UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THE PEOPLE OF THE STATE OF NEW YORK

Plaintiff,

v.

ACTAVIS, PLC, and
FOREST LABORATORIES, LLC,

Defendants.

Case No.: 14-cv-7473

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS AMENDED COMPLAINT

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INTRODUCTION

Defendants Forest Laboratories, LLC and Actavis, plc[1] submit this memorandum in support of their motion to dismiss the Amended Complaint with prejudice for failure to state a claim upon which relief can be granted. The Bureau's Amended Complaint is an admission that its novel monopolization theory did not state a claim.[2] At first, the Bureau complained that Forest was effectively discontinuing an older version of Namenda and asked the Court to impose an antitrust duty to sell an older product to assist its competitors. But when the Bureau finally appreciated that the older version of Namenda would remain available nationwide, the Bureau developed a new theory: that Forest's agreement to continue distributing the older version of Namenda is an illegal conspiracy in ***restraint*** of trade, and that the Court should mandate the minimum volume and appropriate distribution channel to be used in selling Forest Lab's older products. The Bureau's new theory, like its old theory, must be dismissed.

Forest Labs is an innovative pharmaceutical company and pioneer in the treatment of Alzheimer's disease. This case relates to two brand-name memantine Alzheimer's treatments that Forest Labs sells: older, twice-a-day Namenda IR tablets and the newer, more convenient, once-a-day Namenda XR capsules. Am. Compl. ¶ 4. Forest Labs also sells a third memantine Alzheimer's treatment, Namenda IR oral solution, which the Bureau admits remains available as an alternative to Namenda XR. *See id.* ¶¶ 58, 89; P.I. Mem. at 21 n.57.[3]

The primary issue in this case is whether the antitrust laws should be read for the first

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[1] On July 1, 2014, Actavis, plc acquired Forest Laboratories, LLC. The New York Attorney General Antitrust Bureau ("Bureau") brings this action against Actavis and Forest Laboratories (hereinafter together, "Forest Labs").

[2] The Bureau filed its Amended Complaint without seeking leave to amend under Rule 15(d). *See Groves v. Davis*, 2014 WL 4684998, at *16-17 (N.D.N.Y. Sept. 19, 2014) (requiring leave for such amendments). The Bureau's amendments—served long after it knew of Foundation Care—are prejudicial, unduly delayed, and futile.

[3] The Court can take judicial notice of the filings in this case. *See Mai Sa v. Doe*, 406 F.3d 155, 158 (2d Cir. 2005); *Weisman Celler Spett & Modlin, P.C. v. Trans-Lux Corp.*, 2014 WL 476348, at *2 n.1 (S.D.N.Y. Feb. 6, 2014) (court can take judicial notice of court filings).

time to impose a mandatory, affirmative duty on an innovator—such as Forest Labs—to continue selling an older product, solely for the benefit of its generic competitors. The Bureau asks this Court to create that novel duty and order unprecedented remedies to force Forest Labs to continue manufacturing and selling its old Namenda IR tablets and to compel notice to doctors, solely to help Forest Labs' generic rivals compete and take sales away.

But nearly 125 years after enactment of the Sherman Act, no court has ever read the antitrust laws as imposing a duty to market old products to help rivals. As the Supreme Court and Second Circuit have held repeatedly, the antitrust laws encourage innovation and vigorous competition. Particularly here, where the Bureau does not contest that (1) the new version of Namenda is better than the old version, and (2) Forest Labs' conduct fully complied with all rules and regulations governing pharmaceutical products, this Court should not require Defendants to slow the pace of innovation for the sake of competitors.

The Bureau's own Complaint—and its request for extraordinary injunctive relief—show why this case should proceed no further. According to the Bureau, Forest Labs' plan to discontinue twice-a-day Namenda IR in favor of once-a-day Namenda XR (or distribute Namenda IR through a specialty pharmacy) constitutes unlawful "maint[enance] and enhance[ement] [of a] monopoly" in violation of Section 2 of the Sherman Act. Am. Compl. ¶ 121. The Bureau claims hyperbolically that Forest Labs' marketing of once-a-day Namenda XR "will ***destroy*** the market for the generic form of Namenda IR," "***prohibit*** generic manufacturers from providing generic Namenda to this needy patient population," "***exclude*** generic competition," "***prevent*** manufacturers of generic memantine from ***engaging in effective price competition***," and "***hobble***[] the overall competitive significance of generic memantine." *Id.* ¶¶ 4, 5, 6, 71, 102 (emphasis added). The Bureau demands the extraordinary remedy of a

preliminary and permanent injunction, and compelled speech, arguing that if the Court does not act now, there will ***never*** be substantial sales of generic memantine, and Forest could monopolize the market forever. *See* Am. Compl. at 40 ¶ d; Not. of Mot. for P.I. (ECF 25).

While the evidence presented at the preliminary injunction hearing decisively would refute these conclusory and misleading claims, the Court does not even need to hear that evidence to reject the Bureau's novel case theory. The Complaint's overreach is clear now. "In considering a motion to dismiss, the Court may rely on documents . . . in Plaintiff's possession or which he knew about, which were integral to bringing the claim," *Cipollaro v. N.Y.C. Transit Auth.*, 2014 WL 4589828, at *1 n.1 (S.D.N.Y. Sept. 12, 2014) (Sweet, J.)—and indeed, "any document upon which the complaint heavily relies," *In re Thelen LLP*, 736 F.3d 213, 219 (2d Cir. 2013). Consider two documents upon which the Bureau most "heavily relies." The first is a transcript of an analyst call in which Forest's CEO, Brent Saunders, discusses "potentially doing a forced switch" to Namenda XR. Am. Compl. ¶¶ 2, 87 & n.12 (relying on earnings transcript). The Complaint ignores what Mr. Saunders said in nearly the same breath:

- "I think with respect to Namenda, what happens after the patent expiry, which is July of 2015, the product goes—***the franchise goes into decline***. . . . [W]hat we're trying to do is . . . have a ***long, prolonged decline*** . . . ."
- "[W]e will fight for new RX's, . . . will be fighting with a better formulation, more convenient dosing, as well as a combination product, and so I think it's—***price is still very important. It will be a dog fight at that point***, but we do have some weapons in the stable."

Transcript of Forest Labs., Inc. Earnings Call at 18, 19 (Jan. 21, 2014) (emphasis added) (Pace Decl. Ex. 1). The very document upon which the Complaint relies establishes that price competition—a "dog fight"—***will*** come once generic versions are launched in July 2015, and that this generic competition will destroy ***Forest's*** market share—***not*** the other way around.

Similarly, the Bureau alleges that an October 2013 internal Forest presentation [redacted]

[redacted] But the Forest presentation actually shows [redacted]

[redacted] In neither case will generic competition be "destroy[ed]," "prohibit[ed],"

"exclude[d]," "prevent[ed]," or "hobble[d]." Am. Compl. ¶¶ 4, 5, 6, 71, 102.

That, by itself, should end the case. "Monopoly power is the power to control prices or exclude competition." *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956). But as the Complaint documents make clear, Forest Labs will not have "the power to control prices or exclude competition" after it loses patent exclusivity in July 2015, and Forest will not "reap several more years of monopoly profits than they would have earned otherwise." Am. Compl. ¶ 4. To the contrary, as Mr. Saunders observed, "[i]t will be a dog fight at that point," a fight in which "price [will] still [be] very important." Pace Decl. Ex. 1 at 19.

Accordingly, the Complaint should be dismissed. ***First***, the Bureau fails to allege that Forest possessed an illegal monopoly. The Bureau concedes that any exclusivity of Forest Labs over Namenda products comes from lawful "patent monopolies" and FDA authorizations through July 2015 that the Bureau does not challenge. *See, e.g.*, Am. Compl. ¶¶ 3, 53-63; *see also* 35 U.S.C. § 154 (describing patent power to exclude); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1204 (2d Cir. 1981) (patent owner has no duty to license its patents).

Second, the Bureau fails to allege any exclusionary conduct by Forest Labs. "[A]ny firm, even a monopolist, may generally bring its products to market ***whenever and however*** it chooses." *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 286 (2d Cir. 1979) (emphasis added). As noted, no conduct by Forest Labs will block generic competition—only lawfully obtained patent and regulatory exclusivities will—and the documents relied upon in the Bureau's own Complaint confirm that generic competition will be substantial.

Third, the Bureau has failed to state a claim under the Donnelly Act. N.Y. Gen. Bus. Law § 340 *et seq.* The Donnelly Act does not address single-firm conduct of the type primarily alleged here, and the Bureau's last-minute addition to its complaint does not save its claims.

Fourth, the Bureau's asserted fraud claims rely on a remedies statute that requires a separate, viable claim—which the Bureau does not have—and are not pleaded with particularity despite seven months of pre-Complaint discovery. N.Y. Exec. Law § 63(12).

Fifth**,** the Bureau's last-minute vertical conspiracy claim cannot avoid dismissal.

Finally, the Bureau suggests it is bringing this case to protect patients—portraying the sophistication of patients, physicians, and healthcare payors in New York as dim indeed. But the Bureau's novel case theory is badly out of touch with the reality of healthcare, and itself is anticompetitive. The Bureau's claims assume that patients, doctors, and insurers will not learn of the entry of generic competitors to this "blockbuster" drug—and therefore cannot be trusted to choose the generic versions of twice-a-day Namenda IR over the new and improved once-a-day Namenda XR. Am. Compl. ¶¶ 38-41. But the Bureau never alleges physicians will be prevented from prescribing a generic version of twice-a-day Namenda IR after patent expiry, or that large healthcare providers will be prevented from incentivizing pharmacies and patients through their power to control reimbursement. As such, no competition will be excluded, and there is simply no antitrust claim here. The only anticompetitive aspect of the case is the Bureau's request to compel the sale of older products for the benefit of competitors.

STATEMENT OF FACTS AND ALLEGATIONS

Forest Labs has been a leader in Alzheimer's treatment and research for more than a decade and sells several products used to treat Alzheimer's patients. Am. Compl. ¶¶ 4, 57. Forest Labs exclusively licenses U.S. Patent No. 5,061,703, which covers the twice-a-day Namenda IR product and expires in April 2015. *Id.* ¶¶ 53, 55. In addition, in recognition of Forest Labs' work to study the potential use of memantine to treat pediatric autism, the FDA has granted Forest Labs a lawful six-month extension of regulatory exclusivity in the sale of

Namenda IR and Namenda XR. *Id.* ¶¶ 53, 59, 63. Although this exclusivity expires in October 2015, Forest Labs has granted licenses to a number of companies so that they can begin selling generic versions of Namenda IR three months early, in July 2015. *Id.* ¶¶ 61, 63.

Forest has sold twice-a-day Namenda IR in the United States for over a decade. *Id.* ¶¶ 57, 66. Twice-a-day administration can present challenges to patients and caregivers due to the debilitating nature of Alzheimer's disease and the potential for missed medication. As one physician explains: "'Given the day-to-day challenges of caring for someone with Alzheimer's disease, there is a need for treatments that simplify a patient's daily regimen and may help caregivers manage their loved ones' needs.'" Zain Decl. Ex. 33 at 1 (Forest press release).

In 2013, Forest Labs launched once-a-day Namenda XR. Am. Compl. ¶ 66. The response among patients and caregivers was positive: "[A] majority of caregivers responded that they were satisfied with the once daily dosing of NAMENDA XR." Zain Decl. Ex. 33 at 1.[4] The Bureau concedes that "[s]ome patients may benefit from the ability . . . to take Namenda once a day instead of twice," P.I. Mem. at 16, and disavows any objection to the launch of Namenda XR, *id.* at 30 n.67. Any suggestion that Namenda XR presents only a trivial tweak to Namenda IR tablets (*see, e.g.,* Am. Compl. ¶ 77) is undercut by the Bureau's contention that patients will be reluctant to switch back to Namenda IR tablets (*see, e.g.*, Am. Compl. ¶ 4).

Consistent with the marketplace acceptance of the benefits of once-a-day Namenda XR, on February 14, 2014, Forest announced plans to discontinue the sale of twice-a-day Namenda IR tablets and focus its sales on the new and improved version. Am. Compl. ¶ 91. On November 5, 2014, Forest confirmed that while it will "discontinue the general and distribution of Namenda IR® immediate-release tablets," it would continue to make the tablet available

[4] Namenda XR offers other significant benefits. For example, unlike Namenda IR tablets, Namenda XR has FDA approval to be sprinkled over applesauce for patients who have difficulty swallowing pills (Zain Decl. Ex. 33 at 1) and improves cognition and patient functioning when used in combination with certain other drugs (*id.* Ex. 20 at 1).

through Foundation Care, "a full source mail order pharmacy serving patients nationwide." Am. Compl. ¶¶ 111, 115. The Bureau also concedes that Forest continues to manufacture and sell Namenda IR oral solution. *See* Am. Compl. ¶¶ 58, 89; P.I. Mem. at 21 n.57.

On September 15, 2014, the Bureau filed its Complaint seeking an injunction preventing Forest from "discontinuing Namenda IR" until a generic is "available on the market" and for an unspecified, "reasonable" period of time thereafter. *See id.* at 38 (demand for judgment). The Bureau does not allege in either its Complaint or November 5 Amended Complaint how much Namenda IR Forest Labs must manufacture to escape antitrust liability, nor how aggressively Forest Labs must sell the old, twice-a-day version, nor for how long after generic entry must Forest Labs continue to make and sell the old Namenda IR tablets.

ARGUMENT

I. Forest Labs' Lawful "Patent Monopoly" Protects Its Decisions to Sell or Not to Sell Namenda IR

The Complaint alleges illegal monopolization. Am. Compl. ¶ 120-21. Forest Labs, however, is not a Sherman Act monopolist—it holds valid patent and regulatory exclusivities covering Namenda IR and XR. *Id.* ¶¶ 3, 53-63. As a result, Forest Labs has the right to decide whether, when, how much, and for how long to manufacture and sell Namenda IR. *See, e.g.*, *SCM*, 645 F.2d at 1204 ("Simply stated, a patent holder is permitted to maintain his ***patent monopoly*** through conduct permissible under the patent laws.") (emphasis added).

A. Forest Labs' Lawful Monopoly Entitles It to Exclude Competitors through July 2015 and Use Specialty Distribution for Namenda IR

The Bureau does not dispute that Forest Labs' Namenda IR "is protected by patent and regulatory exclusivities that prevent generic versions from entering the market until July 2015." Am. Compl. ¶ 3. Specifically, the Bureau concedes that:

- The U.S. PTO issued a patent covering Namenda IR (¶ 59);

- The FDA approved Namenda IR, and Forest Labs received exclusivity under the Hatch-Waxman Act (¶¶ 20, 55-56);
- The PTO granted a patent term extension, giving Forest Labs five years of additional exclusivity for Namenda IR (¶¶ 20, 59) (*see* 35 U.S.C. § 156);
- The FDA granted Forest Labs six months of additional exclusivity on Namenda IR for pediatric studies, which expires in October 2015 (¶¶ 62-63) (21 U.S.C. § 355a).

The Bureau admits Forest Labs lawfully can exclude competitors and use its lawful exclusivity as it sees fit until July 11, 2015 (the date established by Forest Labs' license agreements with generic manufacturers). Am. Compl. ¶¶ 59, 61.

Forest Labs' patent exclusivity confers freedom to price and freedom to sell. Even a monopolist, "with no duty to deal[,] is free to charge whatever wholesale price it would like." *Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438, 454 (2009). "[A]ntitrust law does not prohibit lawfully obtained monopolies from charging monopoly prices." *Id.*; *see also Schor v. Abbott Labs.*, 457 F.3d 608, 610 (7th Cir. 2006) (lawful patent holder can charge whatever market will bear). If a lawful patent holder can sell at "whatever price," it also may distribute its product as it sees fit. *See SCM*, 645 F.2d at 1206 ("[W]here a patent has been lawfully acquired, subsequent conduct permissible under the patent laws cannot trigger any liability under the antitrust laws.").[5] Forest's specialty distribution of Namenda IR tablets therefore "cannot trigger any liability under the antitrust laws." *See SCM*, 645 F.2d at 1206.

Far from being forced to use a patent in a way that assists competitors, patent holders have the lawful right to exclude competitors. *See* U.S. Const. art. I, § 8, cl. 8 ("Congress shall have [the] power . . . [t]o promote the progress of science and useful arts, by securing for limited times to . . . inventors the exclusive right to their . . . discoveries[.]"); *Eatoni Ergonomics, Inc. v.*

[5] *See also In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1328 (Fed. Cir. 2000) (holding that refusal to sell patented products does not violate Sherman Act); *Sheet Metal Duct, Inc. v. Lindab, Inc.*, 2000 WL 987865, at *5, 6 (E.D. Pa. July 18, 2000) (noting legality of "suppress[ing] an invention" and that "there can be no liability under the antitrust laws for the existence or maintenance of this statutory monopoly"); III Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 708a, at 298 (3d ed. 2008) ("[M]ere non-use of a patent can never be an antitrust violation in and of itself.").

Res. in Motion Corp., 486 F. App'x 186, 190-91 (2d Cir. 2012) (summary order) ("[Section] 2 does not obligate [a patent holder] to share its patented platform technology . . . .").[6]

B. The Bureau Cannot "Alchemize" a Novel Antitrust Cause of Action by Combining the Lawful Specialty Distribution of Namenda IR Tablets and the Lawful Introduction of Namenda XR

The Bureau's claims here are similar to those the Supreme Court rejected in *Trinko* and *Linkline*. In those cases, plaintiffs tried to join a claim "that cannot succeed with [another] claim that cannot succeed, and alchemize them into a new form of antitrust liability," an approach the Supreme Court rejected. *Linkline*, 555 U.S. at 457; *see also Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 410 (2004) (rejecting similar antitrust claim). Here, the Bureau seeks to combine two lawful actions—the lawful specialty distribution of twice-a-day Namenda IR tablets and the lawful introduction of once-a-day Namenda XR[7]—to manufacture an illegal act under Section 2 of the Sherman Act.

The Bureau's antitrust theory is untenable. As the *Linkline* Court held, "[t]wo wrong claims do not make one that is right." 555 U.S. at 457; *see also City of Groton v. Conn. Light & Power Co.*, 662 F.2d 921, 928-29 (2d Cir. 1981) (same). As neither the specialty distribution of an old product nor the launch of a new product is "independently anticompetitive," the cumulative effect is not "anticompetitive either." *Eatoni*, 486 F. App'x at 191.

The Bureau's attempt to conjure an illegality here is particularly inappropriate in light of the regulatory system governing the pharmaceutical industry. The *Trinko* court emphasized the importance in an antitrust case of "an awareness of the significance of regulation." 540 U.S. at 411. The Court held that the presence of the regulatory regime governing the parties' conduct

[6] *See also SCM*, 645 F.2d at 1204 ("No court has ever held that the antitrust laws require a patent holder to forfeit the exclusionary power inherent in his patent the instant his patent monopoly affords him monopoly power over a relevant product market."); *Applera Corp. v. MJ Res. Inc.*, 349 F. Supp. 2d 338, 347-48 (D. Conn. 2004) ("[E]vidence of Applera's refusals to provide end user licenses to MJ cannot show improper exclusion.").

[7] P.I. Mem. at 30 n.67 (withdrawing any challenge to launch of Namenda XR).

(like the complex FDA drug approval process in this case) was one of the strong factors against antitrust liability. *See id.* at 412-13; *In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 135 (2d Cir. 2014) (applying *Linkline* and *Trinko* to refusal to deal claim against pharmaceutical company, and declining to add to existing "regulatory" or "statutorily imposed" duties an antitrust duty to "cooperate with competitors"). Here, the Complaint concedes that the pharmaceutical industry is heavily regulated—and even details the regulatory framework in which Forest operates. *See generally* Am. Compl. ¶¶ 16-27, 53-63. Nor does the Bureau ever allege that Forest violated or may violate any of the governing complex web of FDA rules and regulations in discontinuing twice-a-day Namenda IR tablets or through specialty distribution.

II. The Bureau Fails to Plead That Forest Illegally Monopolized a Relevant Antitrust Market for Namenda IR or XR

Forest's alleged "illegal" conduct is its alleged "strategy" to discontinue twice-a-day Namenda IR sometime after introducing once-a-day Namenda XR. Am. Compl. ¶ 4. But innovating, introducing a new product, and discontinuing or specialty distributing an old one do not violate Sherman Act § 2. "To safeguard the incentive to innovate, the possession of monopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive ***conduct***." *Trinko*, 540 U.S. at 407 (emphasis in original). Section 2 prohibits only monopolies "willfully acquir[ed] or maintain[ed]" through exclusionary conduct. *See id.* (Section 2 violation requires "'willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of superior product, business acumen, or historic accident'") (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966)).

As the documents relied on in the Complaint demonstrate, Am. Compl. ¶¶ 2, 82, 87, even if Forest specialty distributes Namenda IR tablets before the introduction of generics, ***no generic competition will be excluded***. [redacted]

[redacted]; *see AD/SAT v. Associated Press*, 181 F.3d 216, 229-30 (2d Cir. 1996) (per curiam) ("Rapidly developing technology for the transmission of data and low barriers to market entry suggest that the AP will face significant competitors from new entrants. . . . "). The Bureau's theory makes no more sense than a claim that Ford violates the antitrust laws by introducing a new F150 and no longer building the prior model. Ford has no more duty to keep making last year's truck to benefit its competitors than Forest has to continue selling Namenda IR tablets to benefit its competitors.[8]

A. Forcing Forest Labs to Sell an Older Product So That Competitors Can Catch Up Is Inimical to the Antitrust Laws

Second guessing Forest Labs' innovation, the Bureau seeks an order compelling the company to continue selling Namenda IR in all channels ***not*** so that patients may continue to purchase ***Forest Labs'*** Namenda IR, but so that the laws of a handful of states may force a switch to generic versions of Namenda IR sold by Forest Labs' competitors. Am. Compl. ¶ 3. But it would twist the antitrust laws beyond recognition to force a firm to aid its competitors.

"The antitrust laws . . . were enacted for 'the protection of competition, not'"—as the Bureau proposes—"'competitors.'" *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977) (citing *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962)). One competitor gaining market share at the expense of another—such as Forest gaining market share at the expense of generic competitors—is not an injury to competition. *See Cargill, Inc. v. Monfort of Colorado, Inc.*, 479 U.S. 104, 116 (1986) ("The kind of competition that Monfort alleges here, competition for increased market share, is not activity forbidden by the antitrust laws."); *Brunswick,* 429 U.S. at 484 (denying plaintiff "an anticipated increase in market shares" not

[8] For purposes of this motion only, Defendants assume the relevant antitrust product market the Bureau alleges. Compl. ¶¶ 47, 49, 51. Should this case proceed, Defendants reserve the right to challenge the Bureau's implausible product market consisting of only Namenda IR and XR. *See id.*

antitrust injury); *Juster Assoc. v. Rutland*, 901 F.2d 266, 269 (2d Cir. 1990) ("the mere fact of increased competition and reduced profits . . . does not constitute an antitrust injury").

Trinko made clear that the antitrust laws impose "***no duty*** to aid competitors." *See* 540 U.S. at 411 (emphasis added); *see also id.* at 410 ("[A]lleged insufficient assistance in the provision of service to rivals is not a recognized antitrust claim . . . ."); *Linkline*, 555 U.S. at 449-50 (defendant had no antitrust duty to operate under conditions that "rivals find commercially advantageous"). *Trinko* applies to conduct in the pharmaceutical industry, just like any other industry. *See Adderall*, 754 F.3d at 135 (declining to recognize antitrust duty for pharmaceutical company to "cooperate with competitors").[9] Antitrust laws protect even ***"severely" competitive conduct***. *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993) (emphasis added).

The Bureau asserts that "pharmaceutical competition" is different (P.I. Mem. at 33) and that the Court should penalize "severely competitive conduct" in that industry—even going so far as to compel speech by Defendants in violation of the First Amendment.[10] But there is only one Sherman Act, and it applies "to all industries alike." *See Maricopa*, 457 U.S. at 346 (rejecting different application of Sherman Act in health care industry).

1. Antitrust Laws Do Not Impose an Antitrust Duty to Deal on Forest

The Bureau seeks to expand "the outer boundary of [Section] 2 liability" by forcing Forest to deal with its competitors. *See Trinko*, 540 U.S. at 409 (describing duty to deal claim as "at or near the outer boundary of [Section] 2 liability"). But, a manufacturer may "freely . . .

[9] *See also RxUSA Wholesale Inc. v. Alcon Labs.*, 391 F. App'x 59, 60 (2d Cir. 2010) (declining to create duty to deal with competitors in pharmaceutical case); *see also Arizona v. Maricopa Cnty. Med. Soc'y*, 457 U.S. 332, 346 (1982) (Sherman Act "establishes one uniform rule applicable to all industries alike"); *Bookhouse of Stuyvesant Plaza, Inc. v. Amazon.com, Inc.*, 985 F. Supp. 2d 612, 623 (S.D.N.Y. 2013) ("[N]o business has a duty to aid competitors.").

[10] The Bureau asks that the Court "require[e] them [*i.e.*, Forest Labs] to promptly notify physicians, caregivers and the public of any such [injunctive relief] order." P.I. Mem. at 1. Government-compelled speech violates the First Amendment. *See Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2671 (2011) ("[The State] may be displeased that detailers . . . are effective in promoting brand-name drugs. . . . The State may not burden the speech of others in order to tilt public debate in a preferred direction.").

exercise his own independent discretion as to parties with whom he will deal." *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919).[11]

Similarly, any attempt by the Bureau to create a novel antitrust duty to deal with ***customers*** fails. The antitrust laws are loathe to recognize exceptions to the right of a company to deal with whom it wishes, *see Trinko*, 540 U.S. at 408, particularly where the duty "cannot be explain[ed] or adequately supervise[d]," *id.* at 415. Here, a duty to deal would require courts to assume the day-to-day function of the FDA, a fact that doomed a similar claim in *Trinko*. *Id.* Antitrust courts have rejected attempts to create a duty to deal with customers. *See Colgate*, 250 U.S. at 307 (The Sherman Act "does not restrict the long recognized right of [a] trader or manufacturer engaged in an entirely private business freely to exercise his own independent discretion as to parties with whom he will deal"); *Adderall*, 754 F.3d at 135 (existence of contractual duty to sell goods to non-party competitor does not give rise to antitrust duty to deal).

In *Adderall*, customers sought to impose an antitrust duty on a pharmaceutical manufacturer to deal with generic firms that had purchased raw materials from it. 754 F.3d at 130-31. The Second Circuit held that a preexisting contractual duty to supply a customer does not give rise to an antitrust duty to deal with generic competitors. *Id.* at 135. Here, particularly where Forest does not even have a contractual duty to supply generic firms, the Court should not create a new, amorphous duty requiring Forest to sell twice-a-day Namenda IR in all channels of distribution for an undetermined time simply to benefit its generic competitors.

Consistent with the strong antitrust rule that "any firm, even a monopolist, may . . . bring its products to market whenever and however it chooses," *Berkey Photo*, 603 F.2d at 286, courts

[11] The "sole exception" may arise when a "monopolist . . . terminate[s] a prior (voluntary) course of dealing with a competitor." *Adderall*, 754 F.3d at 134. No prior course of dealing is alleged here—generics have not been marketed for the IR form—so even that "sole exception" does not apply. Forest provides no inputs to its Namenda competitors (*e.g.*, raw materials) and has no course of dealing that would support the creation of a duty to deal with competitors here. *See Eatoni*, 486 F. App'x at 189-90.

have refused to force a company to sell a product. *See IBM Corp. v. Platform Solutions, Inc.*, 658 F. Supp. 2d 603, 613-14 (S.D.N.Y. 2009) ("refusal to support and license its [old patented] operating system . . . does not constitute anticompetitive conduct under the Sherman Act").[12]

2. The Antitrust Laws Do Not Compel Brand Companies to Subsidize Generic Marketing and Sales

According to the Bureau, the Court should force Forest to continue selling old Namenda IR in all channels, even if Forest has decided on specialty distribution in its business judgment. The Bureau seeks to impose this extraordinary duty to sell so that Forest's generic competitors will not incur the expense of marketing generic Namenda IR themselves. *See* Am. Compl. ¶¶ 21, 24 & n.3. Of course, nowhere does the Bureau allege that Forest's generic competitors will be prevented or blocked from promoting generic Namenda IR themselves. Instead, the Bureau wants this Court to facilitate Forest's competitors' free-riding on Forest's promotional efforts.

The antitrust laws are clear that Forest has no duty to enable free riding by competitors. *See, e.g., Olympia Equip. Leasing Co. v. W. Union Tel. Co.*, 797 F.2d 370, 377-78 (7th Cir. 1986) ("You cannot conscript your competitor's salesmen to sell your product even if the competitor has monopoly power and you are a struggling new entrant. . . . [I]t is the antithesis of competition.").[13] As the Second Circuit made clear, courts "must always be mindful lest the Sherman Act be invoked perversely in favor of those who seek protection against the rigors of competition." *Berkey Photo*, 603 F.2d at 273; *see also Buffalo Courier-Express, Inc. v. Buffalo Evening News, Inc.*, 601 F.2d 48, 55 (2d Cir. 1979) ("Courts must be on guard against efforts of plaintiffs to use the antitrust laws to insulate themselves from the impact of competition.").

[12] *See also Trinko*, 540 U.S. at 408 (institutional concerns weigh against courts "identifying the proper price, quantity, and other terms of dealing"); *Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912, 925 n.7 (3d Cir. 1999) ("A business's decision to not produce a product . . . is not a violation of the antitrust laws . . . .").

[13] *See also Abcor Corp. v. AM Int'l, Inc.*, 916 F.2d 924, 929 (4th Cir. 1990) ("The plaintiff had no right to 'free ride' on the sales force of the defendant."); *Adamson v. Ortho-McNeil Pharm., Inc.*, 463 F. Supp. 2d 496, 504 (D.N.J. 2006) (no duty to market competitor's products).

3. A Subset of State Substitution Laws Provides No Basis for the Bureau's Claim of Exclusionary Conduct under the Sherman Act

The Bureau alleges that Forest's alleged conduct in transitioning from twice-a-day Namenda IR tablets to new, once-a-day Namenda XR "prevent[s] the application of generic substitution laws." Am. Compl. ¶ 72. But the Bureau's allegation mischaracterizes state law and suggests an unworkable federal duty that would vary by state.

State substitution laws are not a monolith. After generic versions of twice-a-day Namenda IR are available in July 2015 (Am. Compl. ¶ 63), whether generic Namenda IR is mandatorily substituted for branded Namenda IR will vary significantly state by state:

- **Mandatory substitution:** Only **11 states**, including New York, mandate substitution of a generic for a brand, but even in those states the generic will not be dispensed if the physician specifies that the brand be dispensed (*e.g.*, "DAW"—Dispense As Written);[14]
- **Permissive substitution:** **39 states** permit, but do not mandate, substitution of a generic for a brand—again, unless the physician specifies that the brand be dispensed (*id.*);
- **Permissive non-AB-rated substitution:** **20 states** permit substitution of a generic for a brand, but the generic that is substituted may not be the AB-rated generic version, depending on the pharmacist's discretion.[15]

Creating a ***federal duty*** to help facilitate the laws of a ***subset of states***—*i.e.*, states in which pharmacists are forced to dispense a particular generic when a brand is prescribed—would make no sense. The Bureau's novel theory would mean Forest Labs' conduct was anticompetitive under the Sherman Act in ***some states*** but not others, and for ***some prescriptions*** but not others.

4. So-Called "Regulatory Gaming" Is Not Exclusionary Conduct Nor Actionable under the Antitrust Laws

The Bureau seeks to condemn Forest Labs' lawful conduct as an "effort to game the

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[14] *See* Jesse C. Vivian, *Generic-Substitution Laws*, U.S. Pharmacist, at table 2 (June 19, 2008), *available at* http://www.uspharmacist.com/content/s/44/c/9787.

[15] Tom Wan-Chih & Kayla Dotson, *State Regulations on Generic Substitution*, Pharmacist's Letter (2006, updated 2009), *available at* http://pharmacistsletter.therapeuticresearch.com/pl/ArticleDD.aspx?nidchk=1&cs=&s=PL&pt=2&segment=1186&dd=220901&AspxAutoDetectCookieSupport=1; *see also, e.g.,* Minn. Stat. § 151.21(3) (2007) (allowing substitution based on pharmacist discretion).

regulatory system," Am. Compl. ¶ 43, but strategically complying with regulations is not exclusionary conduct under the Sherman Act. Nowhere does the Bureau allege that Forest Labs has violated or will violate *any* FDA regulation, state substitution law, the Hatch-Waxman Act, or other law. Instead, the Bureau mischaracterizes the Hatch-Waxman Act as supporting generic pharmaceuticals and argues that Forest Labs somehow violates the "intent" of that law. *See* Am. Compl. ¶ 27. But Hatch-Waxman was enacted to assist both brand name manufacturers and generics and therefore is competition- and competitor-***neutral***. Am. Compl. ¶ 17; *see* H.R. Rep. No. 98-857, at 41 (under Hatch-Waxman, "[t]he Committee expects that research intensive companies will have the necessary incentive to increase their research and development activities"); *see also Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005) (balance struck by Hatch-Waxman "quintessentially a matter for legislative judgment"). Compliance with competition-neutral laws cannot be anticompetitive.[16] In any event, Forest Labs is aware of no antitrust court that has held that violating the "intent" of a law is exclusionary conduct under the Sherman Act.[17]

B. The Court Should Reject the Bureau's Attempt to Punish Innovation

The Bureau has sought to avoid arguments about the undeniable benefits of once-a-day Namenda XR by claiming that it is not challenging Forest's launch of a new product, but rather

[16] *See Kamine/Besicorp Allegany L.P. v. Rochester Gas & Elec. Corp.*, 908 F. Supp. 1194, 1207-08 (W.D.N.Y. 1995) (stating "[t]he [agreement], which [Plaintiff] is attempting to enforce, was not created as a result of market forces or a competitive process; it is a creature of a statutory scheme set up for reasons that have nothing to do with competition *per se*."); *Mylan Labs., Inc. v. Akzo, N.V.*, 770 F. Supp. 1053, 1062-63 & n.9 (D. Md. 1991) (taking advantage of regulatory system "does not necessarily lead to the conclusion that [Plaintiff] suffered an antitrust injury"); *see also Crooks v. Harrelson*, 282 U.S. 55, 59-60 (1930) (declining to apply "spirit" of statute, noting that "[c]ourts have sometimes exercised a high degree of ingenuity in the effort to find justification for wrenching from the words of a statute a meaning which literally they did not bear").

[17] Moreover, the laws and regulatory schemes with which pharmaceutical manufacturers are required to comply break the chain of causation here. *See In re Canadian Imp. Antitrust Litig.*, 470 F.3d 785, 791 (8th Cir. 2006) (dismissing complaint where injury caused by "federal statutory and regulatory scheme"); *RSA Media, Inc. v. AK Media Grp.*, 260 F.3d 10, 15 (1st Cir. 2001) (injury caused by regulatory scheme, not competitor's threats); *City of Pittsburgh v. W. Penn Power Co.*, 147 F.3d 256, 268 (3d Cir. 1998) ("[T]he interposition of the regulatory scheme . . . interferes with the chain of causation.").

its potential discontinuation or specialty distribution of an old product. P.I. Mem. at 30 n.67. But the Bureau cannot escape its own anti-innovation position. Nowhere does the Bureau assert that, had Forest ***not*** launched a new version of Namenda, the Court could prevent Forest from discontinuing or specialty distributing old Namenda IR tablets. This is not war-time steel production; a firm can stop selling a product when it wishes to. The Bureau is challenging the specialty distribution ***only because*** Forest has launched a new, improved version of Namenda. The Bureau thus seeks to punish innovation in a way directly contrary to the antitrust laws.

1. Antitrust Law Encourages Innovation; Innovation Conceded Here

Innovation is essential to competition. "[N]ew products and new brands are essential to a dynamic economy." *Leegin Creative Leather Products, Inc. v. PSKS, Inc.*, 551 U.S. 877, 891 (2007); *see also Anchor Sav. Bank, FSB v. United States*, 81 Fed. Cl. 1, 8 n.3 (Fed. Cl. 2008). As Bureau counsel has written, "[e]ven ***product changes that at first blush seem trivial may eventually have far-reaching***, even revolutionary, consequences." Jay L. Himes & Saami Zain, *Anti-competitive Innovation: Is There a Role for Antitrust in Evaluating Product Line Extensions?*, at 12, Am. Conf. Inst. (May 15-16, 2007) (Pace Decl. Ex. 2) (emphasis added).

The Second Circuit made clear in *Berkey Photo* that the antitrust laws protect innovation. *Berkey Photo* involved the markets for cameras, photo film, and photo processing. 603 F.2d at 269. Kodak, for a long time, controlled a dominant share of all three markets. *Id.* at 269-71. In 1973, Berkey Photo, a manufacturer of cameras using Kodak film, sued Kodak alleging that Kodak violated the antitrust laws by introducing a new camera with a new film format, without providing notice to Kodak's competitors. *Berkey Photo*, 603 F.2d at 269-71, 278. Berkey Photo alleged that Kodak had moved demand to new film incompatible with the competitors' cameras, and that Kodak's product shift prevented competitors from selling cameras. *Id.* at 278-81.

The Second Circuit rejected Berkey Photo's claim that Kodak's conduct was

exclusionary or anticompetitive. Leaving no doubt that the antitrust laws protect innovation, the Court explained that "[a] monopolist is permitted, and indeed encouraged, by § 2 to compete aggressively on the merits, any success that it may achieve through 'the process of invention and innovation' is clearly tolerated by the antitrust laws." *Id.* at 281.

The challenge to Kodak's new product was particularly inappropriate because, as the Bureau concedes here, the new product offered benefits over the old product. *See Berkey Photo*, 603 F.2d at 282-83 & n.25 ("red-eye" problem experienced by users of new system did not "detract from the fact that the new camera was . . . ***more convenient*** than its predecessors") (emphasis added). Here, as the Bureau grudgingly acknowledges, "[s]ome patients may benefit from the ability . . . to take Namenda once a day [with Namenda XR] instead of twice." P.I. Mem. at 16, 30 n.67 (disavowing any challenge to superiority of twice-a-day Namenda XR). As *Berkey Photo* teaches (603 F.2d at 282-83 & n.25), replacing an old product with a new and more convenient product is not anticompetitive, it is ***pro***-competitive.[18]

In 2010, the Southern District of New York granted a motion to dismiss under Rule 12(b)(6) in a case asserting claims nearly identical to those asserted here. Generic manufacturer Mylan asserted that AstraZeneca's launch of new omeprazole products was illegal "product switching." *See AstraZeneca AB v. Mylan Labs. Inc.*, 2010 WL 2079722 (S.D.N.Y. May 19, 2010). Mylan further alleged, as here, that the innovator defendant violated the Sherman Act by attempting to "convert sales of" Prilosec to Nexium, "before substantial or additional generic competition to Prilosec ® could occur." *Id.* at *2. The court rejected Mylan's theory:

Mylan has failed to plausibly allege "predatory or exclusionary acts or practices that have

[18] *See also Billhofer v. Flamel Techs., S.A.*, 2012 WL 3079186, at *12 (S.D.N.Y. July 30, 2012) (Sweet, J.) (in securities action involving once-a-day and twice-a-day products, finding that it "is essentially tautological" that "reduced medication dosing provides patients a convenience benefit and leads to improved patient compliance" because "more convenient dosing regimens have obvious benefits") (internal quotation marks omitted); IIIB Areeda & Hovenkamp at ¶ 776a, at 287 ("[W]e would recognize antitrust liability only for innovations that were clearly not superior to the older technology, measured by an *ex ante* test.").

> the effect of preventing or excluding competition within the relevant market," . . . as required to state a claim under § 2 of the Sherman Act, because ***the alleged conduct—introducing new products—is generally considered pro-competitive***.

Id. at *6 (emphasis added) (citations omitted). For similar reasons, the Court should dismiss the Bureau's claims of "product switching" for Namenda.

2. The Bureau Fails to Allege Any Coercion That Would Justify Antitrust Scrutiny

The Bureau's Complaint offers no limiting principle for how a court should decide whether and how to compel a firm to sell and distribute an old product. *See Linkline*, 555 U.S. at 453 (antitrust theory without "safe harbor" is "most troubling"). *Berkey Photo* makes clear that antitrust courts should not condemn innovators unless a defendant's conduct is "coercive" and blocks competition: "If a monopolist's products gain acceptance in the market . . . it is of no importance that a judge or jury may later regard them as inferior, as long as that success was not based on any form of coercion." 603 F.2d at 287. The *Berkey Photo* court was concerned with tying arrangements, which could require the purchase of a product if another product is purchased. *See Twin Labs., Inc. v. Weider Health & Fitness*, 900 F.2d 566, 570-71 (2d Cir. 1990) (distinguishing *Berkey Photo* as a tying case). Here, the Bureau fails to allege any form of tying, exclusive dealing, or other arrangement requiring the purchase of a product.

The Bureau fails to allege any "coercion" that would justify punishing Forest for seeking to transition to a better product. The Bureau concedes that under the specialty distribution arrangement, patients can still use Namenda IR where it is "medically necessary." Am. Compl. ¶¶ 111, 115. After Forest's patent and regulatory exclusivities end, nothing will prevent physicians from prescribing either Namenda XR from Forest, Namenda IR oral solution from Forest, or Namenda IR tablets from generic competitors. This is fatal to the Bureau's claims because no patient is "force[d] . . . to purchase [Namenda XR]." *Unijax, Inc. v. Champion Int'l,*

Inc., 683 F.2d 678, 684-85 (2d Cir. 1982).[19] Moreover, especially with the specialty distribution arrangement, to suggest that doctors, as learned intermediaries, would be "forced" or "coerced" in their prescribing decisions by the launch of a new product is absurd. *See, e.g.*, *Heindel v. Pfizer, Inc.*, 381 F. Supp. 2d 364, 382 (D.N.J. 2004) ("It is for the prescribing physician to use his own independent medical judgment . . . to prescribe a given drug.").

3. The Antitrust Laws Do Not Authorize Courts to Weigh the Sufficiency of Innovation

Courts have been reluctant to hold that a new product is not "innovative enough" to avoid antitrust liability—or, as alleged here, not innovative enough to allow discontinuance of the old version or specialty distribution. *See, e.g.*, *Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 1000 (9th Cir. 2010) ("[T]he ultimate worth of a genuine product improvement can be adequately judged only by the market itself."); *Berkey Photo*, 603 F.2d at 286-87. That is because, at least in part, evaluating a firm's conduct based on the merit of its innovation would be "unadministrable." As *Berkey Photo* held, "no one can determine with any reasonable assurance whether one product is 'superior' . . . . The only question that can be answered is whether there is sufficient demand for a particular product . . . ." 603 F.2d at 287. Consistent with *Berkey Photo*, the Ninth Circuit held in *Allied Orthopedic*:

> To weigh the benefits of an improved product design against the resulting injuries to competitors is ***not just unwise, it is unadministrable***. There are no criteria that courts can use to calculate the "right" amount of innovation, which would maximize social gains and minimize competitive injury. A ***seemingly minor technological improvement*** today can lead to much greater advances in the future.

592 F.3d at 1000 (emphasis added); *see also, e.g.*, *Walgreen*, 534 F. Supp. 2d at 151 (dismissing product hopping case: "Courts . . . are not tasked with determining ***which product among***

[19] *See also Times-Picayune Pub. Co. v. United States*, 345 U.S. 594, 605 (1953) (coercion occurs where "existing or potential sellers are foreclosed from offering up their goods to a free competitive judgment"); *Walgreen Co. v. AstraZeneca Pharm. L.P.*, 534 F. Supp. 2d 146, 151 (D.D.C. 2008) (dismissing product hopping claim as defendant did not completely eliminate choice); *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 422 (D. Del. 2006) (coercion where sham patents blocked competitors, eliminating "choice between fenofibrate formulations").

several is superior. Those determinations are left to the marketplace") (emphasis added).

Such weighing is particularly inappropriate because "no administrable rule could be fashioned that would not exact an unreasonably heavy toll in the creation of incentives to innovate." III Areeda & Hovenkamp, ¶ 704c, at 225.[20] Here, the Bureau offers this Court no "administrable rule" to determine whether Namenda XR is "sufficiently innovative."

III. The Bureau Fails to State a Donnelly Act Claim

The Complaint alleges no viable claim for monopolization under the Donnelly Act (third cause of action) and must be dismissed. The Donnelly Act does not prohibit single-firm conduct. *See Worldhomecenter.com, Inc. v. KWC Am., Inc.*, 2011 WL 4352390, at *6 (S.D.N.Y. Sept. 15, 2011) ("[A] manufacturer's independent, unilateral actions" fall outside the Donnelly Act."); *Global Reins. Corp.-U.S. Branch v. Equitas Ltd.*, 18 N.Y.3d 722, 731 (N.Y. 2012) ("An antitrust claim under the Donnelly Act, or under its essentially similar federal progenitor, section 1 of the Sherman Act, must allege both ***concerted action by two or more entities*** and a consequent restraint of trade within an identified relevant product market." (emphasis added)). As this Court held in *Martindale-Hubbell*, "the Donnelly Act does not prohibit the nonreciprocal, unilateral practices of a monopolist." *Saxe, Bacon & Bolan, P.C. v. Martindale-Hubbell, Inc.*, 1981 WL 2115, at *4 (S.D.N.Y. July 22, 1981) (Sweet, J.). Here, the Bureau primarily alleges the unilateral action of Forest. *See, e.g.*, Am. Compl. ¶¶ 5, 9, 81. And the Bureau's attempt to conjure a last-minute concerted action claim to tack on to these claims fails. *See* below Section V. The Bureau's Donnelly Act claim therefore must be dismissed.

[20] *See also Linkline*, 555 U.S. at 452 ("We have repeatedly emphasized the importance of clear rules in antitrust law."); *Trinko*, 540 U.S. at 414 ("Mistaken inferences and the resulting false condemnations 'are especially costly, because they chill the very conduct the antitrust laws are designed to protect.'"); *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 775 (1984) ("Subjecting a single firm's every action to judicial scrutiny for reasonableness would threaten to discourage the competitive enthusiasm that the antitrust laws seek to promote."); Pace Decl. Ex. 2 at 12 (article by Bureau counsel conceding that "***[J]udicial second-guessing of product change is inherently problematic***. . . . [T]here is no ready measuring stick[] to help judges distinguish 'truly' innovative changes from those that are nominal at best . . . .") (emphasis added).

IV. The Bureau Fails to State (or Create) a Claim under New York Executive Law

The Bureau's persistent illegality "claims" under Section 63(12) of the New York Executive Law (fourth and fifth causes of action) also must be dismissed. ***First***, the Bureau may pursue a remedy under Section 63(12) *only* when the Bureau has a viable claim under another statute. NY Exec. Law § 63(12). As such, Section 63(12) "does not create any new cause[s] of action," but a remedy. *See People v. Frink Am., Inc.*, 2 A.D.3d 1379, 1380-81 (N.Y. App. Div. 2003). As discussed above, the Bureau has failed to state a claim under the Donnelly Act or any other statute, so its Section 63(12) "causes of action" must also fail.

Second, the Bureau's Complaint contains none of the factual allegations required to support a fraud claim. *See In re Public'n Paper Antitrust Litig.*, 2005 WL 2175139, at *3 (D. Conn. Sept. 7, 2005) (No indication "to [whom misrepresentations] were made, when they were made, or what was said."); *People v. Direct Revenue, LLC*, 2008 WL 1849855, at *6-7 (N.Y. Sup. Ct. 2008) (dismissing Section 63(12) claim, in part, because underlying fraud claim was not pled with sufficient particularity). Here, the Bureau identifies no fraudulent statements—and certainly none with the necessary particularity. *See Rombach v. Chang*, 355 F.3d 164, 170 (2d Cir. 2004) (a plaintiff must "explain why the statements were fraudulent").

The Bureau's failure is particularly striking given that—exercising its investigative power under Section 63(12) for seven months—the Bureau had ample "opportunity to take discovery." *See Devaney v. Chester,* 813 F.2d 566, 569 (2d Cir. 1987). But after its extensive investigation, the Bureau has only developed claims having "substantive problems" that a "better pleading will not cure." *Lastra v. Barnes & Noble Bookstore*, 2012 WL 12876, at *9 (S.D.N.Y. Jan. 3, 2012) (Sweet, J.) (citing *Cuoco v. Moritsugu*, 222 F.3d 99, 112 (2d Cir. 2000)), *aff'd*, 523 F. App'x 32 (2d Cir. 2013). Dismissal with prejudice therefore is appropriate.

V. The Bureau Fails to State a Claim under Sherman Act § 1 or the Donnelly Act

In its Amended Complaint, the Bureau for the first time asserts conspiracy claims under Sherman Act § 1 and the Donnelly Act. Although the Bureau's theory in this case has been that the alleged "discontinuation" of Namenda IR would somehow be unlawful, the Bureau now also attacks Forest's plan to continue distributing Namenda IR through Foundation Care LLC ("Foundation Care"). This last-gasp claim fails on multiple levels.[21]

First, the Bureau's conspiracy claims are bare-bones and fail any reading of *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). The Bureau alleges only that Namenda IR will be distributed through Foundation Care when medically necessary for a patient (Am. Compl. ¶¶ 111, 115), and that this somehow constitutes an agreement in restraint of trade (*id*. at ¶¶125, 127). The Bureau offers nothing to explain how competition is allegedly harmed by the distribution of Namenda IR, nor could it. Absent a basis for pleading such harm, the Bureau cannot make out an antitrust claim simply by claiming that some other form of distribution might be more procompetitive. *See Trinko,* 540 U.S. at 415-16 (2004) (antitrust does not condemn conduct simply because "some other approach might yield greater competition").

Second, the Bureau cannot create an antitrust claim by alleging that Forest Lab's distribution of its older product should be unlimited, rather than through Forest's preferred distributor. *See, e.g.*, *Berkey Photo*, 603 F.2d at 286 ("[A]ny firm, even a monopolist, may generally bring its products to market whenever and however it chooses."). Manufacturers

[21] The Bureau also claims in a paragraph that unspecified "contracts" with "health plans" will somehow restrain trade in light of unspecified acts by CMS, as CMS will somehow prevent Medicare plans from encouraging members to use Namenda IR. Am. Compl. ¶ 116. The Bureau characterizes this as a violation of Sherman Act § 1 and the Donnelly Act. *Id.* at 125; 127. Despite extensive discovery in this case, the Bureau has failed even the fundamental notice pleading requirement of Fed. R. Civ. P. 8, as the Amended Complaint fails to identify any contracts that violate the antitrust laws, much less explain how they do so, and offers nothing to even identify the "health plans" alleged to be Forest's co-conspirators. *See also Twombly*, 550 U.S. at 555 ("Factual allegations must be enough to raise a right to relief above the speculative level . . . ."). At most, the Bureau seems to be complaining about CMS's policy of requiring approval for formulary changes—something over which Forest has no control and which could not be the basis for a claim (much less a conspiracy claim). This allegation therefore fails on its face.

generally control the distribution of their products, and only in very rare circumstances—not present here—will courts find a restraint of trade based on such distribution. *See, e.g.*, *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36 (1977) (upholding territorial distributorship restrictions as such "[v]ertical restrictions promote interbrand competition by allowing the manufacturer to achieve certain efficiencies in the distribution of his products").[22]

Finally, the Bureau's conspiracy claims are nonsensical in light of the contractual relationship between Forest Labs and Foundation Care.[23] Under the distribution agreement, Foundation Care does not stand at arms' length from Forest, as is necessary for a conspiracy claim under Sherman Act § 1 and the Donnelly Act, [redacted] Work Order No. 1, Ex. A (Exhibit C – "Fees") (Pace Decl. Ex. 3). The law on this point is clear: "an agreement between a . . . corporation and its . . . agents is not a concerted action for purposes of the [Sherman] Act." *Capital Imaging Assoc., P.C. v. Mohawk Valley Med. Assoc., Inc.*, 996 F.2d 537, 542 (2d Cir. 1993) (citing *Copperweld Corp. v. Independence Tube Corp.,* 467 U.S. 752, 771 (1984)).[24] The Bureau's last-ditch conspiracy claim therefore cannot rescue its claims from dismissal.

CONCLUSION

All of the Bureau's claims should be dismissed with prejudice.

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[22] *See also E & L Consulting, Ltd. v. Doman Industries Ltd.*, 472 F.3d 23, 30 (2006) (manufacturer can control distribution without violating Section 1, because a "typical exclusive distribution case" has no "*actual* adverse effect on competition as a whole in the relevant market"); *Electronics Communs. Corp. v. Toshiba Am. Consumer Prods.*, 129 F.3d 240, 245 (2d Cir. 1997) ("[E]xclusive distributorship arrangements are presumptively legal.").

[23] As the Bureau has incorporated the Forest / Foundation Care agreement into the Amended Complaint by reference, *see* Am. Compl. ¶ 115, the Court can consider its terms on a motion to dismiss. *Int'l Audiotext Network, Inc. v. Am. Tel. & Tel. Co.*, 62 F.3d 69, 72 (2d Cir.1995) ("[A]lthough the amended complaint . . . does not incorporate the Agreement, it relies heavily upon its terms and effect; ... [t]he Agreement is 'integral' to the complaint, and we consider its terms" on a motion to dismiss). Defendants attach the agreement as Exhibit 3.

[24] *See also Bill's Birds Inc. v. Trademarketing Resources Inc.*, 920 F. Supp. 2d 357, (E.D.N.Y. 2013) (where agent does not exercise economic discretion or serve as separate step in distribution process, it is not "separate economic entity" and therefore cannot be held to have conspired with principal under Sherman Act or state law) (citing *Fuchs Sugars & Syrups, Inc. v. Amstar Corp.*, 602 F.2d 1025, 1031 n.5 (2d Cir.1979), *cert. denied,* 444 U.S. 917 (1979)).

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Stephen Fraser, certify that on November 7, 2014, I caused a true and correct copy of the foregoing Memorandum of Law in Support of Defendants' Motion to Dismiss to be served by hand upon counsel for the plaintiff, and by email upon all other counsel.

Date: November 7, 2014

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