UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,	)	
	)	
Plaintiff,	)	
v.	)	Civil Action No.: 05 Civ. 12237 WGY
	)	
F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GmbH, and HOFFMANN-LA ROCHE INC.,	)	
Defendants.	)	

MEMORANDUM OF COUNTERCLAIM-PLAINTIFF ROCHE IN OPPOSITION TO AMGEN'S MOTION TO DISMISS ROCHE'S COUNTERCLAIM COUNTS I-IX AND XII

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I. INTRODUCTION

Counterclaim-plaintiffs F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche"), respectfully submit this memorandum of law in opposition to the motion of counterclaim-defendant Amgen, Inc. ("Amgen"), to dismiss Roche's counterclaims counts I-IX and XII.

Amgen has enjoyed a 17-year monopoly over the sale of Erythropoiesis Stimulating Agent ("ESA")[1] drugs to treat anemia in patients receiving dialysis because of an advanced kidney disease known as End Stage Renal Disease ("ESRD"). Amgen also has obtained a dominant position over ESA drugs sold for the treatment of anemia associated with less severe (non-dialysis) Chronic Kidney Disease ("CKD"), where Amgen's only rival is its licensee, Ortho Biotech Products, L.P. ("Ortho").

Faced with an upstart competitive threat from Roche's new and different ESA medicine, CERA (short for Continuous Erythropoiesis Receptor Activator), Amgen has embarked on an anticompetitive campaign to unlawfully maintain its ESA dominance. As detailed in Roche's antitrust counterclaims, Amgen is anticompetitively foreclosing Roche through newly-minted exclusive dealing contracts, punitive threats to other customers who consider purchasing CERA, and bundled discounts across product lines. Amgen also has sought to impede CERA through baseless litigation against Roche before the International Trade Commission ("ITC"), and by seeking in this action to enforce six patents that it obtained only through fraudulent conduct before the United States Patent and Trademark Office ("PTO").

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[1] Amgen has pointed out a typographical error in Roche's counterclaim. The acronym ESA stands for Erythropoiesis Stimulating Agent, not Erythropoietin Stimulating Agent, as in the counterclaim. Roche has filed a motion to amend its counterclaim to reflect this change, among others.

Tellingly, Amgen's motion to dismiss does not challenge the sufficiency of Roche's substantive allegations that Amgen's efforts to deny CERA to customers violate the Sherman Act. Instead, Amgen contends that Roche lacks standing, arguing that because CERA is not yet FDA-approved Roche cannot suffer, and thus cannot allege, antitrust injury. This meritless argument fails first because it ignores settled law that a potential competitor establishes standing when it shows intent and preparedness to enter. Roche's own allegations, and this Court's prior ruling that CERA sales were sufficiently imminent to support Amgen's request for declaratory patent relief, amply meet this test. In any event, Roche's costs of defending against anticompetitive and illegal litigation constitute ***present*** antitrust injury that independently supports antitrust standing.

Amgen's other arguments in support of its motion to dismiss are equally baseless. Roche has adequately pled two relevant ESA markets because patients who suffer from ESRD and CKD have no alternative for anemia treatment other than available products approved for those respective indications. Roche's allegations that Amgen had no objective basis for bringing its ITC action, and that Amgen brought that action solely to harm Roche through the litigation process rather than its outcome, adequately allege sham litigation. Amgen even now provides *no* basis for asserting that Roche engaged in the ***actual*** infringement necessary to have a valid ITC cause of action. Amgen's contention that the ITC caused Roche's injury is unavailing because the "ministerial act" doctrine is inapplicable to baseless litigation, and because the ITC recognizes that its act of opening an investigation does not establish a reasonable basis for the litigation.

Moreover, Roche's claims pursuant to *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965), are adequately pled for the reasons explained in

Roche's accompanying response to Amgen's Motion to Strike. Finally, Roche's pendant state law claims are adequately pled, and should not be dismissed.

II. SUMMARY OF ROCHE'S ANTITRUST CLAIMS

Counts I through IX of Roche's counterclaims allege that Amgen has violated sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and various state laws, by taking actions to unreasonably restrain trade in, and monopolize, and/or attempt to monopolize markets for ESA drugs sold for the treatment of ESRD (the "ESRD ESA" market), and for ESA drugs sold for the treatment of CKD (the "CKD ESA" market). Roche details how CERA is poised to threaten Amgen's dominance of these markets and how Amgen has embarked on a course of anticompetitive conduct to thwart that threat by cementing a long-term exclusive dealing arrangement with the largest ESA buyer, threatening customers that purchase CERA with retaliation, bringing baseless litigation in the ITC, and by seeking to enforce against Roche fraudulently obtained patents.[2]

In short, Roche alleges, Amgen is seeking to snuff out the CERA threat before Roche can gain a foothold. Roche seeks damages and a declaration that Amgen's conduct violates the antitrust laws, and all other appropriate relief, which could include injunctive relief if warranted. As established below, Roche's counterclaims are sufficiently pled and Amgen's motion should be denied.

[2] Roche also asserted a number of patent-related counterclaims. The sufficiency of Count XII, which seeks a declaration of unenforceability and Amgen challenges as improperly pled, is addressed in Roche's response to Amgen's Motion to Strike.

III. ARGUMENT

A. STANDARDS GOVERNING MOTIONS TO DISMISS

In deciding a motion to dismiss, a court must accept as true "the well-pleaded facts as they appear in the complaint, extending [the] plaintiff every reasonable inference in his favor." *Coyne v. City of Somerville*, 972 F.2d 440, 442-43 (1st Cir. 1992). The complaint may not be dismissed unless "it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Roeder v. Alpha Indus., Inc.*, 814 F.2d 22, 25 (1st Cir. 1987). This standard is no less applicable in antitrust, where "dismissals prior to giving the plaintiff ample opportunity for discovery should be granted very sparingly." *Hosp. Bldg. Co. v. Trustees of Rex Hosp.*, 425 U.S. 738, 746 (1976); *see also Hewlett-Packard Co. v. Boston Scientific Corp.*, 77 F. Supp. 2d 189, 195 (D. Mass. 1999). Thus, "[t]he issue is whether the complaint states a claim under the Sherman Act, assuming the factual allegations to be true and indulging to a reasonable degree a plaintiff who has not yet had an opportunity to conduct discovery." *Morales-Villalobos v. Garcia-Llorens*, 316 F.3d 51, 53 (1st Cir. 2003) (internal quotations omitted).

B. ROCHE HAS STANDING TO ASSERT ANTITRUST CLAIMS AGAINST AMGEN

Amgen's central argument is that Roche lacks antitrust standing because it has not alleged antitrust injury (Amgen Br. 2-6).[3] This argument is baseless. The antitrust standing inquiry "is not a black-letter rule, but rather 'a balancing test comprised of many constant and variable factors.'" *Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 90 F.

[3] "Amgen Br." refers to the Memorandum In Support of Amgen Inc.'s Motion To Dismiss Roche's Counterclaims Counts I-IX and XII (Nov. 27, 2006, Docket No. 151).

Supp. 2d 540, 543 (D.N.J. 2000). To allege antitrust injury, a key element of antitrust standing, a plaintiff must merely aver injuries "of the type the antitrust laws were intended to prevent and that flows from that which makes defendant's acts unlawful." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977).

Roche has done just that. Roche's counterclaims allege that Roche has experienced ***present*** injuries from the expenses incurred combating Amgen's sham litigation and enforcement of fraudulently-obtained patents. (Cclaim ¶¶ 45, 48, 49, 59).[4] In addition, Roche alleges that Amgen's anticompetitive actions foreclose CERA from potential customers, thereby inflicting further competitive injury on Roche. Contrary to Amgen's argument, Roche, a potential competitor impeded by anticompetitive conduct, has standing to seek relief even though it presently lacks FDA approval.

1. LITIGATION EXPENSES RELATED TO THE SHAM LITIGATION AND *WALKER PROCESS* CLAIMS CONSTITUTE PRESENT ANTITRUST INJURY

Amgen's motion completely ignores the ***present*** injuries that flow from Amgen's baseless ITC action and Roche's *Walker Process* claims. Roche alleges that Amgen's litigation activity is "improperly raising already high barriers to entry into [the relevant ESA markets] and anticompetitively imposing higher costs on a new entrant, Roche." (Cclaim ¶ 59). Roche incurred costs defending Amgen's baseless ITC action as well as costs defending the current action (Cclaim ¶¶ 47, 71, 77).

Under settled First Circuit law, increased litigation expenses incurred defending baseless litigation constitute antitrust injury. In *CVD, Inc. v. Raytheon Co.* 769 F.2d 842 (1st Cir. 1985), the First Circuit held that legal expenses incurred in defending against

[4] "Cclaim" refers to Roche's counterclaims in Defendants' Answer and Counterclaims To Plaintiff's Complaint (Nov. 6, 2006, Docket No. 140).

sham litigation constitute antitrust injury because that injury "reflects the anticompetitive effect of acts with an anticompetitive intent." *Id.* at 858. The court in *CVD* explained that a potential competitor faced with baseless suits has three choices: defend the litigation, refrain from competing, or seek a license from the patent holder. *Id.* Each choice, the court stated, "would have had an adverse economic impact on the plaintiffs, as well as an anticompetitive effect." *Id.*[5] Numerous other courts have likewise held that legal expenses incurred in defending against sham litigation constitute antitrust injury, including some of the very cases Amgen itself cites (*see* Amgen Br. at 9 n.34).[6]

Thus, Roche has standing to seek damages from Amgen for present injuries in the form of legal expenses it has been forced to incur as a result of Amgen's baseless litigation. These damages constitute antitrust injury sufficient to confer standing on Roche to sue Amgen under the antitrust laws.

2. ROCHE'S INTENT AND PREPAREDNESS TO MARKET CERA ESTABLISHES STANDING

Roche seeks, in addition to present damages from defending illegal litigation, damages based on its diminished anticipated CERA sales because of Amgen's

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[5] *Bristol-Myers Squibb Co. v. Copley Pharm., Inc.*, 144 F. Supp. 2d 21 (D. Mass. 2000), which Amgen's elsewhere cites, is not to the contrary. In sharp contrast to this case, the plaintiff in *Copley* did not allege defense costs as a source of injury. *See id.* at 25. Moreover, *Copley* failed to cite *CVD*, which controls here.

[6] *See, e.g., Handgards, Inc. v. Ethicon, Inc.*, 601 F.2d 986, 997 (9th Cir. 1979) ("[i]n a suit alleging antitrust injury based upon a bad faith prosecution theory ***it is obvious*** that the costs incurred in defense of the prior patent infringement suit are an injury which 'flows' from the antitrust wrong" (emphasis added)); *Novo Nordisk of N. Am., Inc. v. Genentech, Inc.*, 885 F. Supp. 522, 525 (S.D.N.Y. 1995) ("costs incurred in connection with defending a litigation in which a patentee attempts to enforce patents that are invalid and unenforceable" is "a ***well recognized type of antitrust injury***" (emphasis added)); *see also Ben Venue*, 90 F. Supp. 2d at 546 (similar); *Kearney & Trecker Corp. v. Cincinnati Milacron Inc.* 562 F.2d 365, 374 (6th Cir. 1977) ("[w]hen the antitrust violations are causally connected to the infringement action it is permissible to include the expenses of defending that action in the award of damages").

anticompetitive conduct. Relying on cases in which antitrust claims were asserted by entities that were not potential competitors (Amgen Br. at 3 n.9), Amgen contends that FDA approval is a necessary prerequisite for a competitor to allege such antitrust injury (Amgen Br. at 5). Amgen misstates the law and ignores this Court's earlier ruling that CERA's entry is imminent enough to support declaratory relief.

a. POTENTIAL COMPETITORS CAN ESTABLISH STANDING

A potential competitor does not lack antitrust standing merely because it is not yet in the market. *See Amtrol, Inc. v. Vent-Rite Valve Corp.*, 646 F. Supp. 1168, 1176-78 (D. Mass. 1986) (Young, J.). Amgen's contrary argument is refuted by the very case it cites, *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001). There, the court held that a potential competitor yet to receive FDA approval could establish standing to seek damages by demonstrating "both its intention to enter the market and its preparedness to do so." *Id.* at 806; *see also Hecht v. Pro Football, Inc.*, 570 F.2d 982, 987 (D.C. Cir. 1977) ("courts have generally not insisted that a plaintiff actually be engaged in a going business in order to have antitrust standing; it is sufficient if he has manifested an intention to enter the business and has demonstrated his preparedness to do so"); *see generally Amtrol*, 646 F. Supp. at 1177-78 (same).

That FDA approval is not a prerequisite for meeting the "intent and preparedness" test is also demonstrated by *Ben Venue*, which held that a pharmaceutical competitor yet to receive FDA approval had standing to assert antitrust damages claims, 90 F. Supp. 2d at 545-46 (citing cases). Indeed, the *Ben Venue* court specifically rejected the very argument Amgen now makes, holding that the plaintiff "need not demonstrate that the

FDA has first approved its product" to have standing. *Id.* at 546.[7] That a potential competitor suffers a present antitrust injury sufficient to confer standing is also demonstrated by cases holding that potential competitors' antitrust damages claims can accrue before entry (or even if entry never occurs). *See, e.g., Pace Indus., Inc. v. Three Phoenix Co.*, 813 F.2d 234, 240 (9th Cir. 1987) (plaintiff's damages not inherently speculative merely because it never entered market); *N.C. Elec. Membership Corp. v. Carolina Power & Light Co.*, 780 F. Supp. 322, 329-34 (M.D.N.C. 1991) (citing cases). Amgen's cases are not to the contrary. Indeed, the lone First Circuit case Amgen cites, *SAS of Puerto Rico, Inc. v. Puerto Rico Tel. Co.*, 48 F.3d 39 (1st Cir. 1995), states that "the presumptively 'proper' [antitrust] plaintiff" is "a competitor *who **seeks** to serve that market."* *Id.* at 44 (emphasis added).[8]

b. ROCHE SUFFICIENTLY PLED ITS INTENT AND PREPAREDNESS TO ENTER

As this Court has explained, in the context of a claim by a potential competitor: "At the core of the [standing] inquiry is the question whether the litigant is a serious potential competitor, distinguishable from the great horde of opportunists who 'would've, could've, or might've.'" *Amtrol*, 646 F. Supp. at 1177. Roche easily meets this test. Roche alleges that CERA is poised to enter the relevant markets and compete with Amgen's ESA products (Cclaim ¶ 4). Moreover, Roche has alleged that it has taken

[7] *See also Xechem, Inc. v. Bristol-Myers Squibb Co.*, 274 F. Supp. 2d 937, 943 (N.D. Ill. 2003) (denying motion to dismiss for lack of standing even though plaintiff lacked FDA approval), *rev'd on other grounds*, 372 F.3d 899 (7th Cir. 2004).

[8] *Copley*, relied upon by Amgen (Amgen Br. at 4 n.10), is inapposite because it relied on the decision that the D.C. Circuit overturned in *Biovail*. Moreover, the many cases finding ripe antitrust damages claims brought by potential competitors refutes Amgen's contention (*id.*) that only claims challenging the manipulation of regulatory entry barriers warrant permitting potential entrants standing to bring suit.

steps to obtain FDA approval for CERA, which is the result of years of research aimed at developing a unique anemia medicine (Cclaim ¶ 38). Roche also has demonstrated preparedness in that it is a leading healthcare organization that has been active in developing and marketing medicines for more than 100 years (Cclaim ¶ 8). Thus, Roche has standing because it has demonstrated "a substantial likelihood of undertaking the claimed enterprise." *Amtrol*, 646 F. Supp. at 1178. Moreover, the prudential goals of antitrust standing support it here. No party is better situated than Roche to challenge Amgen's unlawful campaign to "prevent [Roche] from engaging in a [new] business," *id.* (quoting Areeda & Turner), and thereby illicitly preserve Amgen's monopoly power.

Moreover, Amgen is estopped from contesting that Roche intends and is prepared to enter the ESA markets. Amgen has made numerous assertions that FDA approval of CERA is imminent and that Roche is making "meaningful preparations" to market CERA.[9] Accepting Amgen's arguments, the Court denied Roche's motion to dismiss under Rule 12(b)(1), making factual findings that Roche's approval to sell CERA is "sufficiently imminent" to create an actual controversy for purposes of Amgen's patent claims for declaratory relief (Oct. 20, 2006 Order, Docket No. 121, at 17-19). Amgen cannot now disavow its admissions that CERA's approval and entry are imminent when the Court made factual findings that accepted those contentions and rejected Roche's

[9] For example, Amgen acknowledges in its complaint in this case that Roche has filed a Biologic License Application ('BLA') with the FDA for CERA and has been "making meaningful preparations to market and sell [CERA] in the United States." Amgen Am. Cplt. ¶¶ 27-29 (Apr. 25, 2006, Docket No. 52). In opposing Roche's motion to dismiss the patent infringement claims, Amgen informed this Court numerous times that FDA approval of CERA that would permit Roche to market CERA was "sufficiently certain and imminent" to provide this Court with declaratory judgment jurisdiction. Amgen's Opp. To Defs. Motion To Dismiss 1-3 (Apr. 25, 2006, Docket No. 56-1).

contrary contentions. By ignoring the Court's ruling on Roche's 12(b)(1) motion, it is Amgen, rather than Roche, that wants to "have it both ways" (Amgen Br. at 6).

3. A SUFFICIENTLY CONCRETE CONTROVERSY EXISTS TO SUPPORT DECLARATORY RELIEF

For precisely the same reason, Amgen's argument that CERA's entry is not sufficiently imminent for declaratory relief is meritless. Having found a "sufficiently imminent" controversy for Amgen's patent claims, there is no reason to hold differently with respect to Roche's antitrust counterclaims, to the extent those claims (like Amgen's patent claims) presuppose CERA's approval and entry. Moreover, as demonstrated above, Roche's present and anticipated injuries are plainly non-speculative.[10]

C. ROCHE HAS ADEQUATELY PLED THE RELEVANT MARKETS

Amgen's contention that Roche fails to allege a "legally cognizable market" (Amgen Br. at 6) is also meritless. Market definition "is a highly-fact based analysis that generally requires discovery." *Found. for Interior Design Educ. Research v. Savannah Coll. of Art & Design*, 244 F.3d 521, 531 (6th Cir. 2001). For this reason "courts hesitate to grant motions to dismiss for failure to plead a relevant product market." *See, e.g.*, *Todd v. Exxon Corp.*, 275 F.3d 191, 199-200 (2d Cir. 2001) (citing cases). Roche's relevant market allegations are more than sufficient and Amgen's contrary arguments at bottom simply ignore Roche's allegations.

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[10] Amgen's contention (Amgen Br. at 4-5, citing Article III injury-in-fact cases) that a Declaratory Judgment requires "imminent" "injury" is in any event incorrect. In the context of declaratory relief, "some *interest* may suffice even without present or even imminent injury." *In re Indian Motocycle Co.*, 452 F.3d 25, 29 n.3 (1st Cir. 2006). Thus, the very cases Amgen cites demonstrate that Article III's "imminence concept" requires only a non-speculative interest subject to judicial resolution. *See, e.g.*, *Berner v. Delhanty*, 129 F.3d 20, 24 (1st Cir. 1997); *Tandy v. City of Wichita*, 380 F.3d 1277, 1283-84 (10th Cir. 2004).

An alleged relevant market is sufficient if proposed "with reference to the rule of reasonable interchangeability." *NicSand, Inc. v. 3M Co.*, 457 F.3d 534, 547 (6th Cir. 2006). Reasonable interchangeability is determined from the perspective of consumers: "the relevant market must include all products 'reasonably interchangeable for consumers for the same purposes.'" *United States v. Microsoft Corp.*, 253 F.3d 34, 52 (D.C. Cir. 2001) (*en banc*) (per curiam) (*quoting United States v. E.I du Pont de Nemours & Co.*, 351 U.S. 377, 395 (1956)); *accord George R. Whitten, Jr., Inc. v. Paddock Pool Builders*, 508 F.2d 547, 552 (1st Cir. 1974).

The two relevant markets delineated in Roche's counterclaims easily meet this test, which is especially generous at the pleading stage.[11] With respect to the ESRD ESA market, the counterclaims allege that patients on dialysis requiring treatment for anemia have *no* substitutes for ESAs indicated and sold for the treatment of ESRD (Cclaim ¶ 18). The counterclaims similarly allege, with respect to the CKD ESA market, that Chronic Kidney Disease patients requiring treatment for anemia have no alternatives to an ESA indicated and sold for treatment of CKD (Cclaim ¶ 31). The counterclaims also allege that the markets are distinguished by distinct pricing levels (Cclaim ¶ 26), to a significant extent different customers (Cclaim ¶¶ 24-25, 34), and different products (Cclaim ¶ 26). These averments suffice at the pleading stage to allege the ESRD ESA and CKD ESA markets. *See, e.g.*, *NicSand*, 457 F.3d at 547.

Amgen nevertheless insists that it is "incongruous" for Roche to define a market Roche cannot enter without FDA approval (Amgen Br. at 7-8). Amgen confuses the

[11] "Our notice pleading system requires only that such allegations give notice of what markets are being brought into issue. Whether or not the alleged market is in fact the relevant one . . . is a matter for proof and not pleading." *AG Fur Industrielle Elektronik AGIE v. Sodick Co.*, 748 F. Supp. 1305, 1316-17 (N.D. Ill. 1990).

extent of the relevant market with its *participants*. Because Roche poses a "nascent" threat to Amgen, "no contradiction exists" between the alleged markets and Roche's present inability to sell into them. *Microsoft*, 253 F.3d at 54. As explained, Roche, a *potential entrant* into those markets, has standing to challenge Amgen's anticompetitive conduct. *See supra* Part III.B; *Amtrol*, 646 F. Supp. at 1176-78. Amgen's baseless suggestion that numerous well-situated potential entrants exist is for discovery.

Amgen's further contention (Amgen Br. 6-8) that the counterclaims improperly fail to "reference to the cross-elasticity of demand between consumers of ESA products generally," relying on *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430 (3d Cir. 1997), is twice flawed. First, specific allegations respecting cross-elasticity of demand are not required when the plaintiff alleges that the products in the market(s) have *no* reasonable substitutes from the perspective of consumers. *See NicSand*, 457 F.3d at 547 (rejecting same argument). Here, the counterclaims allege that ESAs available and approved for treating ESRD lack good substitutes for treating ESRD-related anemia (Cclaim ¶¶ 18, 26). Drugs approved only for *other* indications and/or sold only for other uses are *not* reasonable alternatives (Cclaim ¶ 22). The same is alleged with respect to the CKD market. Such allegations meet *Queen City*, which requires "only that a plaintiff plead a market with reference to the rule of reasonable interchangeability." *NicSand*, 457 F.3d at 547.[12] The precise extent of supply or demand elasticity presents a factual issue, not one of the sufficiency of allegations. *See, e.g.*, *id.*; *Continental Airlines, Inc. v.*

[12] Amgen's franchise cases, such as *Queen City* and *Mumford v. GNC Franchising LLC*, 437 F. Supp. 2d 344 (W.D. Pa. 2006), are inapposite. The plaintiffs there wrongly excluded products that *were* substitutes for consumers. *See, e.g.*, *id.* at 354-55. Here, by contrast, Roche's markets are properly defined by what is "reasonably interchangeable by *consumers* for the same purpose." *Id.* at 354 (internal quotations omitted).

United Airlines, Inc., 120 F. Supp. 2d 556, 569 (E.D. Va. 2000); *Envirosource, Inc. v. Horsehead Res. Dev. Co.*, 1997 WL 525403, at *3 (S.D.N.Y. Aug. 21, 1997). Of course when, as here, the complaint plausibly alleges the absence of good substitutes, cross-elasticity obviously is low, which is precisely why such allegations "are not 'magic words' that must appear in the pleadings." *Foam Supplies, Inc. v. The Dow Chem. Co.*, 2006 WL 2225392, at *4 (E.D. Mo. Aug. 2, 2006).

Second, Amgen objects to delineating distinct ESRD and CKD ESA markets because products sold in each market are indicated for other uses (Amgen Br. at 7). But the counterclaims allege that the ESRD ESA and CKD ESA markets are characterized by distinct pricing, to a significant extent distinct customers, and, in part because of the contractual arrangements between Ortho and Amgen, almost entirely distinct products (Cclaim ¶¶ 24-26, 33-34). These are well-recognized factors that can support defining distinct markets,[13] even when products have multiple uses. *See, e.g., SmithKline Corp. v. Eli Lilly & Co.*, 427 F. Supp. 1089, 1096-98 (E.D. Pa. 1976) (cephalosporins in distinct market from other antibiotics despite interchangeability for some uses), *aff'd*, 575 F.2d 1056 (3d Cir. 1978). Put simply, the counterclaims *do* allege "why [the] two alleged markets are distinct from one another" (Amgen Br. at 8).

Moreover, Amgen is wrong that the relevant markets exclude "all of the customers who can and do purchase or use such products" (Amgen Br. at 7), which again confuses the *extent* of the market with its *participants*. The counterclaims conservatively calculate CKD ESA market shares based on *all* sales of ESA products available for CKD

[13] *See, e.g., Geneva Pharm. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 497-99 (2d Cir. 2004); *U.S. Anchor Mfg., Inc. v. Rule Indus., Inc.*, 7 F.3d 986, 995 (11th Cir. 1993); *Mutual Pharm. Co. v. Hoechst Marion Roussel, Inc.*, 1997 WL 805261, at *3 (E.D. Pa. Dec. 17, 1997).

use, even if *also* sold and used for other purposes (such as oncology) (Cclaim ¶ 35). The ESRD ESA market shares similarly include *all* sales of ESA products available for dialysis use (*i.e.*, Amgen's 100% share excludes Procrit because the Amgen/Ortho license precludes Procrit's sale for ESRD use). Although facts developed in discovery ultimately may justify calculating shares differently, the counterclaims conservatively include precisely the sales that Amgen contends Roche improperly excluded.

Finally, even if Amgen is correct that all three ESA products (Epogen, Aranesp, and Procrit) compete in the same market, that would not justify dismissal. The counterclaims allege facts that support the conclusion that Amgen possesses monopoly power in a broader "ESA" market.[14] Where, as here, the counterclaims allege facts that alternatively support market and monopoly power in a broader relevant market, dismissal is inappropriate. *See Ben Venue*, 90 F. Supp. 2d at 547 (evidence supported broader market than originally alleged). After all, "doubts about market power cannot be resolved on a motion to dismiss." *Town of Norwood, Mass. v. New Eng. Power Co.*, 202 F.3d 408, 421 (1st Cir 2000).[15]

[14] The counterclaims allege that Amgen has more than two-thirds of the combined sales of all three products. *See* Cclaim ¶ 20 (Amgen sold $2.4 billion of Epogen in 2005); *id.* ¶ 21 (Amgen sold $2.1 billion of Aranesp in 2005); *id.* ¶ 35 (Procrit sales approximately equal Aranesp sales). A 67% share protected by high barriers to entry can support an inference of monopoly power. *See, e.g., Broadway Delivery Corp. v. United Parcel Servs. of Am., Inc.*, 651 F.2d 122, 129 (2d Cir. 1981).

[15] Roche could (and is willing to) amend to allege in the alternative an "all ESA" market were the Court to find that necessary. As *Ben Venue* instructs, however, it is not necessary at this stage of a case.

D. ROCHE HAS ADEQUATELY PLED ITS SHAM LITIGATION CLAIM

1. NO HEIGHTENED PLEADING IS REQUIRED

Amgen's contention that a "heightened pleading standard" applies to sham litigation claims ignores that courts in this district have uniformly held the opposite. *See Skinder-Strauss Assocs. v. Mass. Continuing Legal Educ., Inc.*, 870 F. Supp. 8, 11 (D. Mass. 1994) ("[defendant's] additional assertion, that a heightened pleading requirement applies to cases brought under the sham exception, is not persuasive"); *Honeywell Consumer Prods., Inc. v. Windmere Corp.*, 993 F. Supp. 22, 24 (D. Mass. 1998) (similar). Moreover, Roche's allegations would meet a heightened pleading standard.

2. ROCHE SUFFICIENTLY ALLEGES SHAM LITIGATION

Amgen cannot contest that Roche has pled that Amgen's ITC action was objectively baseless and intended to harm Roche through the process rather than through the ITC action's outcome (Cclaim ¶¶ 45-48), the two prerequisites for a sham under established law. Instead, Amgen contends that the ITC action was not objectively baseless because Amgen "reasonably believed that Roche had ***or*** would ***imminently***" infringe. (Amgen Br. at 13 (emphasis added)). Any such asserted belief (itself not cognizable on a motion to dismiss) is irrelevant because the ITC (unlike this Court) only can provide relief where there has been an *actual* importation of infringing product. *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 WL 1049707 (U.S.I.T.C. Aug. 17, 1999).[16]

[16] The sole case Amgen cites, *In re Certain Variable Speed Wind Turbines & Components Thereof*, Inv. No. 337-TA-376, 1996 ITC LEXIS 251 (U.S.I.T.C. May 30, 1996) (Amgen Br. at 13), is inapposite because the ALJ found *actual* infringing sales "in

Accordingly, that Amgen had no reasonable basis for alleging *actual* infringement suffices to allege a baseless ITC action. The statutory definition of infringement excludes the making, using, or selling of a patented invention "solely for uses reasonably related to the development and submission of information" to the FDA. 35 U.S.C. § 271(e). The counterclaims also allege that Amgen had, when it filed the ITC action, *no* basis to believe that any Roche conduct fell outside this safe harbor (Cclaim ¶ 45). Even today, after the ITC summarily rejected its baseless action, Amgen cannot articulate the basis for its suit.[17]

Finally, Amgen's attempt (Amgen Br. at 14-15) to shift the blame for Roche's harm to the ITC, contending that the ITC's opening of an investigation is not a "ministerial" act and thus breaks the causal chain, is misconceived. First, whether government action is "ministerial" pertains to whether *Noerr-Pennington* protection applies in the first place, not to whether the sham litigation *exception* to *Noerr* applies. *See, e.g., Organon Inc. v. Mylan Pharms., Inc.*, 293 F. Supp. 2d 453, 457-60 (D.N.J. 2003). Here, Roche sufficiently alleges that Amgen's sham litigation strips its ITC action of *Noerr* immunity it might otherwise enjoy, not that *Noerr* is inapplicable.

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satisfaction of the plain language of the statute." *Id.* at 32. Moreover, the ITC has no jurisdiction to enter declaratory judgments absent actual infringing importation. *See In re Certain Fluidized Bed Combustion Sys.*, Inv. No. 337-TA-213, 1985 WL 303713 (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"). Finally, Amgen's uncognizable assertion that it believed its patents enforceable (Amgen Br. at 12-13) is irrelevant to Roche's sham litigation claim, which concerns Amgen's baseless invocation of the ITC's limited jurisdiction.

[17] Amgen is wrong that the ALJ's granting of discovery (which imposed significant burdens on Roche) demonstrates a valid suit. As this Court has held, that a litigant "has won certain discovery battles . . . is simply insufficient at this point to establish as a matter of law that those [] suits are not baseless." *Shepherd Intelligence Sys., Inc. v. Def. Techs., Inc.*, 702 F. Supp. 365, 366 (D. Mass. 1988) (Young, J).

Second, where, as here, the plaintiff alleges sham litigation, involvement of government machinery does not "break" the causal chain. If Amgen's argument were correct, there could never be a sham litigation claim, as the harm always flows from defending a baseless suit and responding to legal process. Not surprisingly, the cases Amgen cites (*Allied Tube*; *Session Tanks*) involve situations where the antitrust plaintiff claimed harm flowing from government legislative action subsequent to the asserted non-petitioning activity, not sham litigation.[18] Indeed, another case Amgen cites *denied* a motion to dismiss sham litigation claims, *see In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002), as of course have other cases, *see, e.g.*, *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006); *cf. In re Relafen Antitrust Litig.*, 346 F. Supp. 2d 349, 360-61 (D. Mass. 2004) (Young, J.) (factual issue on probable cause for instituting action precluded summary judgment on sham litigation claim).

Finally, even if the "ministerial" action doctrine applied, it would not warrant dismissal. The ITC itself has held that "institution of an investigation by the Commission is not a finding of probable cause" that "makes the complaint per se not objectively baseless." *In re Certain Radios & Components Thereof*, 2002 WL 31521163 (U.S.I.T.C. Nov. 8, 2002); *cf., In re Certain Salinomycin Biomass & Preparations Containing Same*, 1997 WL 329651 (U.S.I.T.C. May 14, 1997) (awarding sanctions against plaintiff for bringing baseless litigation despite ITC's opening of investigation). In other words, the ITC itself has recognized that instituting an investigation *is* a ministerial act that reflects

[18] Amgen's reliance on *Biovail* (Amgen Br. 14 n.55) is misplaced, because Amgen fails to note that the cited dicta is taken from a portion of Professor Areeda's treatise concerning *valid* litigation, not sham litigation. The latter, the treatise recognizes, can cause antitrust injury. *See* 1 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 202c, at 159-62; ¶ 205a, at 214-17 (2d ed. 2000).

no finding of substantive legitimacy. Amgen's contrary position, that ITC actions can *never* amount to shams if opened, is flatly contradicted by ITC jurisprudence.

E. ROCHE'S WALKER PROCESS CLAIM IS PROPERLY PLED

For reasons explained in Roche's Response to Amgen's Motion to Strike, Roche has sufficiently alleged its *Walker Process* claims and proposed amendments that supply further detail of those claims.

F. ROCHE'S STATE LAW CLAIMS ARE SUFFICIENTLY PLED

1. ROCHE SUFFICIENTLY ALLEGES PROSPECTIVE ADVANTAGE

Roche alleges a claim for tortious interference with prospective economic relations under New Jersey and California law. Amgen's only basis for seeking dismissal of these claims is that Roche alleges no present protectable right and no present injury, because Roche's FDA application for CERA has not yet been approved. Amgen is wrong. As Amgen concedes, a "protectable right" does not require a plaintiff to have a present right to income, only that there be a "***prospective*** economic or contractual relationship," or "reasonable ***expectation*** of economic advantage." (Amgen Br. at 16, n.64 (emphasis added)); *accord Printing Mart-Morristown v. Sharp Elecs. Corp.*, 563 A.2d 31, 37 (N.J. 1989). Indeed, under New Jersey law, a plaintiff need only demonstrate "that without the interference, there was a reasonable probability that he would have received the anticipated economic benefit." *Patel v. Soriano*, 848 A.2d 803, 831-32 (N.J. Super. Ct. App. Div. 2004) (affirming liability where surgeon was tortiously denied privileges without requiring proof that surgeon would have actually performed any surgeries had he obtained privileges). Similarly, California law requires only "a colorable economic relationship . . . with the ***potential*** to develop into a full contractual

relationship." *Buckaloo v. Johnson*, 537 P.2d 865, 873 (Cal. 1975) (emphasis added), *disapproved in part on other grounds, Della Penna v. Toyota Motor Sales*, 902 P.2d 740, 751 n.5 (Cal. 1995).

Because Roche is poised to enter with CERA and Amgen admits that Roche has made meaningful preparations to enter, *see supra* n.9, Roche has alleged a "reasonable probability" that Amgen's tortious conduct denied Roche profits from the customers that Amgen's conduct has foreclosed. *See, e.g., Patel*, 848 A.2d at 831-32. Moreover, Roche also alleges present injury in the form of the costs of defending baseless litigation, harm that flows from Amgen's tortious interference. *See, e.g., Viviano v. CBS, Inc.*, 597 A.2d 543, 551 (N.J. Super. Ct. App. Div. 1991).

2. AMGEN'S COLLECTION OF OTHER OBJECTIONS IS BASELESS

Amgen's only basis for seeking dismissal of Roche's claim under California's Cartwright Act, Cal. Bus. & Prof. Code §§ 16720, *et seq.*, is that ***one section*** of that Act, addressing "tying" claims, requires a contract for sale of goods "for use within the State." (Amgen Br. at 17-18). But Roche alleges that Amgen has violated other sections of the Cartwright Act that prohibit exclusive dealing, trusts and other agreements in restraint of trade, *see* CAL. BUS. & PROF. CODE §§ 16720, 16726, which impose no requirement of sale of goods "for use within the State."

Amgen's argument that Roche's claims under the New Jersey Antitrust Act, N.J.S.A. §§ 56:9-3, 56:9-4, and California antitrust laws are deficient for failure to allege a "geographic situs" within those States (Amgen Br. at 18) is misconceived. Roche alleges that Amgen's products are sold throughout the United States, which includes those States. As for Massachusetts, because showing that the challenged conduct did not

take place "primarily and substantially" in Massachusetts is an affirmative defense, *see* Mass. Gen. L. 93A § 11, and that issue "is fact intensive and unique to each case," *Kuwaiti Danish Computer Co. v. Digital Equip. Corp.*, 781 N.E.2d 787, 798 (Mass. 2003), dismissal on that ground is inappropriate. *See Workgroup Tech. Corp. v. MGM Grand Hotel*, 246 F. Supp. 2d 102, 118 (D. Mass. 2003) ("Since a court does not make [factual] findings when ruling on a motion to dismiss, it would seem that a motion to dismiss is no longer an appropriate vehicle for raising the [situs] issue").

IV. CONCLUSION

For the reasons set forth above, the Court should deny Amgen's motion to dismiss Roche's counterclaims I-IX and XII.

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Boston, Massachusetts

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 (NEF) and paper copies will be sent to those indicated as non registered participants on the above date.

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