

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

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

**ROCHE’S MEMORANDUM IN OPPOSITION TO  
AMGEN’S MOTION FOR SUMMARY JUDGMENT ON  
ROCHE’S ANTITRUST AND STATE LAW COUNTERCLAIMS**

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## INTRODUCTION AND STATEMENT OF FACTS<sup>1</sup>

Amgen has enjoyed a two-decade monopoly, one of America's most lucrative, over erythropoiesis stimulating agents ("ESAs") sold to treat End Stage Renal Disease ("ESRD")-associated anemia, and has nearly achieved monopoly power over other ("non-ESRD") ESA sales. Impending entry by Roche's Mircer<sup>®</sup> now threatens Amgen's ESA dominance. Amgen recognized it could not beat Mircer on the merits; indeed, Amgen foresaw, it would lose a discounting war. Amgen thus executed an exclusionary plan, approved at the highest levels, to impede Roche assuming a "worst case" patent-suit outcome. Ex. 193 at AM44 0009451. Amgen invested *hundreds of millions* of dollars to lock up the largest ESA purchaser (Fresenius) in a long-term exclusive deal, sacrificed goodwill by threatening its own customers, and increased penalties for hospitals buying rival ESAs, all for a simple reason: "Every month we delay [Mircer] is the equivalent of \$100MM to the top-line." Ex. 55 at AM 44 0061053.

Amgen's conduct thus strikes at Section 2 of the Sherman Act's very core. By insulating itself from the pro-consumer effects of unimpeded Mircer entry before Roche can contract with customers, Amgen obtains enormous benefits from monopoly illicitly maintained. Indeed, *conceding* competitive harm, Amgen's expert opined that Amgen's exclusive Fresenius contract makes it "unlikely that Amgen would find engaging in a discount war" a "necessary or attractive option." Ex. 27 at ¶ 228 (Bernheim Rep.).

Strikingly, Amgen does not dispute (i) that it is a monopolist; (ii) that distinct

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<sup>1</sup> Roche's Response to Amgen's Statement of Undisputed Material Facts Pursuant to Local Rule 56.1 is cited as "Fact" with paragraph references; Amgen's 56.1 Statement is cited as "Amgen Fact No." Exhibits are to the Cousineau Declaration, except that those offered in support of Amgen's Motion are "Amgen Ex." Amgen's Memorandum of Law in support of its Motion is cited as "Mem."

ESRD and non-ESRD ESA markets exist; or (iii) that it engaged in the challenged conduct. Instead, Amgen seeks summary judgment on Roche’s antitrust and state-law claims based on eight putative “undisputed facts” that purportedly show the absence of exclusionary conduct that harms competition or Roche. But those “facts” are unsupported, controverted by triable evidence, or based on flawed legal contentions. The *material* facts amply establish Roche’s claims and require denial of Amgen’s motion.

*Amgen’s Anticompetitive Plan to Block Roche.* Mircera is the “greatest” threat to Amgen’s multibillion-dollar ESA franchise. Ex. 189 at AM44 1925399-402; Ex. 188 at AM44 1223286. Amgen enjoys monopoly power in the ESRD ESA market with Epogen and near-monopoly power in the distinct non-ESRD ESA market with Aranesp (Facts 7.1-5). To impede Mircera if it loses the patent suit, Amgen assembled dedicated teams to chart “high priority” anti-Mircera tactics. Ex. 131 at AM44 0237534-35. Amgen plotted as early as 2004 to (i) “[o]ffer long-term contracts at [a] strategic point in time” (Ex. 51 at AM44 0094998), (ii) “raise switching costs by offering product bundle options” “.5-1 year before [Mircera] launch” (Ex. 90 at AM44 0000987), and (iii) “[i]nitiate litigation at a *strategic* point in time,” (Ex. 247 at AM44 0024352; Ex. 246 at AM44 0086376 (emphasis added)). Taking its “street fight” (Ex. 252 at AM44 0216338-339) with Roche to customers, Amgen planned to “blunt customer adoption” of Mircera by “expos[ing] uncertainties” (Ex. 111 at AM44 0192567, -71), both “legal” and, if the customer returns to Amgen seeking a “new contract,” financial (Ex. 193 at AM44 0009446). Senior Amgen management approved these tactics (Facts 5.1, 6.5, 8.3).

*Amgen’s Five-Year Exclusive Fresenius Contract.* As Mircera’s entry approached, Amgen implemented its anticompetitive scheme. After Amgen war games

showed Roche winning a price war and capturing both large dialysis organizations (“LDOs”), Fresenius and DaVita, Amgen’s senior executives directed Amgen to “retain a minimum of one LDO” in 2007. Ex. 26 at AM44 0007137. In early 2006, Amgen developed a “hedging strategy” to “[a]pproach LDOs/SDOs [small dialysis organizations] with a one-time opportunity in advance of [Mircera’s] patent resolution with more attractive rebate terms in exchange for an exclusive contract.” Ex. 56 at AM44 0007897. Preempting one LDO, Amgen’s expert admits, reduces its need to lower price to others (Fact A.1.a). Implementing its “hedging strategy,” by May 4, 2006 – over two weeks *before* the supposedly unsolicited Fresenius letter seeking a five-year term (Amgen Ex. 31) and contravening Amgen Fact No. 5 – high-ranking Amgen and Fresenius executives had discussed a “co-exclusive worldwide” “arrangement.” Ex. 63 at AM44 1027895. The resulting contract contained two novel features: (i) five years of exclusivity for Amgen; and (ii) hundreds of millions of dollars in back-end rebates for Fresenius. Contrary to Amgen’s litigation claim of efficiencies, contemporaneous documents betray the real reason for securing exclusivity: “New contract spends \$300M to buy insurance against potential ~\$2.5B sales loss.” Ex. 58 at AM44 1516870.

***Amgen’s Customer Threats.*** In 2006, Amgen implemented its plan to threaten its own customers. Small, vulnerable dialysis customers, who have no alternative to Amgen ESAs, bravely testified that Amgen’s VP for Sales, Leslie Mirani, warned them that buying Mircera would result in financial penalties (Fact 8.4), threats Mirani’s boss, Helen Torley, admits (Fact 8.6). Customers understood Mirani’s words as a “threat” to their viability and a clear warning “that if I strayed away it was going to cost me.” Ex. 72 at 22:11-14 (Mooney Dep.); Ex. 3 at 50:14-22 (Michael Dep.). Amgen also menaced

infringement suits for employing Mircera. Contrary to supposed Amgen Fact No. 8, Amgen's threats have had their intended effect. One threatened organization that includes 70% of SDOs, Renal Purchasing Group ("RPG"), sought "security" in an exclusive Amgen loyalty contract (Fact 8.9).

***Amgen's Penalties for Hospital Switching.*** Amgen has also hindered Roche's non-ESRD entry by penalizing hospital purchasers of its monopoly Neupogen and Neulasta products for switching from Aranesp. As Mircera's entry approached, Amgen raised the thresholds for avoiding price penalties (Fact 6.5). Amgen viewed "leveraging" its portfolio (Ex. 110 at AM44 0434181) not as a way to cut prices to customers Roche could never obtain, but rather as a way to "raise switching costs" (Ex. 90 at AM44 0000987). Amgen's hospital contracts are anticompetitive and (controverting Amgen's supposed Fact No. 6), when properly analyzed, fail an "attribution" test because they require even a zero-cost rival to pay customers millions to overcome Amgen's penalties for switching to non-Amgen ESAs (Facts 6.8-18).

***Anticompetitive Effects and Damages to Roche.*** Amgen's anticompetitive plan is succeeding. Amgen has blocked Roche from selling to Fresenius, "raised switching costs" for hospitals (Fact 6.1), and wielded threats to cause customers to seek "security" with Amgen (Fact 8.9). Contrary to supposed Amgen Fact No. 7, Amgen's anti-Mircera campaign has substantially foreclosed Roche and reduced its otherwise expected penetration of the relevant ESRD and non-ESRD markets (Facts 7.3-7.7, A.1.b). Such foreclosure, at least 30% of the ESRD market alone, is likely to cause substantial anticompetitive effects by raising costs and prices and reducing physician choice (Facts A.1-3, B.2-7, which also belie Amgen Fact No. 4). Amgen's own expert admitted that

Amgen’s conduct deters price competition (Fact A.1.a); Fresenius listed as a “[p]ositive” of its exclusive contract that it “impedes competition that could ‘spiral down’ ASP reimbursement” – that is, keeps market-wide prices *up*. Ex. 77 at FMCNA 002490.

Amgen will thereby reap immense benefits of incremental monopoly power illicitly maintained to the detriment of consumers, who (contrary to supposed Amgen Fact 3) otherwise stand over time to save hundreds of millions of dollars from Mircera’s unimpeded entry (Facts 3.11-3.15). Amgen’s fraudulent patent suit similarly harms, and will continue to harm, competition and Roche by raising already high entry barriers and blunting Mircera’s adoption. Finally, Amgen’s unlawful conduct continues to inflict substantial damages on Roche; and, contrary to Amgen’s argument: (i) Roche’s tortious interference claim does not turn on its antitrust claims and (ii) Roche’s damages accrue now, do not require continuation of all Amgen conduct beyond trial, and claim no harm caused by lawful conduct. Accordingly, Amgen’s motion should be denied.

## **ARGUMENT**

### **I. Roche’s Antitrust Claims Are Supported by Abundant Triable Evidence of Anticompetitive Conduct**

#### **A. Evidence Establishes Roche’s ESRD ESA Monopolization Claim**

Amgen concedes (Mem. at 7) that a monopolist’s “anticompetitive” conduct “that reasonably appears capable of making a significant contribution to creating or maintaining monopoly power” is exclusionary and violates Sherman Act Section 2.

*Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d 227, 230 (1st Cir. 1983); *United States v. Microsoft Corp.*, 253 F.3d 34, 58-59 (D.C. Cir. 2001) (*en banc*) (per curiam).

Tellingly, Amgen does not contest its monopoly power in the distinct ESRD ESA market.

Nor does Amgen deny that, with competitive entry looming, Amgen locked up Fresenius

in a five-year exclusive contract (“Fresenius Contract”), threatened customers with retaliation to deter them from purchasing Mircera, and increased the penalties for hospitals’ switching ESAs. Amgen only argues that this conduct is “normal competitive behavior” that is neither exclusionary nor harms competition (Mem. at 1).<sup>2</sup> But “[b]ehavior that might otherwise not be of concern to the antitrust laws – or that might even be viewed as procompetitive – can take on exclusionary connotations when practiced by a monopolist.” *Eastman Kodak Co. v. Image Tech. Servs., Inc.* 504 U.S 451, 488 (1992) (Scalia, J., dissenting); see *United States v. Dentsply Int’l, Inc.*, 399 F.3d 181, 187 (3d Cir. 2005). Here, ample evidence demonstrates anticompetitive Amgen conduct that harms competition and unlawfully reinforces Amgen’s ESRD ESA monopoly.

1. Amgen’s long-term Fresenius Contract alone violates Section 2. Competitive harm from exclusive dealing can be inferred from foreclosure of a significant market share coupled with “structural” factors showing that share to be substantial. See 11 Herbert Hovenkamp, ANTITRUST LAW ¶ 1821, c, at 182 (2d ed. 2005) (even “20 percent foreclosure” can be “anticompetitive”). The Fresenius Contract forecloses over 33% of the relevant ESRD ESA market (Fact 7.3), a concededly substantial level.<sup>3</sup> Other factors

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<sup>2</sup> This Court previously correctly rejected Amgen’s meritless argument, repeated here (Mem. at 16), that lack of FDA approval precludes Roche’s counterclaims. See Memorandum and Order 8-12 (Mar. 30 2007; Docket No. 342) (reasoning that if Mircera’s entry is sufficiently imminent for Amgen’s patent case, it is sufficiently imminent to support Roche’s antitrust claims).

<sup>3</sup> *Stop & Shop Supermarket Co. v. Blue Cross & Blue Shield*, 373 F.3d 57, 68 (1st Cir. 2004) (30% foreclosure can be substantial) (cited Mem. at 14); see also *Twin City Sportservice, Inc. v. Charles O. Finley & Co.* 676 F.2d 1291, 1301-02, 1307-08 (9th Cir. 1982) (24% substantial); *Masimo Corp. v. Tyco Health Group, L.P.*, 2006 WL 1236666, at \*6 (C.D. Cal. Mar. 22, 2006) (reasoning that “the jury could conclude . . . that competitors were foreclosed from greater than 24% of the market and that the foreclosure was substantial”); *Applied Med. Res. Corp. v. Ethicon, Inc.*, 2006 WL 1381697, at \*3 n.5 (C.D. Cal. Apr. 27, 2006) (*Stop & Shop* established no foreclosure floor).

reinforce substantiality: Roche may not obtain victories elsewhere to compensate for its Amgen-created inability to compete for Fresenius (Fact A.1.b). Candid Amgen documents “confirm both the anticompetitive effects and intent of [Amgen’s] actions.” *Microsoft*, 253 F.3d at 77; *Barry Wright*, 724 F.2d at 233 (intent illuminates effects). Amgen locked up Fresenius pursuant to a strategy of “[o]ffer[ing] long-term contracts at [a] strategic point in time” to impede Roche. Ex. 51 at AM44 0094998; Fact 5.1.

Amgen’s reply – that the Fresenius Contract forecloses an insufficient 15% of a broader “all ESA” market – founders on evidence of distinct ESRD and non-ESRD ESA markets (Fact 7.1). Foreclosure is assessed in the relevant market, not some amalgam of markets. *See, e.g., In re Lorazepam & Clorazepate Anti. Litig.*, 467 F. Supp. 2d 75, 82-84 (D.D.C. 2006) (assessing foreclosure in generic drug market rather than broader market). Although invoked by Amgen (Mem. 15 n.30), *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320 (1961), refutes its argument. The Court analyzed foreclosure in “the relevant market”: “the market area in which the seller operates, **and to which the purchaser can practicably turn for supplies**,” *id.* at 330, 327 (emphasis added). Here, ESRD customers cannot turn to non-ESRD ESAs (Fact 7.1).<sup>4</sup> The two markets also exhibit distinct scale economies, structures, and price trends, all of which support assessing foreclosure separately in each (Fact 7.1; Ex. 85 at ¶¶ 44-46 (Elhauge Rep.)).

Amgen’s argument that Roche cannot “clear” a foreclosure “safe harbor” (Mem. at 1) is also wrong because there is no “safe harbor” in this monopolization case.

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<sup>4</sup> *Stop & Shop* also defined the market from the customer’s (pharmacies’) perspective. *See* 373 F.3d at 67. *Eastern Food Servs., Inc. v. Pontifical Catholic Univ. Servs. Ass’n., Inc.*, 357 F.3d 1 (1st Cir. 2004), is inapposite because the facts, unlike here, did not support the plaintiff’s market, *see id.* at 7. “[M]arket definition is a question of fact.” *Coastal Fuels of P.R., Inc. v. Caribbean Petroleum Co.*, 79 F.3d 182, 196 (1st Cir. 1996).

Foreclosure otherwise insufficient to infer anticompetitive effects (*i.e.*, in a Sherman Act Section 1 case) can be shown in a Section 2 monopolization case to cause competitive harm. *See Microsoft*, 253 F.3d at 70; *U.S. Healthcare, Inc. v. Healthsource, Inc.*, 986 F.2d 589, 597-98 (1st Cir. 1993). Here, Amgen’s expert, Dr. Bernheim, **conceded** that the Fresenius Contract harms competition. Absent the agreement, he opined, Amgen would discount more – that is, **lower price** – to combat Mircera’s entry (Fact A.1.a.1). Amgen documents support Dr. Bernheim’s admission: if Mircera can compete for both LDOs (Fresenius and DaVita), they explain, Amgen must discount deeply; but if Amgen locks up one LDO, it need not compete as hard for remaining customers (Fact A.1.a.2). Amgen’s admission that its exclusive Fresenius Contract deters price competition alone requires denial of its motion. *See Town of Concord v. Boston Edison Co.*, 915 F.2d 17, 22 (1st Cir. 1990) (conduct anticompetitive if it harms the competitive process).

Moreover, the Fresenius Contract anticompetitively raises Roche’s costs and for that reason likely will push prices higher than in the agreement’s absence (Fact A.1.b, A.3). Higher marginal costs cause firms to price higher,<sup>5</sup> even in markets (such as for ESAs) where prices are well above marginal costs (Facts 4.1-6).<sup>6</sup> Here, Professor Elhauge’s amply supported analysis shows, Amgen’s blunting of Roche’s expected penetration by locking up Fresenius will prevent or delay Roche from achieving

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<sup>5</sup> *See, e.g.*, Thomas G. Krattenmaker & Steven C. Salop, *Anticompetitive Exclusion: Raising Rivals’ Costs to Achieve Power over Price*, 96 Yale L.J. 209, 246-47 (1986); Michael H. Riordan & Steven C. Salop, *Evaluating Vertical Mergers: A Post-Chicago Approach*, 63 Antitrust L.J. 513, 551, 555 (1995).

<sup>6</sup> *See also* Ernst R. Berndt, *Pharmaceuticals in U.S. Health Care: Determinants of Quantity and Price*, 16 J. of Econ. Perspectives 45, 55-56 (2002) (recognizing that most marketing expenses are variable at launch and that “optimal profit maximizing price [equals] marginal cost plus a positive margin”).

economies of scale, raise Roche's marginal costs, and likely will lead Roche to charge higher prices than it otherwise would (Fact A.1.b).<sup>7</sup> Fresenius itself listed a "Positive" of the "New Amgen Agreement" that it would "[i]mpede competition that could 'spiral down' ASP reimbursement" (Fact 5.5.b). Amgen's assertion (Amgen Fact No. 4) that costs play no role in Mircera pricing is wrong. Roche's pricing model does not set actual prices, which will be influenced by many factors, including variable costs (Fact 4.3).

Finally, Amgen's argument that Fresenius allegedly sought and benefits from Amgen's payments (Mem. at 9) – citing the declaration of a Fresenius witness *not* identified in Amgen's Rule 26.1 disclosures – is a controverted cover story. First, paying customers for exclusivity does not absolve a monopolist of liability or show efficiencies. *See, e.g., LePage's Inc. v. 3M*, 324 F.3d 141, 159 (3d Cir. 2003) (*en banc*) (exclusive dealing purchased by monopolist unlawful); *Microsoft*, 253 F.3d at 70-71 (condemning AOL's restrictions on promoting non-Microsoft browsers even though Microsoft gave AOL significant consideration). Customers exchange payments for

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<sup>7</sup> Amgen thus is wrong (Mem. at 17) that the only increased costs Professor Elhauge identified were sunk litigation and marketing expenses. Amgen's cases recognize that average variable costs, which rise here as output declines (Fact A.1.b), are a surrogate for hard-to-measure marginal costs. *See Ramallo Bros. Printing, Inc. v. El Dia, Inc.*, 392 F. Supp. 2d 118, 139 (D.P.R. 2005). Another reason locking up Fresenius leads to higher prices, ignored by Amgen, is that, because of switching costs (Fact A.3), reducing Roche's otherwise expected share lessens its ability to expand sales and constrain Amgen's power (Fact A.1.c). Despite Amgen's contention to the contrary (Mem. at 16 & n.32), § 2 is violated by exclusionary conduct that delays the erosion of monopoly power, even if Roche is not entirely excluded. *See Dentsply*, 399 F.3d at 191 ("Consumer injury results from the delay" that "the dominant firm imposes on its smaller rival's growth" from "[a] set of strategically planned exclusive dealing contracts" (quoting 11 Hovenkamp, *supra*, ¶ 1802c)); *see also Conwood Co., L.P. v. U.S. Tobacco Co.*, 290 F.3d 768, 789 (6th Cir. 2002) (issue under § 2 is incremental impact of challenged conduct). Finally, Amgen appears to have abandoned its experts' suggestion, foreclosed by settled law, that Roche's entry is anticompetitive. *See United States v. Nat. Soc'y of Prof. Eng'rs*, 435 U.S. 679, 695-96 (1978) ("[T]he Rule of Reason does not support a defense based on the assumption that competition itself is unreasonable.").

exclusionary terms because they get the entire bribe instead of only some of the market-wide benefit of competition. *See, e.g.,* Ilya R. Segal & Michael D. Whinston, *Naked Exclusion: Comment*, 90 Am. Econ. Rev. 296, 296-97 (2000); Ex 85 at ¶ 198 (Elhauge Rep.). Here, Fresenius recognized and acted on this externality (Fact 5.5), while Amgen paid to eliminate a perceived risk of Fresenius choosing Roche (Fact 5.1).<sup>8</sup>

Second, Amgen’s purported justifications for exclusivity, which are Amgen’s burden to establish as “nonpretextual,” *Microsoft*, 253 F.3d at 58-59, and are weighed against competitive harm, *id.*, are pretextual and cannot save the restraint (Fact 5.7; Ex. 85 ¶¶ 196-209 (Elhauge Rep.)). The agreement’s timing, its history, novel terms, and entry-barrier-erecting purpose all evidence pretext (Facts 5.2-5.7). *See, e.g., LePage’s*, 324 F.3d at 164. The agreement reflects Amgen executing its preexisting plan to secure exclusive deals to blunt Mircera’s threat to its monopoly (Facts 5.1-2). These and other facts also belie Amgen’s contention that Fresenius sought the agreement because it views unapproved Mircera as inferior to Epogen (Facts 5.3-4), an irrelevant contrivance because exclusivity does not help Fresenius choose between Mircera and Epogen or support any of Amgen’s unquantified asserted justification (Facts 5.6-7). *See Kodak*, 504 U.S. at 483-85 (lack of fit shows pretext); *Microsoft*, 253 F.3d at 74 (that exclusionary term part of “overall agreement” “irrelevant” and “does not mean it has any procompetitive justification”). Finally, Amgen’s claim that the restraint lowers price is pretextual because (i) Fresenius has incentives to exchange payments for anticompetitive terms, and (ii) Amgen cannot establish that absent exclusivity *market-wide* prices would

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<sup>8</sup> Amgen’s Dr. Teece admitted that the agreement reduced the risk of Fresenius defecting to Roche, Ex. 89 at 186:1-23 (Teece Dep.), a concern reflected in Amgen’s documents (Fact 5.1). Roche, too, believed it might secure Fresenius (Fact 5.4.h).

be higher (Ex. 49 at 183:20-25 (Elhauge Dep.)). On the contrary, Amgen admits and Fresenius recognizes, the agreement keeps prices *up* (Facts 5.5; A.1.a).

*Barry Wright* lends Amgen no support. Then-Judge Breyer stressed that the agreement there was neither long-term nor exclusive. *See* 724 F.2d at 237. Amgen cannot deny the Fresenius Contract is a five-year exclusive agreement. Moreover, although the *Barry Wright* trial record supported justifications and cast doubt on a motive to impede competition, *id.* at 237-38, here evidence shows the opposite.

2. Beyond the Fresenius Contract, other Amgen anticompetitive conduct also illicitly maintains Amgen’s ESRD ESA monopoly. *See City of Anaheim v. S. Cal. Edison Co.*, 955 F.2d 1373, 1376 (9th Cir. 1992) (“[I]t would not be proper to focus on specific acts of an accused monopolist while refusing to consider their overall combined effect.”). Most notably, Amgen threatened its own customers with lawsuits and financial retaliation if they employ Mircera yet later purchase Amgen ESAs and targeted industry leaders as part of Amgen’s scheme to “blunt adoption of Mircera.” (Fact 8.1-2).

Amgen does not dispute that Leslie Mirani, VP of Sales, threatened customers as part of an approved anti-Roche strategy. Amgen instead asserts that, unless customers state that Amgen’s threats induced them not to purchase Mircera, the threats caused no competitive harm (Mem. at 12).<sup>9</sup> But the evidence meets even this flawed “strict” (*Id.*) causation test: Amgen ignores its intent to hinder Mircera’s adoption (Fact 8.1-2) and evidence that Amgen’s threats, having precisely their intended effect, drove RPG’s leadership to seek “security” in the form of an exclusive “loyalty” agreement with

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<sup>9</sup> Beyond its flawed causation argument, Amgen does not dispute that its threats were exclusionary, with good reason. *See Microsoft*, 253 F.3d at 77 (threat to Intel exclusionary); *cf. 3M v. Appleton Paper Inc.*, 35 F. Supp. 2d 1138, 1146 (D. Minn. 1999) (defendant “start[ed] rumors” regarding rival’s viability) (summary judgment denied).

Amgen, effectively foreclosing its membership from Roche (Facts 8.8-9).<sup>10</sup>

In any event, Roche need not identify customers who “rejecte[d] future purchases” (Mem. at 12-13). Because Roche cannot yet sell Mircera, such a requirement would be perverse: “To require that § 2 liability turn on a plaintiff’s ability or inability to reconstruct the hypothetical marketplace absent the defendant’s anticompetitive conduct would only encourage monopolists to take more and earlier anticompetitive action.”

*Microsoft*, 253 F.3d at 79 (invoking *Barry Wright*). The anticompetitive tendency of Amgen’s bare-knuckle threats – a “type” of conduct that “**reasonably appears capable** of making a substantial contribution to monopoly power” – sufficiently evidences competitive harm, *id.* (internal quotations omitted) (emphasis added). “To some degree, ‘the defendant is made to suffer the uncertain consequences of its own undesirable conduct.’” *Id.* (quoting 3 Areeda & Hovenkamp, ANTITRUST LAW, ¶ 651, at 78).<sup>11</sup>

3. Finally, Amgen ignores evidence (Fact A.2) that its foreclosing conduct, by

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<sup>10</sup> Amgen’s threats conservatively increase the foreclosure in the ESRD ESA market to near 50% (Mem. at 15), close to levels “routinely condemned.” 11 Hovenkamp, *supra*, ¶ 1821c, at 177. Such foreclosure also causes the same adverse price-increasing effects as the Fresenius agreement. Ex. 85 at ¶¶ 155-56, 171-82 (Elhauge Rep.).

<sup>11</sup> The First Circuit does not apply Amgen’s flawed “strict” causation test even to damages. *See, e.g., Sullivan v. NFL*, 34 F.3d 1091, 1103 (1st Cir. 1994) (standard is “material cause” not “sole cause”); cases cited *infra* note 21. Amgen’s cases are inapposite. In *Amerinet, Inc. v. Xerox Corp.*, 972 F.2d 1483 (8th Cir. 1992), the court, finding the claim advanced “implausible,” required “more persuasive evidence to support their claim **than would otherwise be necessary**,” *id.* at 1495 (emphasis added) (internal quotation omitted). Here, by contrast, threatening customers to protect Amgen’s monopoly was precisely Amgen’s plan. In *RSA Media, Inc. v. AK Media Group, Inc.*, 260 F.3d 10, 15 (1st Cir. 2001), the court found no causation because a “regulatory scheme prevents new billboards from being built.” By contrast, this Court correctly held Roche’s current lack of FDA approval no bar to its claims. *See supra* note 2. *J.B.D.L. Corp. v. Wyeth-Ayerst Labs., Inc.*, 2007 U.S. App. LEXIS 11003 (6th Cir. May 10, 2007), involved a **customer** suit where the plaintiff’s theory of injury required showing, but its evidence did not, that the challenged conduct caused prices to rise, *id.* at \*25-26. By contrast, Roche seeks lost profits and related damages from foreclosing conduct.

reducing physician and patient choice, makes the “market unresponsive to consumer demand,” a distinct “injur[y to] competition.” *Sullivan v. NFL*, 34 F.3d 1091, 1101 (1st Cir. 1994) (upholding jury verdict).

**B. Evidence Establishes Roche’s Non-ESRD Attempted Monopolization and Other Antitrust Claims**

Amgen’s hospital contracts leverage its monopoly products (Neupogen and Neulasta) to impose penalties for failing to purchase certain levels of Aranesp (Facts 6.2-6.4). Under cases Amgen ignores, these contracts violate Section 2. *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1065 (3d Cir. 1978), and *LePage’s, Inc. v. 3M*, 324 F.3d 141, 155-57 (3d Cir. 2003) (*en banc*), recognize that Section 2’s rule of reason is violated when (i) discounts on monopoly products are conditioned on other purchases; (ii) anticompetitive effects can be inferred or are shown; and (iii) the defendant establishes no offsetting justification. *See also Applied Med. Res. Corp. v. Ethicon Inc.*, 2006 WL 1381697, at \*3-6 (C.D. Cal. Apr. 27, 2006) (summary judgment on § 2 denied).

Evidence here establishes each. As in *SmithKline*, Amgen links “all [bundled] products on a non-competitive basis in what otherwise would have been a competitive market,” forcing Roche to compete “three on one.” 575 F.2d at 1062, 1065; Facts 6.4-11. Amgen’s contracts foreclose over 20% of the relevant non-ESRD ESA market (Facts 6.9-10), above the leading antitrust treatise’s threshold for anticompetitive effects. *See* 11 Hovenkamp, *supra*, ¶ 1821c, at 182. Reducing Roche’s expected share through foreclosure is likely to raise prices (*see supra* Part I.A; Facts 6.12-13, B.1-4), and, as with its other conduct, to deprive affected physicians and patients of a potentially superior

ESA (Facts B.5-8).<sup>12</sup> Amgen intended precisely such adverse effects, having devised its new hospital contracts to “raise switching costs” (Fact 6.1).

Amgen retorts that its hospital contracts are *per se* lawful unless they fail a cost-based “attribution” test (Mem. 10-11).<sup>13</sup> This test, which asks if an equally efficient single-product rival can absorb the “tax” the bundle imposes and still price above cost, should not apply here. Attribution tests have been employed by a handful of courts that view multi-product bundles as threatening competition in the same way as predatory pricing.<sup>14</sup> But respected economists and others reject the attribution test as “unlikely to be directly useful.”<sup>15</sup> They recognize that, in circumstances applicable here, “bundled discounts are best viewed as a form of tying or exclusive dealing, not as a form of predatory pricing.”<sup>16</sup> Amgen’s hospital contracts threaten competition not through price

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<sup>12</sup> Because “[p]atients respond differently to different medicines,” use of conditioned discounts to distort choice and “reduc[e] variety,” as Amgen has, carries “special weight in a rule of reason analysis.” Neil W. Averitt and Robert H. Lane, *Using the “Consumer Choice” Approach to Antitrust*, 74 *Antitrust L.J.* 175, 233 (2007).

<sup>13</sup> Attempted monopolization requires demonstrating (i) anticompetitive conduct; (ii) specific intent to monopolize; and (iii) a dangerous probability of achieving monopoly power. *See Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993). Amgen only challenges the first element, evidence of which establishes the second. *See id.* at 459.

<sup>14</sup> *See Ortho Diagnostic Sys., Inc. v. Abbott Labs., Inc.*, 920 F. Supp. 455, 466-67 (S.D.N.Y. 1996); *cf. Virgin Atl. Airways Ltd. v. British Airways PLC*, 257 F.3d 256, 269 (2d Cir. 2001) (rejecting plaintiff’s cost-based approach). *Masimo*, 2006 WL 1236666, at \*1, which Amgen cites (Mem. at 10 n.15), did not apply an attribution test. *Ramallo* is inapposite because it distinguished *LePage’s, inter alia*, on the ground that the “Plaintiff was the dominant incumbent,” 392 F. Supp. 2d at 138 n.6, a rationale inapplicable here.

<sup>15</sup> Patrick Greenlee *et al.*, *An Antitrust Analysis of Bundled Loyalty Discounts*, at 12 (EAG Dis. Paper No. 04-13 Oct. 30, 2006), available at <http://ssrn.com/abstract=600799>; *see also* Ex. 89 at 208:6-9 (Teece Dep.); Einer Elhauge & Damien Geradin, *GLOBAL ANTITRUST LAW AND ECONOMICS* 628-31 (2007); Ex. 85 at ¶ 128 (Elhauge Rep.).

<sup>16</sup> Patrick Greenlee, *et al.*, *An Antitrust Analysis of Bundled Discounts*, at 5 (EAG Dis. Paper No. 04-13 Oct. 2004), available at [http://www.stern.nyu.edu/networks/phdcourse/greenlee\\_reitman\\_sibley\\_Bundling\\_Royalty\\_Discounts.pdf](http://www.stern.nyu.edu/networks/phdcourse/greenlee_reitman_sibley_Bundling_Royalty_Discounts.pdf); Elhauge &

predation, but rather through foreclosure (Ex. 85 at ¶¶ 127, 135-36 (Elhauge Rep.)), the same harm threatened by exclusive dealing. Yet, no cost-based safe harbor applies to exclusive dealing. The attribution test also suffers from numerous other flaws.<sup>17</sup>

In any event, contrary to Amgen's supposed Fact No. 6, Amgen's contracts fail the attribution test. The part of Professor Elhauge's analysis Amgen cites shows that Aranesp is sold above cost *if* Roche obtains 100% of all hospital ESA purchases (Ex. 85 ¶ 132 (Elhauge Rep.)); but this 100% assumption spreads Amgen's penalties over an artificially larger base of sales and is unrealistic: Amgen itself argues that Mircera's lack of an oncology indication will limit its hospital success. Moreover, many hospitals split ESAs, which is why Roche expects some substantial hospital sales (Facts 6.15-16). Accordingly, as Professor Elhauge explains, under a more realistic assumption that Roche obtains a smaller hospital share (taking a mere 11.1% of hospital ESA sales, all from Aranesp), and employing an aggregate (or average) approach consistent with the parties' use of standard agreements, Amgen's contracts *fail* the attribution test (Facts 6.17-18). Even if Mircera's costs were *zero*, Roche would need to *pay* hospitals millions

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Geradin, *supra*, at 626-31.

<sup>17</sup> See generally Elhauge & Geradin, *supra*, at 628-31 (summarizing critiques). Applying an attribution test to Amgen's efficiency-impairing conduct is improper because it "assumes away the very anticompetitive effect being tested," *id.* at 629, and problematically "assumes disequilibrium behavior," Greenlee et al. (2006); see Elhauge & Geradin, *supra*, at 629-30 (prey has disincentive to cut price because monopolist can always profitably reduce bundle's price further). The test also "creates serious administrability difficulties." Thomas A. Lambert, *Evaluating Bundled Discounts*, 89 Minn. L. Rev. 1668, 1729 (2005). The Antitrust Modernization Commission, which Amgen cites, recognizes that existing law (*e.g.*, *LePage's*) has condemned conditioned discounts without applying an attribution test. The Commission and its witnesses also recognized that the attribution test is underinclusive, permitting anticompetitive conduct other tests would prohibit. See *Report and Recommendation* 99-100 (Apr. 2007). Because Amgen's contracts lack justification yet impede rivals, this Court ought not apply an admittedly underinclusive test here.

to take Mircera to overcome Amgen's pricing penalties (Facts 6.14-18). While Amgen's expert has a different opinion, the facts a jury could find support Roche's analysis.

Amgen's contention that Mircera's lack of an oncology indication and anticipated launch price, not Amgen's contracts, will limit Roche's hospital sales (Mem. at 11), is controverted by evidence that Roche could expect *greater* sales absent Amgen's exclusionary contracts (Fact 6.12). That non-Amgen factors might limit Roche's potential sales is beside the point. *See Ford Motor Co. v. Webster's Auto Sales, Inc.*, 361 F.2d 874, 886 (1st Cir. 1966). Amgen's claim that its contracts lower price (Mem. at 16) is belied by Amgen's ability to discount without exclusionary cross-product linkage (Fact 6.7), and Amgen's purpose to raise barriers to switching through its contracts (Fact 6.1).<sup>18</sup>

### C. Evidence Establishes Roche's *Walker Process* Claims

In its March 30 Order, this Court correctly rejected Amgen's argument that defense costs must jeopardize entry to support *Walker Process* antitrust injury. Amgen now recycles the same flawed contention to argue that imposing millions in entry costs on Roche causes no competitive harm. Amgen is wrong because antitrust injury reflects harm from *competition-reducing* conduct. *See CVD, Inc. v. Raytheon Co.*, 769 F.2d 842, 858 (1st Cir. 1985); *Handgards, Inc. v. Ethicon, Inc.*, 601 F.2d 986, 997 (9th Cir. 1979). Forcing Roche to spend millions to combat *Walker Process* fraud is anticompetitive because it raises already high entry barriers (Fact 7.2.c); Ex 85 at ¶ 186 (Elhauge Rep.). *See* 1 Herbert Hovenkamp *et al.*, IP AND ANTITRUST § 11.4, at 11-43 to 11-44 (2007)

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<sup>18</sup> The foregoing evidence that Amgen's Fresenius Contract, hospital contracts, and customer threats are anticompetitive amply establishes triable evidence of Roche's § 2 claims even in an "all ESA" market, where foreclosure is above 30% and Amgen has monopoly power (Fact 7.7). The same evidence establish Roche's § 1 claims.

(explaining that “impos[ing] costs on competitors” is anticompetitive and concluding, “in general, antitrust claimants who can demonstrate that a monopolist” engages in *Walker Process* fraud “**should be able to demonstrate anticompetitive conduct as a matter of course**” (emphasis added)); *Grappone, Inc. v. Subaru of New Eng., Inc.*, 858 F.2d 792, 795-96 (1st Cir. 1988) (raising entry barriers harms competition).<sup>19</sup>

Amgen also overlooks (i) that its litigation-related customer threats dampen anticipated Mircera sales and forced Roche to spend funds to counteract them (Facts 8.9-10, C.7); and (ii) that Mircera likely will be approved for sale before appellate courts affirm rejection of Amgen’s fraudulent suit, yet sales will continue to be chilled, and inroads into Amgen’s monopoly delayed, pending appeal (Fact C.2). *See Nobelpharma AB v. Implant Innovations, Inc.*, 930 F. Supp. 1241, 1257-58 (N.D. Ill. 1996) (inference of reduced sales supported *Walker Process* verdict), *aff’d*, 141 F.3d 1059 (Fed. Cir. 1998). A “pernicious effect” of *Walker Process* fraud includes, “because litigation is uncertain, the possibility that the plaintiff may win will scare off potential competitors **or their customers.**” 1 Hovenkamp, *et al.*, *supra*, § 11.4, at 11-44 (emphasis added).

#### **D. Roche has Standing to Seek Damages**

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<sup>19</sup> *Cf. Kearney & Trecker Corp. v. Cincinnati Milacron Inc.*, 562 F.2d 365, 373 (6th Cir. 1977) (dangerous probability of success established *inter alia* by evidence that enforcement of fraudulently procured patent was designed “to exclude competition”); *Novo Nordisk of N. Am., Inc. v. Genentech, Inc.*, 885 F. Supp. 522, 527 (S.D.N.Y. 1995) (similar allegations stated a claim). *Brunswick Corp. v. Riegel Textile Corp.*, 752 F.2d 261 (7th Cir. 1984), cited by Amgen, is inapposite; the court found no competitive harm because the plaintiff sought transfer to it of a patent-based monopoly, circumstances inapplicable here, *see id.* at 265-67. *Brotech Corp. v. White Eagle Int’l Techs. Group*, 2004 WL 1427136, at \*6 (E.D. Pa. June 21, 2004), and *Chip-Mender, Inc. v. Sherwin-Williams Co.*, 2006 U.S. Dist LEXIS 2176, at \*14-\*15 (N.D. Cal. Jan. 3, 2006), both are premised on the already-rejected contention that litigation expenses cannot support antitrust injury. Finally, unlike *Augustine Med., Inc. v. Mallinckrodt, Inc.*, 2003 U.S. Dist. LEXIS 6079 (D. Del. Apr. 9, 2003), there *is* here evidence of “a perception by customers of the risks” from Amgen infringement suits. *Id.* at \*25.

Roche presented evidence of lost profits (Fact C). Amgen’s sole challenge, that lost profits “could only arise later if Amgen’s challenged conduct continued for months after the trial of this matter” (Mem. at 20), is thrice flawed. First, this Court’s ruling that Roche meets the intent and preparedness test, *see supra* note 2, refutes Amgen’s premise that “[a]ctual past injury is a prerequisite for [damages] standing” (Mem. at 19). Damages that require entry are recoverable now.<sup>20</sup> Second, not all lost profits – and *none* of Roche’s out-of-pocket damages – require continuing misconduct. Amgen’s customer threats will continue to chill Mircera’s adoption after they cease (Fact C.2), and Amgen’s fraudulent patent suit will chill sales until termination of appeals (*Id.*; *supra* Part I.D).

Third, Amgen’s conduct *is* likely to continue well after Roche begins selling Mircera. Amgen concedes (Mem. at 20) that FDA approval may be forthcoming in “four or five months” (*i.e.*, October or November). Contrary to Amgen’s suggestion, Roche will promptly sell (*i.e.*, take orders for) Mircera upon approval (Facts 2.1, C.1). By contrast, with a September trial followed by post-trial, injunction and stay pending appeal proceedings, Amgen’s unlawful conduct likely will continue into 2008 (Fact C.2). Amgen’s expert had no view on the matter. Ex. 89 at 44:20-45:23 (Teece Dep.). These circumstances support lost profits because when an antitrust plaintiff “seeks recovery for injuries from a partial or total exclusion,” damages “are rarely susceptible of the kind of concrete, detailed proof of injury which is available in other contexts.” *Zenith Radio*

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<sup>20</sup> *See, e.g., Cent. Telecomms., Inc. v. TCI Cablevision, Inc.*, 800 F.2d 711, 727-28 (8th Cir. 1986) (“[A]t least seven of the Circuit Courts of Appeal . . . have ruled that an unestablished business can recover future lost profits under the federal antitrust laws if a sufficiently advanced state of preparation for entering a market has been achieved.”). Amgen’s cases (Mem. at 19 & n.37), *CIA. Petrolera Caribe, Inc. v. Arco Caribbean, Inc.*, 754 F.2d 404, 411-12 (1st Cir. 1985) (no damages sought); *In re Relafen Anti. Litig.*, 286 F. Supp. 2d 56, 63-64 (D. Mass. 2003) (customer suit), are not to the contrary.

*Corp. v. Hazeltine Res., Inc.*, 395 U.S. 100, 123 (1969). “[J]uries are allowed to act on probable and inferential as well as (upon) direct and positive proof. Any other rule would enable the wrongdoer to profit by his wrongdoing at the expense of his victim.” *Bigelow v. RKO Radio Pictures, Inc.*, 327 U.S. 251, 264 (1946) (citations omitted).<sup>21</sup>

Equally incorrect is Amgen’s assertion (Mem. at 20) that Roche failed to identify the part of its out-of-pocket damages Amgen caused. Roche spent all of the \$5.5 million in expenses thus far claimed defending Amgen’s fraudulent patent action (Fact C.12). Similarly, the \$1.1 million in marketing expenses claimed resulted solely from Amgen’s illegal customer threats (Facts C.6-11).<sup>22</sup> Finally, the jury could award Roche nominal damages. *See Romano v. U-Haul Int’l*, 233 F.3d 655, 671 (1st Cir. 2000).

## **II. Roche’s Tortious Interference Claim Is Supported by Abundant Triable Evidence**

Amgen dismisses Roche’ tortious interference claim with a footnote assertion that it fails “for the same reasons as [Roche’s] Sherman Act claims” (Mem. at 20 n.39). But under applicable New Jersey law, a Sherman Act violation is not required to establish the tort.<sup>23</sup> “These causes of action vindicate widely differing policies; the

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<sup>21</sup> *See also J. Truett Payne Co. v. Chrysler Motors Corp.*, 451 U.S. 557, 565-67 (1981) (“our traditional rule excuse[s] antitrust plaintiffs from an unduly rigorous standard of proving antitrust” damages); *Ford Motor*, 361 F.2d at 887 (“This court has recognized that older standards requiring ‘certainty’ of damages have given way to ‘proof of losses which border on the speculative, in order to implement the policy of the antitrust laws.’” (citation omitted)); *Coastal Fuels*, 79 F.3d at 200; *Sullivan*, 34 F.3d at 1103.

<sup>22</sup> Upon verifying (*see* Ex. 46 (Graf Decl.)) that Amgen’s threats caused all claimed increased costs, Roche now seeks only \$1.1 million rather than \$1.7 million for those damages. Amgen cites inapposite testimony for its flawed assertion (Mem. at 20) that lawful conduct caused Roche’s harm. Roche seeks only \$10,000 (Ex. 46 at ¶ 9 (Graf Decl.)) of the \$1.2 million “Discover Roche” campaign, not that entire amount.

<sup>23</sup> Amgen conceded that the law of New Jersey, Roche’s place of business (Fact D), governs the claim. *See* Mem. in Support of Amgen’s Motion to Dismiss at 17 & n.61

first is wholly personal to the plaintiff-competitor and the second requires the plaintiff to demonstrate harm to competition at large and antitrust injury.” *Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 187 (3d Cir. 1992). Here, with specific intent to injure Roche, Amgen wielded its monopoly power to threaten retaliation against customers who deal with Roche, and imposed unjustified contracts that penalize switching. *See supra* Part I. Courts have held a powerful supplier’s threat of economic retaliation against customers for dealing with a rival to comprise tortious interference, even absent an antitrust violation. *See Fineman*, 980 F.2d at 191-94, 197, 203; *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1167-69 (3d Cir. 1993).

Evidence also shows causation and damages; *viz.*, “without the interference, there was a reasonable probability that [Roche] would have received the anticipated economic benefits.” *Patel v. Soriano*, 848 A.2d 803, 831-32 (N.J. Super. Ct. App. 2004). As explained (*see supra* Part I.D), Amgen’s tortious acts will continue to reduce expected sales, permitting recovery of lost profits, *see Lightning Lube*, 4 F.3d at 1174-78, and funds spent in mitigation, *see O’Brien (Newark) Cogeneration, Inc. v. Auto. Sprinkler Corp.*, 825 A.2d 524, 520 (N.J. Super. Ct. App. 2003). Roche need not show that it lost specific customers’ business. *See Patel*, 848 A.2d at 840; *Grillo v. Bd. of Realtors*, 219 A.2d 635, 651-52 (N.J. Super. Ct. Ch. Div. 1966).

## CONCLUSION

For the foregoing reasons, Amgen’s Motion for Summary Judgment on Roche’s Antitrust and State Law Counterclaims should be denied.

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(Nov. 27, 2006, Docket No. 151); *Engine Specialties, Inc. v. Bombardier, Ltd.*, 605 F.2d 1, 19 (1st Cir. 1979) (applying law of place of injury).

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#### **CERTIFICATE OF SERVICE**

I hereby certify that a version of this document was filed through the ECF system and was sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies were sent to those indicated as non-registered participants on June 29, 2007.

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