UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

MEMORANDUM IN SUPPORT OF AMGEN INC.'S MOTION TO DISMISS ROCHE'S COUNTERCLAIMS COUNTS I – IX AND XII

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I. INTRODUCTION

In response to Amgen's Amended Complaint for Declaratory Judgment of Infringement, F. Hoffman-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively, "Roche") have asserted twelve separate counterclaims against Amgen. At bottom, Roche's counterclaims are founded on the assertions that Amgen's patents are invalid, that Amgen knows this, and that Amgen, despite this knowledge, is seeking to enforce these patents against Roche's peg-EPO product to illegally or otherwise impermissibly squash competition. But these assertions ignore the fact that Amgen's patents have previously been enforced, and in each instance where Amgen has done battle in the United States, it has successfully enforced its right to exclude others from practicing its claimed inventions. If, contrary to Roche's allegations, Amgen's patents are valid, Roche's counterclaims evaporate.

On the ill-pled premise that Amgen's patents were fraudulently procured or are otherwise unenforceable,[1] Roche asserts a variety of antitrust claims, including alleged monopolization or attempted monopolization of two allegedly distinct markets (Counts III-IV), restraint of trade (Count V), a *Walker Process* claim (Count I) and sham litigation (Count II). In each instance, however, Roche's allegations fail, as a matter of law, either because Roche has failed to allege the requisite *antitrust* injury required to establish standing to sue under the Sherman Act, and/or because Roche has failed to properly allege a relevant market in which competition is allegedly restrained or monopolized. Because Roche's *Walker Process* and sham litigation counterclaims are also based on an ill-pled allegation of inequitable conduct before the Patent Office, with no attempt to distinguish Roche's vague accusations from those previously adjudicated and rejected in this Court, they are further deficient and should be dismissed. Particularly where, as here, the

[1] *See* Amgen's parallel Motion to Strike Roche's Affirmative Defenses, filed herewith.

validity and enforceability of the patents-in-suit have been previously adjudicated and repeatedly upheld, more than a conclusory allegation of fraudulent procurement or sham enforcement is required to withstand a motion to dismiss. Roche's additional allegations regarding sham litigation in the ITC similarly fail to demonstrate an objectively baseless litigation or antitrust harm caused by Amgen. So too with Roche's state law claims, which fail to allege antitrust injury or anticompetitive acts in the relevant geographic regions, and are therefore fatally flawed.

II. ARGUMENT

It is well established that a claim will be dismissed under FED. R. CIV. P. 12(b)(6) if it appears beyond doubt that the claimant cannot prove facts to support any theory of recovery.[2] The court must accept all well-pled factual allegations of the counterclaim as true and draw reasonable inferences in favor of the proponent.[3] Although the burden is heavy on a party moving to dismiss,[4] the counterclaimant must at a minimum allege facts sufficient to establish every requisite element of an asserted claim.[5] "[B]ald assertions, periphrastic circumlocutions, unsubstantiated conclusions, or outright vituperation" will not defeat a motion to dismiss.[6]

A. ROCHE'S ANTITRUST COUNTERCLAIMS I-IX SHOULD BE DISMISSED FOR LACK OF STANDING

Roche's Counterclaims I-V allege federal antitrust violations of Sherman Act §§ 1 and 2. Roche's Counterclaims VI-IX allege state antitrust violations of California's Cartwright Act, the New Jersey Antitrust Act, and Mass. Gen. Laws Chapter 93A, as well as tortious interference with prospective business relationships. Private litigants such as Roche must establish the

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[2] *Tamburello v. Comm-Tract Corp*., 67 F.3d 973, 975 (1st Cir. 1995).

[3] *Aybar v. Crispin-Reyes*, 118 F.3d 10, 13 (1st Cir. 1997).

[4] *Gen. Elec. Co. v. Lyon,* 894 F. Supp. 544, 548 (D. Mass. 1995).

[5] *Roth v.United States*, 952 F.2d 611, 613 (1st Cir. 1991).

[6] *Id*. (quoting *Correa-Martinez v. Arrillaga-Belendez,* 903 F.2d 49, 52 (1st Cir. 1990)).

requisite standing to bring the antitrust claims Roche asserts.[7] As detailed below, Counterclaims I-IX should be dismissed because Roche has failed to allege facts sufficient to establish that it has standing to assert these antitrust claims.

1. Roche lacks standing to seek damages for Counterclaims I-IX

Roche's counterclaims seek antitrust damages under Clayton Act § 4 and a declaration under the Declaratory Judgment Act that Amgen's activities violate the antitrust laws. Significantly, Roche does not seek injunctive relief to enjoin any act of Amgen.

In order to recover antitrust damages under § 4 of the Clayton Act, a claimant must 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.[8] Roche alleges neither. Yet, as numerous courts have recognized, a claimant must allege that it is or was a participant in the relevant market (e.g., a competitor or a consumer) in order to satisfy the standing requirements for an antitrust damages claim.[9] Because Roche admittedly lacks the regulatory approval required to participate in any alleged market, it has not alleged and cannot establish any past or

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[7] *See generally* PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 335 (2d ed. 2000) [hereinafter AREEDA]. A plaintiff must demonstrate that standing exists separately and independently for each claim as of the time the complaint was filed. *See DaimlerChrysler Corp. v. Cuno*, 126 S. Ct. 1854, 1867 (2006); *Tandy v. City of Wichita*, 380 F.3d 1277, 1284 (10th Cir. 2004); *Rifkin v. Bear Stearns & Co.*, 248 F.3d 628, 634 (7th Cir. 2001).

[8] *See Cargill, Inc. v. Monfort of Colo., Inc.*, 479 U.S. 104, 111 (1986); *Assoc. Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 537-45 (1983); *RSA Media, Inc. v. AK Media Group, Inc.*, 260 F.3d 10, 13-14 (1st Cir. 2001); *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 806-12 (D.C. Cir. 2001); AREEDA at ¶¶ 335, 337-38. Injury-in-fact and a causal connection between the injury and the conduct complained of are also two requirements for Article III standing. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992); *Tandy*, 380 F.3d at 1283-84; *McInnis-Misenor v. Me. Med. Ctr.*, 319 F.3d 63, 67-68 (1st Cir. 2003).

[9] *See, e.g.*, *Or. Laborers-Employers Health & Welfare Trust Fund v. Philip Morris Inc.*, 185 F.3d 957, 967 (9th Cir. 1999); *Barton & Pittinos, Inc. v. SmithKline Beecham Corp.*, 118 F.3d 178, 184 (3d Cir. 1997); *SAS of P.R., Inc. v. P.R. Tel. Co.*, 48 F.3d 39, 43-46 (1st Cir. 1995); *Genetic Sys. Corp. v. Abbott Labs.*, 691 F. Supp. 407, 420 (D.D.C. 1988).

present antitrust injury-in-fact to its business or property. Simply put, Roche does not now and never has had the right or ability to compete in any alleged market. Nor can it establish the requisite causal connection between its exclusion from the market and any alleged violation or act of Amgen.[10]

Roche ***acknowledges*** that it cannot legally participate in the allegedly relevant ESRD and CKD markets.[11] Because Roche cannot legally participate in the allegedly relevant markets due to its lack of FDA approval, Roche cannot establish any past or present antitrust injury-in-fact to its business or property or the requisite causal connection to any act of Amgen. Therefore, irrespective of its ability to seek declaratory judgment relief for these alleged antitrust violations, Roche lacks standing to seek antitrust damages for Counterclaims I-IX.

2. Roche lacks standing to seek declaratory judgment relief for Counterclaims I-IX

To establish standing to seek declaratory relief for a future antitrust injury, a claimant must plead facts sufficient to show that the future injury is imminent, not merely hypothetical or

[10] *See Bristol-Myers Squibb Co. v. Copley Pharm., Inc.*, 144 F. Supp. 2d 21, 22-25 (D. Mass. 2000) (granting motion to dismiss antitrust counterclaims for lack of standing because, *inter alia*, defendant generic manufacturer had not received tentative FDA approval); *Andrx Pharms., Inc. v. Friedman*, 83 F. Supp. 2d 179, 184-86 (D.D.C. 2000) (same), *aff'd in part and rev'd in part*, 256 F.3d 799 (D.C. Cir. 2001) (affirming dismissal of antitrust counterclaim but reversing decision to do so with prejudice); *cf. City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 267-68 (3d Cir. 1998) ("The presence of the regulatory scheme and need for approval . . . cuts the causal chain and converts what might have been deemed antitrust injury in a free market into only a speculative exercise."). This is not a case where the antitrust defendant has allegedly manipulated the regulatory framework to prevent or delay the claimant's ability to participate in the market. *See, e.g.*, *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 810-11 (D.C. Cir. 2001).

[11] *See, e.g.*, Roche's 11/6/06 Answer to Am. Compl. and Countercls., Counterclaims at ¶ 18, Docket No. 140 [hereinafter "Answer" or "Counterclaims"] ("[N]o ESA may be marketed for the treatment of anemia in ESRD patients in the United States unless the FDA has approved it for use as a treatment. . . ."); *see also id.* at ¶¶ 2, 22, 31, 33.

speculative.[12] For example, in Amgen's Amended Complaint, Amgen alleged that Roche filed a license application with FDA in April 2006 and "announced [as of April 2006] that it expects to obtain regulatory approval to market and sell PEG-EPO in the United States within the next 12-14 months."[13]

In the context of Roche's antitrust counterclaims, Amgen's alleged anticompetitive conduct cannot cause antitrust injury to Roche unless and until the FDA approves Roche's application to sell CERA in an alleged market.[14] But Roche pointedly avoids any allegation regarding the imminence or likelihood of such approval and market entry. In its Answer and Counterclaims, Roche alleges that it "is seeking FDA approval to introduce CERA into the United States."[15] Nowhere, however, does Roche allege that such approval is imminent, let alone likely. To the contrary, Roche disputes that FDA approval is imminent by ***denying*** the following allegations of Amgen's Amended Complaint:

- Roche denied that "Roche announced that it expects to obtain regulatory approval to market and sell PEG-EPO in the United States within the next 12-14 months."[16]
- Roche denied that "Roche has completed all Phase III clinical trials it believes necessary to support its application for approval in the United States."[17]
- Roche denied that "Roche has been and is making meaningful preparations to market and sell PEG-EPO in the United States."[18]

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[12] *See Lujan*, 504 U.S. at 560; *Tandy*, 380 F.3d at 1283-84 ; *McInnis-Misenor*, 319 F.3d at 67-68; *Berner v. Delahanty*, 129 F.3d 20, 23-24 (1st Cir. 1997).

[13] Amgen's 4/25/06 Am. Compl. For Declaratory J. of Infringement ¶¶ 27-28, Docket No. 52 [hereinafter "Amended Complaint"].

[14] *See infra* Section II.A.1

[15] Counterclaims at ¶ 38.

[16] Answer at ¶ 28; Amended Complaint at ¶ 28.

[17] Answer at ¶ 27; Amended Complaint at ¶ 27.

[18] Answer at ¶ 29; Amended Complaint at ¶ 29.

Roche cannot have it both ways. Either it alleges that its entry into a relevant market is imminent, or its antitrust claims for declaratory relief should be dismissed. Because Roche has not alleged facts sufficient to establish that its entry into any alleged market is imminent, Roche lacks standing to seek declaratory relief for Counterclaims I-IX.[19]

B. ROCHE HAS FAILED TO ALLEGE A LEGALLY COGNIZABLE RELEVANT MARKET

For antitrust purposes, a relevant market is defined in part by the reasonable interchangeability of potential substitute products and in part by the cross-elasticity of consumer demand between product(s) allegedly within the market and all commercially reasonable substitutes for such product(s).[20] Proper delineation of a relevant market is both necessary and important because an improperly defined market will necessarily skew correct identification of the market participants and their respective market power. Consequently, a complaint that alleges an improperly defined relevant market is subject to dismissal under FED. R. CIV. P. 12(b)(6).[21]

A complaint that defines a relevant product market without reference to the rule of reasonable substitutes and their cross-elasticity of demand "or alleges a proposed relevant market that clearly does not encompass all interchangeable substitute products" is legally insufficient

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[19] This same argument would apply if Roche were to seek injunctive relief under Clayton Act § 16.

[20] *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 392-94 (1956); *Brown Shoe Co. v. United States,* 370 U.S. 294, 325 (1962).

[21] *E. Food Servs., Inc. v. Pontifical Catholic Univ. Servs. Ass'n, Inc.*, 357 F.3d 1, 9 (1st Cir. 2004) (affirming dismissal of complaint for, inter alia, failure to adequately plead relevant geographic market); *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 441 (3d Cir. 1997) (affirming dismissal of complaint for failure to allege a valid relevant product market); *Mumford v. GNC Franchising LLC*, 437 F. Supp. 2d 344, 345 (W.D. Pa. 2006) (rejecting narrowly defined relevant market based on contract terms). *See also H.L. Moore Drug Exchange v. Eli Lilly & Co.,* 1978 U.S. Dist. LEXIS 17371 (S.D.N.Y. 1978).

and may be dismissed.[22] Similarly deficient are allegations that attempt to restrict a relevant market to a patentee's products while ignoring reasonable substitutes,[23] or that arbitrarily exclude customers who can and do purchase such products for their intended uses.[24] Because the two markets alleged by Roche are not defined by reference to all of the products that can reasonably be substituted for the products alleged to comprise the market, or all of the customers who can and do purchase or use such products, Roche's market allegations are legally insufficient to support its antitrust claims.[25]

Roche's counterclaims allege two separate and distinct product markets: (1) FDA approved "erythropoietin stimulating agents" (designated as "ESAs" in Roche's counterclaims) used to treat anemic patients with end stage renal disease (dialysis patients) ("ESRD"); and (2) FDA approved ESAs used to treat anemic patients with chronic kidney disease who are not yet on dialysis (designated in Roche's counterclaims as "CKD" patients).[26]

Here again, however, Roche seeks to have it both ways. On the one hand it alleges that the relevant product market is comprised only of products that have already been *approved* by

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[22] *Queen City Pizza,* 124 F.3d at 436. *See also Mumford,* 437 F. Supp. 2d at 352; *H.L. Moore Drug Exchange,* 1978 U.S. Dist. LEXIS 17371.

[23] *See E.I. du Pont*, 351 U.S. at 383; *B.V. Optische Industrie De Oude Delft v. Hologic, Inc*., 909 F. Supp. 162, 172 (S.D.N.Y. 1995); *CCPI Inc. v. Am. Premier, Inc.*, 967 F. Supp. 813, 818 (D. Del. 1997).

[24] *Queen City Pizza*, 124 F.3d at 437-38 (relevant market cannot be restricted to exclude reasonably interchangeable products or customers who purchase such products for their intended uses).

[25] Indeed, none of the Amgen products identified in Roche's counterclaims are ESAs, as Roche has defined that term. Neither EPOGEN® nor ARANESP® stimulate erythropoietin production. For purposes of this motion only, Amgen assumes that Roche is asserting that the relevant product market is erythropoiesis stimulating agents (agents that can stimulate erythopoiesis (the production of red blood cells)). If Roche is actually defining the relevant product market as erythropoietin stimulating agents, it can allege no set of facts under which Amgen is either illegally monopolizing or attempting to monopolize the erythropoietin stimulating agents product market because Amgen is not currently commercializing or developing such agents in the clinic.

the FDA. On the other hand, it incongruously implies that it participates in the relevant market and suffers antitrust injury even though its only alleged product — peg-EPO — is not approved for sale by the FDA.[27] If Roche means to assert that its unfulfilled intent to enter the relevant market is alone sufficient to establish the requisite antitrust injury and thus standing to sue,[28] then *ipso facto* the relevant market must necessarily encompass all similarly situated substitute ESAs – that is, other ESAs not yet approved by the FDA.

Similarly deficient is Roche's attempt to define two separate customer markets without reference to the cross-elasticity of demand between consumers of ESA products generally. As Roche's allegations make clear, ESAs are used to treat a variety of patients beyond anemic CKD patients, including patients having anemia associated with cancer, HIV, pediatric renal disease, surgery, hepatitis C, and stroke.[29] Moreover, Roche fails to allege how or why its two alleged markets are distinct from one another, how or why its two alleged markets are properly circumscribed, or that consumers and physicians are in any way constrained from prescribing or using products purchased in Roche's "CKD market" for patients in Roche's "ESRD market" or, indeed, any other medical use a physician may prescribe. Roche's market allegations fail to define a legally relevant market to support its antitrust claims.

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[26] *See* Counterclaims at ¶¶18-19 ("ESRD ESA" market), ¶¶ 30-32 ("CKD ESA" market).

[27] *See generally Port Dock & Stone Corp. v. Oldcastle Ne., Inc.*, 2006 U.S. Dist. LEXIS 69076 (E.D.N.Y. 2006) (dismissing complaint for lack of antitrust standing where defendant's claimed antitrust injury was not directed to the relevant market pled); *Yellow Page Solutions, Inc. v. Bell Atl. Yellow Pages Co*., 2001 U.S. Dist. LEXIS 18831, at *34 (S.D.N.Y. 2001) (dismissing complaint, stating: "[A]n antitrust plaintiff must prove more than harm to its own business or the loss of a competitor. Rather, it must prove harm to competition as a whole *in the relevant market*." (emphasis added) *citing Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs*., 996 F.2d 537, 543 (2d Cir. 1993)).

[28] See *infra* Section II.A.1 regarding Roche's failure to plead a legally cognizable antitrust injury.

[29] *See* Counterclaims at ¶ 15.

For all of the foregoing reasons, Counterclaims I-V and VII-IX should be dismissed for failure to allege a legally relevant market.

C. ROCHE HAS FAILED TO PLEAD FACTS SUFFICIENT TO SUPPORT A CLAIM FOR *WALKER PROCESS* FRAUD

In *Walker Process* the Supreme Court held that in certain circumstances, the enforcement of a patent procured by fraud on the Patent and Trademark Office ("PTO") may constitute a violation of § 2 of the Sherman Act.[30] To plead a *Walker* Process claim, the claimant must allege both fraud on the Patent Office and knowing assertion of the fraudulently procured patent, as well all the other requisite elements of an antitrust violation.[31]

Because *Walker Process* claims are grounded in fraud, the allegations of fraud must be pled with particularity in accordance with Rule 9(b).[32] Fraud in the procurement of a patent requires proof of the elements of common law fraud which, as applied to patent prosecution, "requires (1) a false representation or deliberate omission of a fact material to patentability, (2) made with the intent to deceive the patent examiner, (3) on which the examiner justifiably relied in granting the patent, and (4) but for which misrepresentation or deliberate omission the patent would not have been granted."[33] Additionally, in order to establish a claim for *Walker Process* fraud, "the defendant must make a greater showing of scienter and materiality than when seeking unenforceability based on conduct before the Patent Office."[34]

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[30] *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp*., 382 U.S. 172 (1965).

[31] *Nobelpharma AB v. Implant Innovations, Inc*., 141 F.3d 1059, 1071 (Fed. Cir. 1998).

[32] *See* FED. R. CIV. P. 9(b); *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1103-04 (9th Cir. 2003) (allegations of fraud must be pled with particularity).

[33] *C.R. Bard, Inc. v M3 Sys., Inc*., 157 F.3d 1340, 1364 (Fed. Cir. 1998).

[34] *Id.* at 1364 (internal quotations omitted); *see also Handgards, Inc. v. Ethicon, Inc*., 601 F.2d 986, 996 (9th Cir. 1979).

As discussed in Amgen's Motion to Strike Roche's Affirmative Defenses, Roche has failed to plead its inequitable conduct defense with sufficient particularity,[35] and its counterclaims add no additional factual allegations beyond those pleaded in Roche's Answer. Thus, for all the reasons discussed in Amgen's Motion to Strike, Roche's *Walker Process* claim fails to satisfy the pleading requirements of FED. R. CIV. P. 9(b).

Moreover, as noted above, the pleading requirements for a *Walker Process* claim require more than the bare elements of an inequitable conduct defense. In addition, *Walker Process* fraud requires a showing that the examiner justifiably relied on the alleged false representation or deliberate omission, and that "but for" the misrepresentation or omission, the patent would not have been granted.[36] The ***only*** statement made by Roche in its Answer and Counterclaims that even arguably relates to these elements is its statement that:

> Amgen intentionally and willfully misled the PTO by misrepresenting and omitting material information, which, if known by the PTO, would have resulted in the PTO not allowing these patents.[37]

This bare assertion does not provide any particularity as to what material statements were allegedly made or omitted by Amgen, nor how the examiner allegedly relied on any such misrepresentations or omissions. Because Roche's claims of fraud also fail to allege detrimental reliance by any person allegedly deceived, Roche's *Walker Process* claim should be dismissed.

In addition, "the antitrust plaintiff must demonstrate that the party asserting the patent was aware of the fraud when it brought suit."[38] Although Roche asserts that this litigation was

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[35] *See* Amgen's Motion to Strike Roche's Affirmative Defenses at Sections II.A -B.

[36] *See C.R. Bard*, 157 F.3d at 1365.

[37] Counterclaims at ¶ 65; *see also* Answer at ¶ 39.

[38] *In re Relafen Antitrust Litig.,* 360 F. Supp. 2d 166, 184 (D. Mass. 2005); *Nobelpharma AB v. Implant Innovations, Inc*., 141 F.3d 1059, 1069-71 (Fed. Cir. 1998).

"brought by Amgen with knowledge that these patents were obtained by fraud on the PTO,"[39] the same allegations of inequitable conduct of which Roche complains were previously litigated and rejected.[40] Because Amgen's belief in the validity of the patents-in-suit is objectively based on a series of judicial decisions, Roche's bare assertion is insufficient to plead a *Walker Process* claim.

Finally, in order to plead a *Walker Process* claim based on fraud, a claimant must not only plead fraud, but also every other element of a § 2 claim, including antitrust injury and a proper definition of the relevant market.[41] As explained above, Roche has failed properly to allege an antitrust injury or a relevant market, and for these reasons as well, its *Walker Process* claim should be dismissed.

D. ROCHE HAS FAILED TO PLEAD FACTS SUFFICIENT TO OVERCOME AMGEN'S FIRST AMENDMENT RIGHT OF PETITION UNDER *NOERR-PENNINGTON*

Roche's Counterclaim II alleges that Amgen has engaged in "sham litigation." But a party that petitions the government in good faith for redress is generally immune from antitrust liability under the *Noerr-Pennington* doctrine, which protects the right of corporations to petition governmental bodies.[42] To avoid any chilling effect on the exercise of the First Amendment right of petition, claims challenging the exercise of such rights are subject to a heightened pleading standard,[43] and are well-suited to a motion to dismiss,[44] particularly where, as here,

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[39] Counterclaims at ¶ 49.

[40] *See, e.g.*, *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 137-47 (D. Mass. 2001) (rejecting allegations of material omissions and misrepresentations, after hearing testimony from the inventor Dr. Lin and Amgen's principal patent prosecutor Mr. Borun, and holding that "Amgen's representatives never intended to deceive the Patent Office."), *aff'd in pertinent part,* 314 F.3d 1313 (Fed. Cir. 2003).

[41] *C.R. Bard*, 157 F.3d at 1367-68; *Nobelpharma*, 141 F.3d at 1067-70.

[42] *See United Mine Workers of Am. v. Pennington*, 381 U.S. 657, 669-72 (1965); *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 137-44 (1961).

[43] *See Franchise Realty Interstate Corp. v. S.F. Local Joint Executive Bd. of Culinary Workers*,

nothing more than conclusory allegations are made.[45]

To overcome *Noerr-Pennington* immunity, courts have established a two-part pleading requirement: (1) facts sufficient to show that the challenged petitioning activity is "objectively baseless" in the sense that no reasonable litigant could realistically expect success on the merits, and (2) facts showing 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.[46] Roche has failed to meet this standard.

1. Amgen justifiably believes that the patents-in-suit are valid and enforceable

To the extent that Roche bases its claims of sham litigation upon an allegation that Amgen knowingly tried to enforce "invalid and unenforceable" patents,[47] such a conclusory allegation does not satisfy the heightened pleading standard. After extensive and extremely hard-fought litigation, this Court held in *Amgen v. HMR/TKT,* and the Federal Circuit affirmed, that the patents-in-suit are not invalid.[48] Given this litigation history, Amgen's confidence that

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542 F.2d 1076, 1082-86 (9th Cir. 1976); *Or. Natural Res. Council v. Mohla*, 944 F.2d 531, 533 (9th Cir. 1991); *Kottle v. Nw. Kidney Ctrs.*, 146 F.3d 1056, 1063 (9th Cir. 1998); *Cash Energy, Inc. v. Weiner*, 768 F. Supp. 892, 897-99 (D. Mass. 1991). *But see Skinder-Strauss Assoc. v. Mass. Continuing Legal Educ., Inc*., 870 F. Supp. 8 (D. Mass. 1994).

[44] *See, e.g.*, *ONRC*, 944 F.2d at 536; *Kottle*, 146 F.3d at 1063-64; *Bio-Tech. Gen. Corp. v. Genentech, Inc*., 267 F.3d 1325, 1333 (Fed. Cir. 2001).

[45] *ONRC*, 944 F.2d at 535.

[46] *Prof. Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61 (1993) (further explaining that the analysis is two-tiered, and only if the challenged litigation is objectively baseless does a Court even examine the subjective motivation of the petitioner).

[47] Counterclaims at ¶ 49.

[48] *See infra* Section II.C; *see also Amgen, Inc. v. Hoechst Marion Roussel, Inc*., 457 F.3d 1293 (Fed. Cir. 2006); *Amgen, Inc. v. Hoechst Marion Roussel, Inc*., 339 F. Supp. 2d 202 (D. Mass. 2004).

its patents-in-suit are valid and enforceable is not "objectively baseless" – it is clearly justified.

2. Roche's § 271(e)(1) allegations fail to establish that the ITC litigation was "objectively baseless"

Roche's additional allegations regarding the ITC action are all based upon the flawed premise that Amgen "had no evidence that Roche had actually imported CERA for any purpose other than those related to seeking FDA approval."[49] In light of Roche's April 2006 FDA filing, Amgen reasonably believed that Roche had or would imminently transgress whatever exemption its infringing imports previously enjoyed from liability for violation of 19 U.S.C. § 1337.[50] The ITC found that Amgen's Amended Complaint merited further investigation, and was sufficient to institute an investigation.[51]

Roche, realizing it had the burden of demonstrating its § 271(e)(1) defense, filed a motion and supporting declarations purporting to show that its activities all fell within 35 U.S.C. § 271(e)(1), but the ITC staff found these declarations "conclusory" in nature and recommended further discovery.[52] ALJ Luckern granted that further discovery.[53] Clearly, based upon the

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[49] Counterclaims at ¶ 45.

[50] *See, e.g.*, *In re Certain Variable Speed Wind Turbines & Components Thereof*, Inv. No. 337-TA-376, Initial Determination, 1996 ITC LEXIS 251, at *31, 32 (May 30, 1996) ("[P]resumably, there could be an imminent importation without a sale, for example, in the case of a single respondent that already owns a stock of infringing goods overseas and is threatening to bring the goods into the United States in short order.").

[51] *See In re Certain Products and Pharmaceutical Compositions Containing Recombinant Human Erythropoietin*, Inv. No. 337-TA-568 ("*In re EPO*"), Notice of Investigation (May 9, 2006) [Brown Decl. Ex. 1]. As noted in *Bio-Tech.*, 267 F.3d at 1333, the entire record of an ITC proceeding may properly be considered by a district court in reviewing a motion to dismiss a claim of "sham litigation."

[52] *See In re EPO*, Commission Investigative Staff's Response to Complainant's Motion for an Extension of the Briefing Schedule for Response to Respondents' Motion for Summary Determination so as to Allow for Discovery (May 25, 2006) [Brown Decl. Ex. 2].

[53] *See In re EPO*, Order No. 3 Granting Complainant's Motion No. 568-2 for Extension, Setting Procedural Schedule for the Section 271(e)(1) Defense and Rescheduling Preliminary Conference to July 18 (May 26, 2006), *previously filed with the Court in* Roche's 7/10/06

record in the ITC, the ITC staff believed there was a reasonable basis for finding that Amgen's Amended Complaint stated a valid claim that merited further discovery. This careful consideration by the ITC and its staff demonstrates that the ITC action was not "objectively baseless."[54]

3. The harm alleged by Roche stems from the ITC's independent governmental action

The right to petition the ITC for an investigation of Roche's importation of peg-EPO falls within *Noerr-Pennington* immunity, which protects those who petition the government for redress, urging government action.[55] The limited *Noerr* exception for government actions which are merely "ministerial" does not apply because the decision to institute an investigation was a discretionary act of the ITC performed after an independent review of Amgen's Amended Complaint.[56] The requirements for instituting an action in the ITC are governed by federal regulations and involve a process of review by the ITC prior to instituting the action – such an

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Supplemental Mem., Ex. B, Docket No. 99.

[54] Regarding the ITC's grant of summary determination, because "the mere fact of losing the underlying lawsuit does not lead to the conclusion that it was a 'sham,'" the Commission's ultimate dismissal of Amgen's complaint does not establish that the complaint was objectively baseless. *Bio-Tech. Gen. Corp. v. Genentech, Inc.*, 886 F. Supp. 377, 381 (S.D.N.Y. 1995).

[55] "'Where a restraint upon trade or monopolization is the result of valid governmental action, as opposed to private action,' those urging the governmental action enjoy absolute immunity from antitrust liability for the anticompetitive restraint." *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 499 (1988) (quoting *Noerr*, 365 U.S. at 136). *See also Sessions Tank Liners, Inc. v. Joor Mfg., Inc.*, 17 F.3d 295 (9th Cir. 1994); *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 818 (D.C. Cir. 2001) ("[I]f anticompetitive harm is caused by the decision of a court, even though granted at the request of a private party, no private restraint of trade occurs because the intervening government action breaks the causal chain.").

[56] *See In re: Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 369 (S.D.N.Y. 2002) (stating "in deciding whether a particular type of conduct is petitioning activity for Noerr-Pennington purposes, it is critical to distinguish between activities in which the government acts or renders a decision only after an independent review of the merits of a petition and activities in which the government acts in a merely ministerial or non-discretionary capacity in direct reliance on the representations made by private parties.").

action is not purely ministerial.

Furthermore, the sham litigation exception does not apply unless it is the process itself, not the requested governmental action, that is used to achieve an anticompetitive effect.[57] Here, the "harm" that Roche alleges all flows directly from the ITC's independent decision to institute the investigation and allow limited discovery.[58] For all these reasons, Roche's Counterclaim II should be dismissed.

In addition, even if Roche pleads facts sufficient to overcome the presumption of *Noerr-Pennington* immunity, Roche must also properly plead a substantive antitrust violation.[59] As noted above, Roche has not alleged standing or a properly-defined relevant market, and thus Counterclaim II should be dismissed for these reasons as well.

E. ROCHE'S ADMISSION THAT IT CANNOT LEGALLY MARKET OR SELL CERA REQUIRES DISMISSAL OF COUNTERCLAIM VI — TORTIOUS INTERFERENCE WITH PROSPECTIVE BUSINESS RELATIONSHIPS

Tortious interference with prospective business relationships is a state law claim.[60] Therefore, the Court must apply the Massachusetts choice-of-law rules to determine the

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[57] "The 'sham' exception to Noerr encompasses situations in which persons use the governmental *process* – as opposed to the *outcome* of that process – as an anticompetitive weapon. . . . [T]he purpose of delaying a competitor's entry into the market does not render lobbying activity a 'sham,' unless (as no evidence suggested was true here) the delay is sought to be achieved only by the lobbying process itself, and not by the governmental action that the lobbying seeks." *City of Columbia v. Omni Outdoor Adver., Inc*., 499 U.S. 365, 380-81 (1991).

[58] Roche alleges that Amgen filed its ITC complaint solely to increase Roche's costs, distract key Roche employees, intimidate clinical investigators through discovery subpoenas, and delay CERA's entry. *See* Counterclaims at ¶¶ 45-47. But here, as in *Sessions Tank*, the harm complained of flows directly from governmental action, and thus Amgen is not liable. *See Sessions Tank*, 17 F.3d at 299 (noting that "Sessions has never proved that it sustained injuries from anything other than the actions of municipal authorities.").

[59] *PRE*, 508 U.S. at 61.

[60] *Globetrotter Software, Inc. v. Elan Computer Group, Inc.*, 362 F.3d 1367, 1374 (Fed. Cir. 2004).

jurisdiction that has "the strongest interest in resolving the particular issue presented."[61] Roche's Counterclaim VI fails to identify any specific prospective economic or contractual relationship with which Amgen has allegedly interfered. Nor does Roche identify any potential customer with whom Amgen has allegedly interfered, leaving the Court to guess which if any state's interests are implicated by the alleged facts.

By default, the most likely choice of law alternatives are New Jersey (the home of at least one counterclaimant identified as "Roche"), California (where Amgen is located) or Massachusetts (the forum state).[62] Applying the Massachusetts *lex loci delicti* conflicts rule, the jurisdiction with the "strongest interest" is New Jersey because, if there were any injury, it would have impacted Roche in New Jersey. [63]

To establish a *prima facie* claim for tortious interference under New Jersey law, Roche must allege: a "protectable right,"[64] intentional and malicious interference with that "protectable right" by Amgen, "pursuit of business" by Roche, and injury to Roche caused by Amgen's interference.[65] Because Roche concedes that it cannot legally market or sell CERA without FDA

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[61] *Engine Specialties, Inc. v. Bombardier Ltd.,* 605 F.2d 1, 19 (1st Cir. 1979) (conducting conflicts of law analysis in a tortious interference case, and applying *lex loci delicti* conflicts rule for torts) (citing *Pevoski v. Pevoski*, 371 Mass. 358, 358-60 (1976)).

[62] *See* Counterclaims at ¶50.

[63] The conflicts-of-law analysis is not outcome determinative because the elements of the claim are similar in Massachusetts or California. *Compare Doyle v. Hasbro Inc.*, 884 F. Supp. 35, 40 (D. Mass. 1995) *overruled on other grounds*, *DeCarlo v. Sullivan*, 981 F. Supp. 59 (D. Mass. 1997) *with Google Inc. v. Am. Blind & Wallpaper Factory, Inc.*, 2005 U.S. Dist. LEXIS 6228, at *36-38 (N.D. Cal. 2005).

[64] *Printing Mart-Morristown, Corp. v. Sharp Elec. Corp.*, 563 A.2d 31, 37 (N.J. 1989). A "protectable right" has been defined as "a prospective economic or contractual relationship." *Id.* Factual allegations must give rise to some "reasonable expectation of economic advantage." *Id.* (quoting *Harris v. Perl*, 197 A.2d 359, 363 (N.J. 1964)).

[65] *Ideal Dairy Farms, Inc. v. John LaBatt, Ltd.*, 90 F.3d 737, 747 (3d Cir. 1996) (affirming the district court's dismissal of the tortious interference claim because the plaintiff failed to show it was in "serious pursuit" of new accounts). *See also Jay Parrino & The Mint, LLC v. Swift*, 2006

approval,[66] Roche has no protectable right, cannot legally pursue such business,[67] and cannot suffer any interference, injury or damages by reason of any alleged interference with such "prospective business." Thus Roche's Counterclaim VI for tortious interference with prospective business relations fails as a matter of law and should be dismissed.[68]

F. ROCHE'S STATE LAW COUNTERCLAIMS VII-IX SHOULD BE DISMISSED

Roche Counterclaims VII-IX allege state antitrust violations of California's Cartwright Act, New Jersey's Antitrust Act, and Massachusetts' Unfair Competition Act, respectively. Because Roche's state law antitrust allegations do not correct any of the deficiencies of its federal antitrust claims, the state law claims should be dismissed for the reasons given above.[69]

In addition, Roche's state law counterclaims should be dismissed because Roche has not alleged the requisite geographic locus or effect for asserting these laws. The elements required to plead a claim under the California Cartwright Act are set forth in CAL. BUS. & PROF. CODE § 16727 (2006) (emphasis added):

U.S. Dist. LEXIS 40361, at *14 (D.N.J. 2006) (dismissing tortious interference claim where the complaint did not allege that plaintiff was actively in "pursuit of business" notwithstanding that the complaint made clear that plaintiff "expected to engage in business" in the future).

[66] Counterclaims at ¶¶ 18, 31.

[67] *See Doyle,* 884 F. Supp. at 40 (dismissing plaintiff's tortious interference claim because the relationship interfered with was not lawful).

[68] *Printing Mart-Morristown*, 563 A.2d at 42 ("The failure to satisfy the requirement for allegation of facts demonstrating that a plaintiff has suffered or will suffer damage can be fatal to a claim."); *Google*, 2005 U.S. Dist. LEXIS 6228, at *39-40 (dismissing claim for tortious interference because plaintiff's allegation that it had "repeat customers," did not give "rise to the level of the requisite 'promise of future economic advantage'" required to sustain a claim (internal quotation omitted)).

[69] *See RSA Media, Inc. v. AK Media Group, Inc.*, 260 F.3d 10, 16 (1st Cir. 2001) (holding that plaintiff's 93A claims perish along with their antitrust hosts); *Knevelbaard Dairies v. Kraft Foods, Inc.*, 232 F.3d 979, 987-89 (9th Cir. 2000) (antitrust injury is required under the Cartwright Act); *N.J. Carpenters Health Fund v. Philip Morris, Inc.*, 17 F. Supp. 2d 324, 340 n.20 (D.N.J. 1998) (acknowledging that the New Jersey Antitrust Act is construed in harmony with ruling judicial interpretations of comparable federal antitrust statutes).

> It shall be unlawful for any person to lease or make a sale or contract for the sale of goods . . . *for use within the State*, . . . where the effect of such [sale] . . . may be to substantially lessen competition or tend to create a monopoly in any line of trade or commerce *in any section of the State*.

The New Jersey Antitrust Act similarly requires allegations of an in-state anticompetitive effect:

> Every contract . . . in restraint of trade or commerce, *in this State*, shall be unlawful.
> and
> It shall be unlawful for any person to monopolize, or attempt to monopolize . . . trade or commerce in any relevant market *within this State*.[70]

And so does the Massachusetts Unfair Competition Act, which adds an additional requirement that actions challenged under the statute occur "primarily and substantially within the commonwealth:"

> *No action shall be brought or maintained under this section unless the actions and transactions constituting the alleged unfair method of competition or the unfair or deceptive act or practice occurred primarily and substantially within the commonwealth* . . . .[71]

Each of the alleged state law claims requires a geographic nexus with the state to assert a violation of its statute. Because Roche nowhere alleges a geographic *situs* for any of the allegedly anticompetitive acts or effects it asserts, Counterclaims VII-IX fail to state claims upon which relief can be granted under the applicable state statutes, and should be dismissed.

G. ROCHE HAS FAILED TO PLEAD ITS DECLARATORY JUDGMENT CLAIM OF UNENFORCEABILITY WITH PARTICULARITY

Roche's Counterclaim XII alleges that Amgen's patents-in-suit are unenforceable because of certain poorly-defined acts of inequitable conduct before the PTO, and because Amgen misused its patents by "initiating sham litigation before the ITC" and "engaging in an

[70] N.J. STAT. ANN. §§ 56:9-3 and 56:9-4 (2006) (emphasis added).

[71] MASS. GEN. LAWS ch. 93A, § 11 (2006) (emphasis added).

anticompetitive scheme to coerce or otherwise induce ESA customers to forgo CERA."[72] Examination of Roche's pleading reveals that Roche's "misuse" allegations rest largely on the same accusations of fraud on the PTO as Roche's inequitable conduct allegations.[73] Thus, Rule 9(b) applies and the Court should require pleading with particularity.[74] If particular allegations of "misuse" are not grounded in fraud, Roche should be required to say so.

Because Roche's allegations based upon inequitable conduct[75] fail to describe each allegedly false or fraudulent representation or omission with the requisite particularity, they should be dismissed for the reasons discussed in detail in Amgen's Motion to Strike Roche's Affirmative Defenses.[76] Should the Court allow Roche to amend its Counterclaims, however, Amgen respectfully requests that it order Roche to specify: (1) "the who, what, when, where, and how" underlying Roche's allegations; (2) all relevant differences, if any, between its current allegations and those litigated in the *Amgen v. HMT/TKT* litigation; and (3) ***all*** specific acts upon which Roche bases its Counterclaim XII.

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[72] Counterclaims at ¶¶ 121-123.

[73] *Compare* Counterclaims at ¶ 123 (alleging misuse) *with* Counterclaims at ¶ 49 (alleging litigation shams because of "patents obtained through knowing and willful fraud on the PTO . . . .") *and* Counterclaims at ¶ 62 (alleging patents misused because of "strong-arm tactics with customers," "sham litigation," and "knowing attempt to enforce in this Court patents obtained through fraud on the PTO. . . .").

[74] *See Ferguson Beauregard/Logic Controls v. Mega Sys., LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003) (accused infringer failed to state an inequitable conduct claim under Rules 9(b) and 12(b)(6)).

[75] *See* Counterclaims at ¶¶ 121, 122. Note that ¶ 121 contains the first and only allusion in Roche's Answer and Counterclaims to an unspecified "double patenting rejection." Like Roche's other inequitable conduct allegations, Roche identifies no specific misrepresentation or omission supporting this allegation.

[76] *See* Amgen's Motion to Strike Roche's Affirmative Defenses at Sections II.A -B, *see also Alternative Sys. Concepts, Inc. v. Synopsys, Inc.*, 374 F.3d 23, 29 (1st Cir. 2004) (In cases alleging fraud, "the pleader usually is expected to specify the who, what, where, and when of the allegedly false or fraudulent representation.").

For all the foregoing reasons, Amgen respectfully requests dismissal of Roche's Counterclaim I — IX and XII.

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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 November 27, 2006.

/s/ Michael R. Gottfried
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