, the claimant has the present right and ability to compete in the alleged market. Here, of course, Roche's allegations fail to establish its "preparedness" to enter the alleged markets, because they fail to allege FDA approval to do so.

1. Roche cannot rely on "litigation expenses" alone for standing.

Roche argues that its allegations of litigation expenses are alone sufficient to establish standing for its sham litigation and *Walker Process* claims and then, ignoring the differences between those claims and its other antitrust claims, suggests that its litigation expenses alone are sufficient to establish standing for any antitrust claim, including its Sherman Act § 1 and § 2 claims.[5] But a claimant must demonstrate that standing exists separately and independently for each claim and form of relief sought as of the time the complaint was filed.[6] In contrast to its *Walker Process* and sham litigation claims, Roche's Third, Fourth and Fifth antitrust counterclaims and its related state law antitrust counterclaims entail different elements of proof, allege different anticompetitive acts (*e.g.*, exclusive dealing, tying, threatening potential CERA customers)[7] and allege different antitrust injury ("diminished anticipated CERA sales" as well as litigation expenses).[8] Because Roche does not allege that it has FDA approval to import and sell peg-EPO, it has no standing to claim "diminished CERA sales," anticipated or otherwise. And

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[5] *See* Roche's Br. at 5-6.

[6] *See DaimlerChrysler Corp. v. Cuno*, 126 S. Ct. 1854, 1867-68 (2006); *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 184-85 (2000); *Tandy v. City of Wichita*, 380 F.3d 1277, 1284 (10th Cir. 2004).

[7] *See, e.g.*, Roche's 11/6/06 Counterclaims ¶¶ 52-56, Docket No. 140 [hereinafter "Counterclaims"]. For purposes of challenging these particular alleged anticompetitive acts, current market participants — in this case, ESA purchasers or FDA-approved competitors, such as Ortho — are superior plaintiffs. *Cf. Serpa Corp. v. McWane, Inc.*, 199 F.3d 6, 10 (1st Cir. 1999) ("Competitors and consumers in the market where trade is allegedly restrained are presumptively the proper plaintiffs to allege antitrust injury."); *Genetic Sys. Corp. v. Abbott Labs.*, 691 F. Supp. 407, 420-21 (D.D.C. 1988).

the allegations of litigation expenses incorporated by reference from its *Walker Process* and sham litigation claims are not the type of "antitrust injury" required to establish standing for its monopolization, attempt to monopolize and restraint of trade claims under the Sherman Act. Thus, even if litigation expenses alone conferred standing on Roche to assert its sham litigation and *Walker Process* claims, such expenses alone do not necessarily establish Roche's standing to seek damages for its other, separately-pled antitrust counterclaims.

Antitrust standing "is not a mere technicality. It is the glue that cements each suit with the purposes of the antitrust laws, and prevents abuses of those laws."[9] It is axiomatic that "[t]he antitrust laws . . . were enacted for the protection of *competition*, not *competitors*."[10] Thus, to establish antitrust standing, a plaintiff must establish that the "challenged conduct affected the prices, quantity or quality of goods or services, not just his own welfare."[11] Allowing litigants like Roche to circumvent this requirement by pursuing treble damages for all varieties of antitrust claims based solely on allegations of private harm resulting from alleged sham litigation or *Walker Process* fraud would effectively vitiate the standing requirements of antitrust injury and causation, opening the door to "endlessly proliferating suits" and "increasingly speculative determinations about the amount and source of remote injuries."[12] Because Roche does not allege that it has FDA approval to import and sell peg-EPO in the United States, it lacks standing

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[8] *See* Roche's Br. at 6.

[9] *HyPoint Tech., Inc. v. Hewlett-Packard Co.*, 949 F.2d 874, 877 (6th Cir. 1991).

[10] *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977) (internal quotations omitted); *see also Assoc. Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 538 (1983) ("[O]ur prior cases have emphasized the central interest in protecting the economic freedom of participants in the relevant market.").

[11] *Mathews v. Lancaster Gen. Hosp.*, 87 F.3d 624, 641 (3d Cir. 1996) (internal quotation omitted).

[12] PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 335g (2d ed. 2000).

to assert that any act of Amgen restrains its ability to compete in the alleged markets, or otherwise causes injury to competition in those markets.

As for Roche's sham litigation and *Walker Process* claims, this Court can and should hold that litigation expenses alone are insufficient to confer standing to seek antitrust damages in this case. Where, as here, Roche has not yet obtained the required regulatory permission to enter and compete in the alleged markets, and there is and can be no credible allegation that the expense of litigation will prevent it from doing so, Roche's pleading fails to allege facts which, if proven, would show that Amgen's ITC discovery caused any harm to competition. As shown by Roche's own allegations, it has the intent and the financial means to enter the alleged markets irrespective of any suit by Amgen. What currently restrains Roche from lawfully selling peg-EPO in the United States is its lack of FDA approval, not some act of Amgen, and that is why Roche currently lacks standing to claim that Amgen has caused Roche to suffer antitrust injury.

This was exactly the result reached in *Brotech Corp. v. White Eagle Int'l Techs. Group, Inc.*,[13] a recent case from the Eastern District of Pennsylvania dismissing the antitrust counterclaims of a potential competitor that had not yet received FDA approval. The *Brotech* court held that litigation expenses do not qualify as "antitrust injury" where there is no allegation that payment of those expenses had any present effect on competition, for example by negatively impacting the price, quantity or quality of a competitor's product, or by impeding a competitor's market entry.[14] Similarly, because Roche has not alleged, and cannot show, that its payment of

[13] 2004 U.S. Dist. LEXIS 11552 (E.D. Pa. June 21, 2004).

[14] *Id.* at *22-24; *see also Chip-Mender, Inc. v. Sherwin-Williams Co.*, 2006 U.S. Dist. LEXIS 2176, at *13-16 (N.D. Cal. Jan. 3, 2006) (similar). *Ben Venue*, which Roche cites, is not to the contrary. In contrast to *Brotech* and this case, the antitrust defendant in *Ben Venue* allegedly manipulated the regulatory structure to impede the claimant's market entry. *See Ben Venue*, 90 F. Supp. 2d at 545 ("For Bristol to insist that its generic competitors have no standing because they are not in the market, ***when Bristol itself foreclosed their access to it***, is meritless.") (emphasis added).

litigation expenses has or will harm any current competition in the market, it has no standing to seek antitrust damages for its sham litigation and *Walker Process* counterclaims.

Roche claims that *CVD* compels the opposite result.[15] But the facts in *CVD* are materially different from those here, and as this Court has noted: "it is the facts peculiar to each case around which the [antitrust standing] determination will revolve."[16] Importantly, the claimant in *CVD* — as in *Handgards* and *Kearney* upon which *CVD* relies — was a present competitor in the market and faced no regulatory barrier to market entry.[17] Moreover, the threatened litigation "would have proved ruinous to the newly formed corporation, and effectively foreclosed competition in the relevant market."[18] Given these significant differences, *CVD* is not controlling.[19]

2. Roche does not sufficiently allege the requisite "preparedness."

Roche also makes a secondary argument that, despite lacking FDA approval, it has sufficiently pled "intent and preparedness" to enter the market and therefore has standing to seek treble damages for all its antitrust counterclaims.[20] This argument is flawed because Roche has not adequately alleged "preparedness."

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[15] Roche's Br. at 6 n.5.

[16] *Amtrol, Inc. v. Vent-Rite Valve Corp.*, 646 F. Supp. 1168, 1177 (D. Mass. 1986).

[17] *CVD*, 769 F.2d at 847-48; *see also Handgards*, 601 F.2d at 988; *Kearney*, 562 F.2d at 374.

[18] *CVD*, 769 F.2d at 851.

[19] *Novo Nordisk*, a district court case cited by Roche, is not persuasive because it relies on *Handgards* but fails to provide ***any*** explanation, let alone a convincing one, why the holding in that case, which involved a current competitor who did not face any regulatory obstacle to market participation, should be extended to the present context. *See Novo Nordisk*, 885 F. Supp. at 524-25.

[20] Roche's Br. at 6-10.

The "intent and preparedness" test requires a claimant to allege facts showing that it is presently ready, willing, ***and able*** to enter the market,[21] or at least that it would have been able to do so but for the alleged anticompetitive acts. Roche has not sufficiently alleged the ***past or present*** preparedness necessary to seek damages for ***past or present*** antitrust injury, nor could it, because Roche is not able to enter the U.S. market due to its lack of FDA approval — an absolute barrier to entry that is not causally connected to any alleged act of Amgen. Roche's counterclaims fail even to establish standing to seek declaratory or injunctive relief for ***future*** antitrust injury under the "intent and preparedness" test because Roche has not alleged that FDA approval is "probable," nor when it is anticipated.[22]

The "intent and preparedness" cases cited by Roche are inapposite because they involved situations where the alleged anticompetitive acts themselves prevented or delayed the claimant's ability to enter the market,[23] or where there was no independent regulatory barrier to market

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[21] *See, e.g.*, *Indium Corp. of Am. v. Semi-Alloys, Inc.*, 781 F.2d 879, 882 (Fed. Cir. 1985) (affirming that claimant who was not "ready, willing, and able" to manufacture a competing product during the relevant time period lacked standing).

[22] *See Brotech*, 2004 U.S. Dist. LEXIS 11552, at *21 (dismissing counterclaims of potential competitor who failed to allege that FDA approval was probable and when such approval was anticipated); *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 274 F. Supp. 2d 937, 943 (N.D. Ill. 2003) (noting that the "preparedness" of a potential competitor lacking FDA approval would rest, in part, on "the likelihood of FDA approval" and "the time that it would take to obtain that approval"), *rev'd on other grounds*, 372 F.3d 899 (7th Cir. 2004); *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 808 (D.C. Cir. 2001) ("Biovail could have alleged its intent and preparedness to enter the market by claiming that FDA approval was probable.").

[23] *See Andrx*, 256 F.3d at 810 ("Although the 180-day provision of the Hatch-Waxman Amendments legally barred [claimant] from selling its product, Andrx's manipulation of the exclusivity period trigger date extended the legal bar."); *Xechem*, 274 F. Supp. 2d at 941 ("Plaintiffs allege that [defendant], however, caused them to postpone their entry into the paclitaxel market when [defendant] filed to extend Taxol's Orphan Drug Status with the FDA and applied for Taxol-related patents."); *Ben Venue*, 90 F. Supp. 2d at 545 ("For Bristol to insist that its generic competitors have no standing because they are not in the market, when Bristol itself foreclosed their access to it, is meritless."); *Hecht v. Pro-Football, Inc.*, 570 F.2d 982, 989 (D.C. Cir. 1977) ("[Claimant] argues that the Redskins frustrated his [market] entry by denying him use of RFK stadium, access to which was a condition precedent to his submitting a

entry.[24] Nor do the damages accrual cases cited by Roche further its cause.[25] To the contrary, these cases support Amgen's position because they recognize that "the cause of action for future damages, if they ever occur, will accrue only on the date they are suffered."[26] Thus, Roche's alleged damages for "diminished anticipated CERA sales"[27] will not accrue unless and until the FDA approves its peg-EPO product, MIRCERA.[28]

Roche's argument that Amgen is estopped from contesting "intent and preparedness" misses the point - this motion to dismiss turns on the allegations in Roche's Answer and Counterclaims, not on statements made by Amgen in other contexts. Because Roche has failed to allege both a past or present ***antitrust injury*** to its business or property, and a ***causal connection*** between the alleged antitrust injury and the alleged violation, Roche lacks standing to seek antitrust damages for Counterclaims I-IX.

B. Roche lacks standing to seek *declaratory relief* for Counterclaims I-IX.

As Roche acknowledged when it sought dismissal of Amgen's declaratory judgment claim,[29] "imminence" is a key requirement for standing to seek declaratory judgment relief.[30] Roche argues in its brief that it has demonstrated "a substantial likelihood" of entering the

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successful franchise application.").

[24] *Amtrol, Inc. v. Vent-Rite Valve Corp.*, 646 F. Supp. 1168 (D. Mass. 1986).

[25] Roche's Br. at 8.

[26] *N.C. Elec. Membership Corp. v. Carolina Power & Light Co.*, 780 F. Supp. 322, 329 (M.D.N.C. 1991).

[27] Roche's Br. at 6.

[28] *Cf. In re Relafen Antitrust Litig.*, 221 F.R.D. 260, 266-67 (D. Mass. 2004) (class damages accrued as of date of generic competitors' tentative FDA approval).

[29] *See* 5/10/06 Mot. Hr'g Tr. at 24:7-10, Docket No. 82 ([Roche:] "The real issue of actual controversy, rather than advisory opinion, is when there is an ***imminence*** of an actual infringement.") (emphasis added).

[30] *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-66 (1992); *McInnis-Misenor v. Me. Med. Ctr.*, 319 F.3d 63, 67-68 (1st Cir. 2003); *Berner v. Delahanty*, 129 F.3d 20, 23-24 (1st Cir.

market,[31] but there are no allegations in its Answer and Counterclaims to support this claim. Even in its proposed amended pleading, Roche stubbornly refuses to allege that FDA approval is likely and imminent.

Cognizant of this shortcoming in its pleadings, Roche attempts to shift the Court's attention to statements made by Amgen in other contexts. But as Roche correctly noted in its brief, a motion to dismiss is decided on "the well-pleaded facts as they appear in the complaint."[32] Thus, it would be entirely consistent for the Court to find a "sufficiently imminent" controversy for Amgen's patent claims but not for Roche's antitrust claims — Amgen's pleading sufficiently alleges that infringement has occurred or is imminent,[33] whereas Roche's pleading ***denies*** these allegations[34] and does not include any other allegations sufficient to show the imminence of its alleged antitrust injury, which, as explained above, depends entirely on FDA approval. Because Roche has not alleged facts sufficient to establish that its entry into any alleged market is likely and imminent, Roche lacks standing to seek declaratory relief for Counterclaims I-IX.[35]

1997).

[31] Roche's Br. at 9.

[32] Roche's Br. at 4 (quoting *Coyne v. City of Somerville*, 972 F.2d 440, 442-43 (1st Cir. 1992)).

[33] *See, e.g.*, Amgen's 4/25/06 Am. Compl. for Declaratory J. of Infringement ¶ 26-29, Docket No. 52 [hereinafter "Amended Complaint"].

[34] *See, e.g.*, Roche's Proposed Am. Redlines ¶¶ 27-29.

[35] Amgen refers the Court to Amgen's 11/27/06 Mem. In Supp. of its Mot. to Dismiss, Docket No. 151, regarding Roche's arguments regarding the alleged relevant markets. For purposes of this Reply, Amgen only points out the Sixth Circuit case on which Roche primarily replies, *NicSand, Inc. v. 3M Co.*, 457 F. 3d 534 (6th Cir. 2006) was vacated by the Sixth Circuit on November 22, 2006 and a rehearing en banc was granted (Order Granting Petition for En Banc Rehearing, *NicSand, Inc. v. 3M Co.*, 05-3431 (6th Cir. Nov. 22, 2006)).

C. Roche Has Failed to Properly Allege Sham Litigation, Despite Roche's Arguments Attempting to Narrow its Claim.

Roche's arguments attempt to narrow its sham litigation claim without proposing to amend its actual pleadings. To plead a claim for sham litigation, a litigant must allege:

- All of the elements of a substantive antitrust violation, ***plus***:
- Facts demonstrating that the challenged petitioning activity was "objectively baseless" in that no reasonable litigant could expect success on the merits, ***and***
- Facts demonstrating that the petitioner was subjectively motivated by an intent to use the act of petitioning — as opposed to the legislative or adjudicated outcome of the petitioning process — to interfere directly with the business relationships of a competitor.[36]

Roche has failed to plead a proper claim for sham litigation based on Amgen's District Court litigation. Roche does not allege that the litigation in this Court is objectively baseless and that no reasonable litigant could expect success on the merits. Roche should be required to acknowledge that it brings no such claim.[37]

Roche's opposition asserts that it is only pursuing a claim of sham litigation based on the parties' ITC action.[38] Moreover, while Roche's sham litigation counterclaim incorporates all of Roche's allegations regarding its *Walker Process* claim, including a knowing and willful attempt to enforce patents procured by fraud,[39] Roche's opposition suggests that these allegations do not underlie its sham litigation claim.[40] Roche has not alleged that Amgen had no reasonable basis

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[36] *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61 (1993).

[37] Roche's Counterclaims make several passing references to "sham litigation" in District Court. *See* Counterclaims ¶¶ 3, 49, 59, 76. Roche's Proposed Amended Counterclaims do not rectify this problem. *See* Roche's Proposed Am. Redlines ¶¶ 3, 49, 59, 77. These unsupported statements should be stricken from Roche's counterclaims.

[38] Roche states that "Amgen's uncognizable assertion that it believed its patents enforceable . . . . is irrelevant to Roche's sham litigation claim, which concerns Amgen's baseless invocation of the ***ITC's limited jurisdiction***." Roche's Br. at 16 n.16 (emphasis added).

[39] *See* Counterclaims ¶ 72; Proposed Am. Redlines ¶ 73.

[40] Roche's Br. at 15-16.

to believe that its patents were valid and enforceable when bringing the ITC action, and its opposition appears to concede this point as it must.[41] Nor does Roche allege that it was objectively unreasonable for Amgen to believe that its asserted patents cover peg-EPO. Roche's sham litigation counterclaim should be amended to clearly reflect this very narrow basis for Roche's claim. The fact that Amgen's EPO patents have previously been tested, upheld, and enforced against other products that also comprise human recombinant EPO — a fact that Roche strenuously seeks to obscure and avoid — cautions a more careful review of allegations of sham litigation based upon those same patents.[42]

1. Roche's allegations fail to establish that the ITC proceeding was objectively baseless.

Roche argues that its sham allegations satisfy the "baseless litigation" element of a sham claim, because it was objectively unreasonable for Amgen to allege actual infringement given Roche's affirmative defense under § 271(e)(1).[43] But Roche distorts the "baseless litigation" element of a sham claim. In order to allege a sham litigation, Roche must allege facts sufficient to show that Amgen's ITC petition was "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits."[44]

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[41] Roche's Br. at 16 n.16.

[42] As Amgen acknowledged in its Opening Brief, the Massachusetts district court has not applied a heightened pleading standard. *See* Amgen's Opening Br. at 12 n.43. But other Courts, in particular the Ninth Circuit, have applied heightened scrutiny of sham pleading. The First Circuit has not ruled on the issue. *Compare Franchise Realty Interstate Corp. v. S.F. Local Joint Executive Bd. of Culinary Workers*, 542 F.2d 1076, 1082-86 (9th Cir. 1976), *Or. Natural Res. Council v. Mohla*, 944 F.2d 531, 533 (9th Cir. 1991), *and Hydro-Tech Corp. v. Sundstrand Corp.*, 673 F.2d 1171, 1177 n.8 (10th Cir. 1982) (citing *Franchise* with approval), *with Skinder-Strauss Assoc. v. Mass. Continuing Legal Educ. Inc.*, 870 F. Supp. 8, 11 (D. Mass. 1994).

[43] *See* Roche's Br. at 16.

[44] *PRE*, 508 U.S. at 60.

According to Roche, "Amgen's uncognizable assertion that it believed its patents enforceable . . . is ***irrelevant*** to Roche's sham litigation claim . . . ."[45] In other words, Roche does not contend that Amgen lacked an objective basis to believe that its patents cover Roche's accused product and process. Moreover, in light of Roche's announced intent to enter the U.S. market, and its application for FDA approval to do so, Amgen objectively believed that Roche was then infringing or would imminently infringe Amgen's asserted patents, as its petition to the ITC plainly stated. Indeed, the ITC independently found that Amgen's petition provided an objective basis to investigate Roche's activities and permit limited discovery.

Roche's central contention is that "Amgen had, when it filed the ITC action, *no* basis to believe that any Roche conduct fell outside [the § 271(e)(1)] safe harbor."[46] But of course, the facts show otherwise. Not only did Amgen have a reasonable basis to believe otherwise, but the ITC agreed and found reason to investigate. Moreover, the possibility that Roche might or might not assert a defense to infringement under § 271(e)(1) was an affirmative defense for Roche to assert and prove, not an element of Amgen's case.

Roche also argues that Amgen's petition was objectively baseless because the ITC can provide relief only "where there has been an *actual* importation," and that Amgen had no reasonable basis to believe that the ITC's jurisdiction extended to acts of incipient infringement, prior to an infringing importation. [47] But that is not the law. As the ITC stated in *Certain Apparatus for the Continuous Production of Copper Rod*, "[t]he provision relating to unfair methods of competition in the importation of goods is broad enough to prevent every type and

[45] Roche's Br. at 16 n.16 (emphasis added).

[46] Roche's Br. at 16 (emphasis in original).

[47] Roche's Br. at 15-16 (emphasis in original).

form of unfair practice" including jurisdiction "to prevent unfair acts in their incipiency."[48] The Commission in *Wind Turbines* reaffirmed its authority to "reach unfair acts in their incipiency" and further noted "there could be an imminent importation without a sale . . . ."[49] An unsettled condition of the law provides probable cause,[50] indicating the action is not a sham. Moreover, a "good faith argument for the extension, modification, or reversal of existing law" similarly indicates that the action is not a sham.[51] Roche's allegations and argument regarding Amgen's ITC petition simply fail to satisfy the first element of a sham litigation claim.

2. Roche's allegations also fail to establish that Amgen attempted to use the ITC process as an anticompetitive weapon.

By focusing on what Roche ***does and does not*** allege (as clarified in Roche's opposition), it becomes clear that Roche fails to allege a "sham litigation" at all. The only harm alleged is ***harm to Roche*** stemming from the grant of discovery in the ITC.[52] Roche is not alleging any ***harm to competition*** stemming from the ITC's investigation or the limited discovery granted by the ITC. Nor is there any allegation that Amgen abused the ITC discovery process by serving discovery beyond the scope sanctioned by the ITC, or that competition in any market was harmed in any respect as a result of improper discovery acts of Amgen.

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[48] *In re Certain Apparatus for the Continuous Production of Copper Rod*, Inv. No. 337-TA-89, 214 U.S.P.Q. (BNA) 892, 895 (1980) (internal quotation omitted).

[49] *In re Certain Variable Speed Wind Turbines & Components Thereof*, Inv. No. 337-TA-376, Initial Determination, 1996 ITC LEXIS 251, at *31 (May 30, 1996). Roche's attempt to distinguish *Wind Turbines* on the fact that the ITC found an actual sale in the case simply ignores that the cited portion of *Wind Turbines* addresses a situation of imminent importation ***where there is no sale***.

[50] *See PRE*, 508 U.S. at 64-65.

[51] *See id.* at 65 (quoting FED. R. CIV. P. 11).

[52] Roche alleges: "Amgen used discovery available in the baseless ITC action to interfere with Roche's clinical trials" and "Amgen employed third-party subpoenas and other litigation tactics in the ITC case in an effort to intimidate potential clinical investigators and hinder Roche's efforts to obtain FDA approval." Counterclaims ¶ 46.

Roche's complaint thus devolves to an argument that the ITC was incorrect in granting Amgen's requested discovery. But that is a quibble with the ITC, not Amgen. And it is categorically different than a "sham litigation," in which the claims of a petition are so devoid of merit as to be objectively baseless. That is why Roche's allegations also fail to satisfy the second prong of the sham litigation test: "whether the baseless lawsuit conceals an attempt to interfere *directly* with the business relationships of a competitor . . . through the use [of] the governmental *process* — as opposed to the *outcome* of that process — as an anticompetitive weapon."[53]

Roche's attempt to analogize Amgen's argument to merely winning a few discovery battles in an overall lawsuit — which it states does not demonstrate that the overall suit was not baseless[54] — entirely misses the point. The only action complained of here by Roche ***is*** the single discovery battle.

Because Roche's allegations fail to state a proper claim for sham litigation, it is appropriate to analyze whether *Noerr* protection applies to Amgen's petitioning activity before the ITC. It does. Roche's argument that the "institution of an investigation" by the ITC is a ministerial action that does not demonstrate probable cause for an overall action is a red herring. Amgen is not arguing that institution of an investigation alone demonstrates that the overall action is meritorious. Instead, Amgen relies upon multiple discretionary acts by the ITC relating to a particular grant of discovery. In particular, the ITC's institution of discovery was not "ministerial" because the ITC had discretion in deciding whether or not to permit discovery.[55]

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[53] *PRE*, 508 U.S. at 60-61 (emphasis in original) (internal quotation omitted).

[54] *See* Roche's Br. at 16 n.17.

[55] A "ministerial" action is one in which the government acts in a "non-discretionary capacity in direct reliance on the representations made by private parties." *In re Buspirone Patent & Antitrust Litig.*, 185 F. Supp. 2d 363, 369 (S.D.N.Y. 2002).

Because Amgen relies upon multiple discretionary actions of the ITC and its staff resulting in the discovery harm that Roche alleges, not just the institution of the investigation, Roche's argument that Amgen's position would preclude any sham claim is simply false.[56]

D. Roche's Proposed Amendment to its *Walker Process* Allegations Demonstrates the Insufficiency of its Initial Counterclaim.

The only substantive amendment Roche has proposed to its counterclaims is the addition of two sentences to its *Walker Process* Counterclaim alleging justifiable reliance by the PTO.[57] Thus, Roche apparently concedes that its original *Walker Process* Counterclaim is not sufficiently particular. However, for the reasons set forth in Amgen's Reply Brief in Support of its Motion to Strike Roche's Affirmative Defenses, Roche's proposed amended inequitable conduct allegations that underlie Roche's *Walker Process* Counterclaim remain deficient.[58]

E. Roche's State Law Counterclaims VII-IX Should be Dismissed.

In addition to dismissal for lack of standing, Roche's state law counterclaims should be dismissed because Roche has failed to allege the requisite geographic locus or effect for asserting these laws. Contrary to Roche's assertions in its opposition, Amgen's objections relate directly to Roche's failure to satisfy the pleading requirements set forth in the plain language of the state statutes and reiterated by case law.

The California Cartwright Act, Cal. Bus. & Prof. Code § 16727, addresses tying claims and requires a contract for sale of goods "for use within the State."[59] Roche apparently does not dispute that Count VII fails for failure to allege a geographic situs.

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[56] *See* Roche's Br. at 18.

[57] *See* Roche's Proposed Am. Redlines ¶¶ 65-66.

[58] *See* Amgen's Strike Reply Br. at 1-4.

[59] *See* Amgen's Opening Br. at 17-18; Roche's Br. at 19.

Roche claims that other sections of the Cartwright Act that prohibit exclusive dealing, trusts and other agreements in restraint of trade (Cal. Bus. & Prof. Code §§ 16720 and 16726) impose no requirement of sale of goods "for use within the State."[60] Roche is incorrect. Section 16726 simply states: "Except as provided in this chapter, every trust is unlawful, against public policy and void." Section 16720(d) defines a trust, in part, to include price-fixing agreements concerning "any article or commodity of merchandise . . . intended for sale, barter, use or consumption ***in this State***." (emphasis added). To the extent § 16726 incorporates the definition of a "trust" set forth in § 16720, it also incorporates the "in this State" language. Thus, California's Cartwright Act in part does impose a requirement for alleging a causal connection in the state of California.

Roche likewise ignores the same basic pleading requirement under the New Jersey Antitrust Act. Sections 56:9-3 and 56:9-4 require wrongful acts "in this State."

Finally, Roche contends that under Mass. Gen. Laws ch. 93A, § 11, showing that the challenged conduct did not take place "primarily and substantially" in Massachusetts is an affirmative defense for which Amgen bears the burden and that dismissal is inappropriate because this inquiry is necessarily "fact intensive and unique to each case."[61] In *In re America Online, Inc*., the plaintiff failed to allege that the defendant's conduct occurred "primarily and substantially" in Massachusetts, yet it claimed that the count could not be dismissed because the defendant had the burden of proof on this issue.[62] The court rejected this argument and held that

[60] Roche's Br. at 19.

[61] Roche's Br. at 20.

[62] *In re America Online, Inc*., 168 F. Supp. 2d 1359, 1380-81 (S.D. Fla. 2001).

this did "***not excuse [the plaintiff] from satisfying the pleading requirements***,"[63] and dismissed that count of the plaintiff's complaint.[64]

Since Roche has failed to allege the proper geographic situs, its Counterclaims VII, VIII and IX should be dismissed.

F. Roche is Without Standing to Assert a Claim for Tortious Interference Because Roche Has No "Lawful Business" Marketing or Selling peg-EPO and Has Not Been Damaged.

Roche has no standing to bring a claim for tortious interference unless and until Roche can establish that it has the lawful right to market and sell its peg-EPO product, MIRCERA. Roche's assertion that a "protectable right" requires only a "***prospective*** economic or contractual relationship," or a "reasonable ***expectation*** of economic advantage" misses the mark.[65] First, it is axiomatic that there is no "protectable right" to commit an unlawful act.[66] Roche flatly ignores the fact that absent FDA approval even an attempt to market or sell peg-EPO would be illegal, and instead, asks this Court to *sua sponte* ***create*** and ***enforce*** that very right.[67] There can be no dispute that this Court has no such power.

Second, without a contemporaneous legal right, Roche can have no "***reasonable*** probability that [it] ***would have received*** the anticipated economic benefit,"[68] because even if

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[63] *Id*. at 1380 (emphasis added).

[64] *Id*. at 1380-81.

[65] Roche's Br. at 18 (emphasis in original).

[66] *See Inhabitants of Worcester v. Eaton*, 11 Mass. 368, 377 (1814) (the course of justice cannot be defeated for the benefit of an individual); *In re Sanborn, Inc*., 216 B.R. 697, 701 (D. Mass. 1998) (discussing "the venerable principle that a court should not aid either party to an illegal contract") (quoting *Doyle v. Hasbro, Inc.*, 884 F. Supp. 35, 39 (D. Mass. 1995) (dismissing tortious interference claim because the plaintiff's business was not lawful)).

[67] *See* Roche's Counterclaim, ¶¶ 18, 31; *see Biovail*, 256 F. 3d at 807 ("In the pharmaceutical industry, FDA approval is a prerequisite to enter *any* drug market.") (emphasis in original) (citing 21 U.S.C. § 355(a)).

[68] Roche's Br. at 18 (emphasis added).

Amgen did nothing, Roche would nevertheless be unable to legally market or sell peg-EPO until it obtains FDA approval. Absent allegations of imminent approval, any such expectation is plainly ***unreasonable***.

Third, the two cases relied upon by Roche to support its claim of a "protectable right" are inapposite because in both cases there was no legal impediment to the work plaintiff was performing.[69] Neither case even remotely resembles the facts of this dispute wherein independent governmental regulations forbid Roche from pursing the very economic relations it seeks to assert. Accordingly, Roche's case law fails to support Roche's claim.

Moreover, Amgen's purported conduct has caused Roche no harm. Roche asserts that it is "poised to enter [the market] with CERA" and that Amgen's tortious conduct "denied Roche profits."[70] But Roche fails to demonstrate ***how*** it could have lost profits when it cannot legally market or sell peg-EPO, and further still, how that damage is traceable to Amgen, given the superseding independent action of the FDA. In short, Roche alleges no facts showing a "causal connection" between its purported injury and the conduct complained of Amgen.[71]

Lastly, if Roche's sham claim is dismissed, its litigation expenses cannot establish "present injury" for the purposes of a tortious interference with prospective business relations claim. As Roche's cited case demonstrates, courts have specifically refused to extend a tortious interference claim to cover the cost and burden of defending potentially meritorious litigation.[72]

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[69] *See Patel v. Soriano*, 848 A.2d 803, 831-32 (N.J. Super. Ct. App. Div. 2004) (surgeon who was tortiously denied hospital privileges had a contemporaneous and lawful ability to perform the surgeries); *Buckaloo v. Johnson*, 537 P.2d 865, 873 (Cal. 1975) (real estate broker who was tortiously denied his commission was an active broker with lawful ability to collect commission).

[70] Roche's Br. at 19.

[71] *See Lujan*, 504 U.S. at 560-61.

[72] *See Della Penna v. Toyota Motor Sales U.S.A., Inc.*, 902 P.2d 740, 749 (Cal. 1995) (noting that the economic relations tort "d[oes] not encompass injury resulting from . . . the filing of a potentially meritorious lawsuit"). *See also Pac. Gas & Elec. Co. v. Bear Stearns & Co.*, 791

Such a cause of action lies only with a claim of malicious prosecution or abuse of process and cannot form the basis for damages in a tortious interference claim.[73]

G. Roche's Declaratory Judgment Claim of Unenforceability Remains Deficient.

For the reasons stated in Amgen's Reply Brief in Support of its Motion to Strike Roche's Affirmative Defenses, Roche's Counterclaim XII remains deficient even under Roche's Proposed Amended Answer and Counterclaims.[74]

For the foregoing reasons, Amgen respectfully requests that:

1. Roche's Counterclaims I-IX and XII be dismissed; and

2. Should Roche be permitted to amend its Counterclaims, it should not be permitted leave to amend in the form proposed. Instead, Amgen respectfully requests that Roche should be ordered to:

    a. Make the amendments requested in Amgen's Reply Brief in Support of its Motion to Strike Roche's Affirmative Defenses;

    b. Remove all references to "sham litigation" in the District Court and clarify the bases for its sham litigation claim;

    c. Not amend its counterclaims unless, consistent with its pleading obligations, Roche believes it can cure the additional defects identified in this memorandum with regard to Roche's antitrust Counterclaims I-V, and state law Counterclaims VI-IX.

P.2d 587, 597-98 (Cal. 1990) ("[W]e have no motivation to expand these torts so that they begin to threaten the right of free access to the courts.").

[73] *See Bear Stearns*, 791 P.2d at 593 ("Under existing law, the only common law tort claim that treats the instigation or bringing of a lawsuit as an actionable injury is the action for malicious prosecution.").

[74] *See* Amgen's Strike Reply Br. at 1-4.

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Respectfully Submitted,

AMGEN INC.,
By its attorneys,

/s/ Michael R. Gottfried
D. Dennis Allegretti (BBO#545511)
Michael R. Gottfried (BBO# 542156)
Patricia R. Rich (BBO# 640578)
DUANE MORRIS LLP
470 Atlantic Avenue, Suite 500
Boston, MA 02210
Telephone: (617) 289-9200
Facsimile: (617) 289-9201

Lloyd R. Day, Jr.
DAY CASEBEER, MADRID & BATCHELDER LLP
20300 Stevens Creek Boulevard, Suite 400
Cupertino, CA 95014
Telephone: (408) 873-0110
Facsimile: (408) 873-0220

William Gaede III
McDERMOTT WILL & EMERY
3150 Porter Drive
Palo Alto, CA 94304
Telephone: (650) 813-5000
Facsimile: (650) 813-5100

Michael F. Borun
Kevin M. Flowers
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive
6300 Sears Tower
Chicago, IL 60606
Telephone: (312) 474-6300
Facsimile: (312) 474-0448

Of Counsel:

Stuart L. Watt
Wendy A. Whiteford
Monique L. Cordray
Darrell G. Dotson
MarySusan Howard
Kimberlin L. Morley
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320-1789
(805) 447-5000

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 18, 2006.

/s/ Michael R. Gottfried
Michael R. Gottfried