UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

DEFENDANTS' PROPOSED SURREPLY TO AMGEN'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO DISMISS ROCHE'S COUNTERCLAIM COUNTS I-IX AND XII

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

FEDERAL CASES

Page(s)

Page(s)

TREATISES

I. INTRODUCTION

Counterclaim-plaintiffs F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche"), respectfully submit this Surreply to Amgen Inc.'s Reply Brief In Support Of Its Motion to Dismiss Roche's Counterclaims Counts I-IX and XII ("Amgen Rp."). Roche explains here why Amgen's standing arguments are incorrect and that Roche has antitrust standing to assert all its antitrust claims (including state law claims to which Amgen raises the same objection).

II. ROCHE'S INTENT AND PREPAREDNESS TO ENTER OVERCOME AMGEN'S STANDING OBJECTION

Amgen's counsel at the December 20, 2006, hearing repeated the argument (Amgen Rp. 4-5) that Roche's present lack of FDA approval bars standing. But the case Amgen told the Court supports its position, *Andrx Pharms., Inc. v. Biovail Corp. Int'l,* 256 F.3d 799 (D.C. Cir. 2001), says precisely the opposite. As *Andrx* explained in a passage Amgen's counsel ignored: "***And even before the FDA approved*** Biovail's ANDA, Biovail could have alleged its intent and preparedness to enter the market by claiming that FDA approval was probable." *Id.* at 808 (emphasis added). Another case, *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 274 F. Supp 937 (N.D. Ill. 2003), *rev'd on other grounds*, 372 F.3d 899 (7th Cir. 2004), also rejected Amgen's argument: "In arguing that an ANDA is required for antitrust standing as a matter of law, Bristol-Myers cites [*Andrx*]. This case, however, supports the opposite conclusion." *Id.* at 943 n.2 (citation omitted). Finally, *Brotech Corp. v. White Eagle Int'l Techs. Group, Inc.*, 2004 WL 1427136 (E.D. Pa. June 21, 2004), a case Amgen asserted doomed Roche's standing, actually supports it. *Brotech*, too, applied *Andrx* to hold that lack of FDA approval interposes no bar to demonstrating "preparedness." *See id.* at *5-6.

Here, Roche's allegations easily meet the "intent and preparedness" test, even apart from this Court's rejection of Roche's 12(b)(1) Motion, which establishes CERA's "imminent" entry as law of the case. Roche alleges that CERA is undergoing FDA review (Amended Cclaims ¶ 42), apprised the Court of that review's status at the hearing, and importantly, avers that Roche "***[a]nticipat[es]*** FDA approval for CERA" (*id.* ¶ 50 (emphasis added)). This is in stark contrast to *Brotech*, where the court found the complaint deficient for failure to allege "how far [plaintiff] has gone in the [FDA] process" or "that FDA approval [is] probable." 2004 WL 1427136, at *6. Obviously, if Roche is "anticipating" (Amended Cclaims ¶ 50) FDA approval, Roche has alleged "probable" approval. *Andrx*, 256 F.3d at 808. Indeed, that Roche alleges preparedness follows *a fortiori* from *Xechem*, which found preparedness sufficiently alleged even when, in contrast to Roche, plaintiff had yet to ***file*** for FDA approval. *See* 274 F. Supp. 2d at 943-44.[1]

Roche also alleges Amgen anticompetitive conduct that makes no sense unless CERA's entry were expected in a "reasonable time." *Xechem*, 274 F. Supp. 2d at 943. Roche alleges that Amgen's newly-cemented exclusive dealing agreement and customer threats serve no purpose except to impede CERA's post-approval entry (Amended Cclaims ¶¶ 50-57). As *Andrx* recognized, such allegations ***presuppose*** the plaintiff's entry and "contradict" the contrary premise. *Andrx*, 256 F.3d at 809. Amgen thus misapprehends the significance of Roche's allegations that Amgen "recognizes . . . that FDA approval of CERA is likely" and believes it

[1] Amgen's argument that a potential entrant can establish "preparedness" only when the defendant's conduct "prevented or delayed" entry (Amgen Rp. at 7) confuses causation with competitive injury. *See generally Andrx*, 256 F.3d at 806-13. The "intent and preparedness" doctrine addresses causation by asking whether entry is probable ***even assuming*** the defendant's exclusionary conduct is redressed. *See Xechem*, 274 F. Supp. 2d at 944. Roche amply alleges both causation (likely timely FDA approval) and antitrust injury from Amgen's anticompetitive conduct (impeded entry prospects). *Andrx*, *Xechem*, and numerous cases sustaining potential competitors' damages claims also refute Amgen's suggestion (Amgen Rp. at 2, 8) that "intent and preparedness" to enter can establish Roche's standing only to seek declaratory relief but not damages.

"imminent" (Amended Cclaims ¶ 43). Those allegations, beyond being admissions, explain ***why*** Amgen is now engaging in new anticompetitive conduct and thus are additional averments supporting an inference that CERA's timely approval is likely.

Finally, *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256 (3d Cir. 1998), which Amgen's counsel invoked at the hearing, is inapposite. There, the plaintiff's injury was found speculative when the defendant had ***withdrawn*** its request for regulatory approval. *See id.* at 268-69. Here, by contrast, Roche has ***sought*** FDA approval. Not surprisingly, the cases reject Amgen's argument (Amgen Br. at 8) that a damages claim cannot accrue and injury is speculative merely because FDA approval has not yet been obtained. *See Andrx*, 256 F.3d at 809 (holding *West Penn* inapplicable); *Xechem*, 274 F. Supp. 2d at 945 (antitrust plaintiff's damages cause of action accrued at time of exclusionary conduct and before FDA filing).[2]

Accordingly, because Roche meets the intent and preparedness test, and Roche's allegations establish the other elements of antitrust injury and standing, this Court should deny Amgen's motion to dismiss all claims that the Court took under advisement at the close of the December 20, 2006, hearing.

III. ROCHE'S LITIGATION EXPENSES INDEPENDENTLY ESTABLISH ANTITRUST INJURY BASED ON AMGEN'S ANTICOMPETITIVE LITIGATION

As Roche explained, in the context of a sham litigation or *Walker Process* claim, litigation expenses are "obvious[ly]" an "injury which 'flows' from the antitrust wrong."

[2] *See also Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 901 (7th Cir. 2004) (finding new exclusionary acts post-1997 within limitations period but not disagreeing with district court's accrual analysis). *In re Relafen Anti. Litig.*, 221 F.R.D. 260 (D. Mass. 2004) (Young, CJ.), concerned when the claim of a customer accrues, not a competitor. *See id.* at 266-67. Finally, Judge Tauro's decision in *Bristol-Myers Squibb Co. v. Copley Pharm., Inc.*, 144 F. Supp. 2d 21 (D. Mass. 2000), is unpersuasive because it relies on the district court decision *Andrx* reversed, *see id.* at 25.

Handgards, Inc. v. Ethicon, Inc., 601 F.2d 986, 997 (9th Cir. 1979).[3] Each argument Amgen advanced for why the Court should eschew this principle here is flawed.

First, Amgen suggests (Amgen Rp. at 6) that litigation costs comprise antitrust injury only when such expenses threaten to drive a rival from the market. The cases refute this argument. In both *Handgards* and *Kearney & Trecker Corp. v. Cincinnati Milacron Inc.*, 562 F.2d 365 (6th Cir. 1977), which the First Circuit followed in *CVD, Inc. v. Raytheon Co.*, 769 F.2d 842 (1st Cir. 1985), the antitrust plaintiff "did not prove direct market place damages" from the challenged conduct, *Kearney*, 562 F.2d at 374; *Handgards*, 601 F.2d at 996, yet litigation expenses were found to comprise antitrust injury. *Accord Novo Nordisk of N. Am., Inc. v. Genentech, Inc.*, 885 F. Supp. 522, 525 (S.D.N.Y. 1995) (plaintiff did not seek lost profits).

This makes good sense. As Professor Areeda explains, competition can be harmed when a monopolist raises its rival's costs, not just went that rival's entry is completely thwarted. *See* 1 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 205a1, at 240 (3d ed. 2006); *see also id.* ¶ 205h, at 285 (litigation expenses reflect "unambiguous injury"). And it is settled that a monopolist can harm competition by impeding nascent threats, not just when the monopolist hinders current rivals. *See United States v. Microsoft Corp.*, 253 F.3d 34, 69, 78-80 (D.C. Cir. 2001) (en banc) (*per curiam*). These principles also doom Amgen's baseless assertion (Amgen Rp. at 6) that only a *present* competitor can assert an antitrust injury based on litigation expenses, a position *Novo Nordisk* refutes. *See* 885 F. Supp. at 525 (firm lacking FDA approval could seek litigation expenses, a "well recognized type of antitrust injury").

[3] Contrary to Amgen's suggestion (Amgen Rp. 2-3), Roche does not assert that litigation expenses can establish antitrust injury or standing for any claims other than sham litigation (which Roche will, as the Court permitted, replead), *Walker Process*, and associated State-law claims.

Second, for precisely these reasons, Amgen is wrong that Roche's injury from Amgen's illegal litigation reflects merely harm to a competitor and not harm to competition (Amgen Rp. at 4). Roche alleges that Amgen's illegal litigation anticompetitively is "raising already high barriers to entry" (Amended Cclaims ¶ 59), imposing costs on a new entrant, which may result in higher prices (Amended Cclaims ¶¶ 47, 63), and hindering CERA's FDA approval process (Amended Cclaims ¶¶ 46-47). That suffices to allege harm to competition from Amgen's illegal litigation. *See CVD*, 769 F.2d at 858 (legal expenses reflected "anticompetitive effects" of defendant's acts).

Third, the cases Amgen cited to the Court are inapposite. *Brotech* and *Chip-Mender, Inc. v. The Sherwin-Williams Co.*, 2006 WL 13058 (N.D. Cal. Jan. 3, 2006), involved cases where the plaintiff, in sharp contrast to this case, failed to explain how litigation expenses related to harm to competition. *See Brotech*, 2004 WL 1427136, at *7; *Chip-Mender*, 2006 WL 13058, at *5-6.[4] As for Judge Tauro's decision in *Bristol-Myers Squibb Co. v. Copley Pharm., Inc.*, 144 F. Supp. 2d 21 (D. Mass. 2000), there the plaintiff "fail[ed] to allege in its complaint that it [was] harmed" by defense costs. *See id.* at 25 (distinguishing *Novo Nordisk*). Here, as explained, Roche has amply pled such injury both to itself and to competition.

[4] Indeed, the plaintiffs' theory of competitive harm in these cases was flawed. In each, plaintiff alleged that defendant could acquire monopoly power only if it *won* the challenged litigation. *See* 2004 WL 1427136, at *5; 2006 WL 13058, at *4. The plaintiff, however, could suffer injury from possibly illegal litigation only if the defendant *lost* (in which case the injury would not be caused by a would-be monopolist). Here, by contrast, Roche alleges that Amgen long has *possessed* monopoly power that Amgen is illegally maintaining by raising Roche's costs through an illegal ITC action (baseless for reasons unrelated to patent validity), and by asserting previously-upheld patents that, as Roche's new arguments demonstrate, are in fact invalid under *Walker Process*. *See Brunswick Corp. v. Riegel Textile Corp.*, 752 F.2d 261, 265 (7th Cir. 1984).

IV. CONCLUSION

For the reasons set forth above, and in Roche's opposition brief, the Court should deny Amgen's Motion to Dismiss Roche's counterclaims I-IX and XII.

Dated: December 22, 2006
Boston, Massachusetts

Respectfully submitted,

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