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

REPLY MEMORANDUM IN SUPPORT OF
DEFENDANTS' MOTION TO DISMISS AMENDED COMPLAINT

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New York fails to state a claim under the Sherman Act or any state law, and this Court should dismiss the Amended Complaint with prejudice now.

New York's opposition to Defendants' motion to dismiss never explains how Forest Labs' patent monopoly makes the company an illegal monopolist or how Forest's sale of once-daily Namenda XR and twice-a-day Namenda IR is "exclusionary" under the Sherman Act. New York's opposition brief is a policy paper arguing for the creation of an antitrust duty to market a product in a particular way—all to prevent an outcome of the Hatch-Waxman Act with which the Antitrust Bureau disagrees. But the Sherman Act is not a Congressional spackle bucket, ready to patch holes in federal legislation where Congress has not. MTD Section II.A.4.

The Sherman Act has never been used as a tool to regulate the choice of sales channels or slow the pace of innovation. But that is what the Bureau's Amended Complaint seeks. As much as New York pleads that it is not seeking to stop innovation (Opp. 20) or impose a duty to deal for the benefit of competitors (Opp. 17), New York cannot avoid that it seeks to force Forest to sell a product at "full distribution" only ***because*** Forest launched a new version and only ***because*** marketing the old version would help competitors. The Bureau cites no cases to support this novel duty to sell, and in fact the unrebutted cases cited in Forest's motion reject it.

As much as New York pleads that it is not questioning that Forest's once-daily Namenda XR is a medical advance—indeed, Dr. Lah testified there was no "***market need***" for twice-a-day Namenda IR anymore—the Bureau continues to argue that Forest's distribution practices should be regulated by the Court because the "benefits" of once-daily Namenda XR are "marginal." Am. Compl. ¶ 77. Yet the Bureau never alleges when a treatment is "innovative enough" to let a pharmaceutical company decide when and how to market FDA-approved products.

The Sherman Act also has never invaded a patent holder's right not to practice its patent.

The Opposition does not address—or cite—*Continental Paper Bag* (S. Ct. 1908), *SCM* (2d Cir. 1981), *Rite-Hite* (Fed. Cir. 1995), or other cases discussing the freedom of a patent holder to decide whether to practice its patent. Instead, the Bureau argues that a patent does not provide "immunity" for the anticompetitive use of patents. Opp. 9. But just days ago the Bureau was forced to concede that "***New York has never made***" the argument that Forest engaged in any "***anticompetitive use of patents***." Pl. Reply Con. Law ¶ 23. Forest's lawful patent monopoly therefore cannot form the basis for New York's novel monopoly claim.

Granting Defendants' motion to dismiss also would warrant denial of the preliminary injunction motion based on New York's failure to show a likelihood of success on the merits.[1] And the extensive pre-complaint discovery and proceedings on the motion for a preliminary injunction confirmed that the Bureau would never be able prove an illegal monopoly, exclusionary conduct, illegal restraint of trade, or any other cause of action asserted in its novel complaint. This Court should dismiss the Amended Complaint with prejudice.[2]

I. The Bureau Fails to State a Claim for Monopolization or Attempted Monopolization

A. The Bureau Fails to Allege That Forest Is an Illegal Monopolist

New York never challenges Forest's lawful patent and regulatory monopoly ***prior to July 11, 2015***, nor the absence of any monopoly ***after July 11, 2015***. New York's monopolization claims must be dismissed with prejudice for that reason alone. MTD 8-11.[3]

First, New York never addresses the world post-July 11, 2015. MTD 2-5. It never

[1] *See Toney-Dick v. Doar*, 2013 WL 1314954, at *11 (S.D.N.Y. Mar. 18, 2013) ("Without an operative complaint, plaintiffs' motion for preliminary injunctive relief . . . is DENIED, without prejudice, as moot."); *Bain v. Hofmann*, 2008 WL 149015, at *3-4 (D. Vt. Jan. 10, 2008) (denying PI as moot to extent related to dismissed claims).

[2] The Bureau asserts that Forest "infuses their papers with new facts," Opp. 1, 4, 7-8, but never identifies any alleged new facts. The motion to dismiss is based on the complaint's bare allegations, the "written instrument[s] attached to the complaint as an exhibit," "statements or documents incorporated in it by reference," and "document[s] upon which the complaint heavily relies." *In re Thelen LLP*, 736 F.3d 213, 219 (2d Cir. 2013); MTD 3.

[3] Defendants assume Plaintiff's implausible market definition for purposes of this motion only. The Amended Complaint should be dismissed on several independent grounds even assuming an overly narrow product market.

alleges or explains how, after Forest Labs' competitors begin selling generic versions of Namenda IR after July 11, and after those generic versions take [redacted] the sales of twice-a-day Namenda IR and [redacted] of the sales of Namenda XR (MTD 3-4), Forest Labs' plausibly could be considered a Sherman Act Section 2 monopolist.

Second, as to competition before July 11, 2015—while twice-a-day Namenda IR "is protected by patent and regulatory exclusivities," Am. Compl. ¶ 3—the Bureau's only argument is that Defendants are seeking "antitrust immunity." Opp. 9. But Defendants are not seeking immunity or arguing that their patent protects them from a claim of anticompetitive use of patents. Importantly, however, New York ***never alleges*** anticompetitive use of patents; in fact it explicitly disavows any such claim. In its Reply Conclusions of Law, New York lists "various legal theories that ***New York has never made***" in this case, including "***anticompetitive use of patents***." Pl. Reply Con. Law ¶ 23 (emphasis added). New York never alleges patent fraud or inequitable conduct, the tying of a patented product with an unpatented product, patent misuse, or any other conduct that conceivably could represent anticompetitive use of a patent.

That is why the Amended Complaint must be dismissed: New York does not challenge the use of a patent monopoly to commit an illegal act—it challenges the ***very exercise of rights granted with the patent***, which include the freedom to practice or not practice the patented invention. *See, e.g., Cont'l Paper Bag Co. v. E. Paper Bag Co*., 210 U.S. 405, 425, 429 (1908) (patent owner has privilege "to use or not use [its patent], ***without question of motive***") (emphasis added); *SCM Corp. v. Xerox Corp*., 645 F.2d 1195, 1204 (2d Cir. 1981) ("patent holder is permitted to maintain his ***patent monopoly*** through conduct permissible under the patent laws") (emphasis added); *Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538, 1547 (Fed. Cir. 1995) (en banc) ("***There is no requirement in this country that a patentee make, use, or***

sell its patented invention.") (emphasis added); MTD 9-10.

The Bureau's citation to the D.C. Circuit's baseball analogy in *Microsoft* only highlights the failure of the Amended Complaint. Opp. 9. Unlike the government in *Microsoft* or the person objecting to the use of a baseball bat to commit an independently illegal tort, New York complains about the very use the baseball bat was designed for. Forest is at the plate lawfully holding its bat. New York proposes liability for the decision of whether and how to swing.

Finally, the Bureau's cases prove Defendants' point. The Bureau cites *Microsoft*, quoting *ISO*, to argue that "'[i]ntellectual property rights do not confer a privilege to violate the antitrust laws.'" Opp. 10. But *ISO* held that a patent holder may enforce its statutory rights "free from liability under the antitrust laws" ***unless*** there is "any indication of illegal tying, fraud in the Patent and Trademark Office, or sham litigation." 203 F.3d at 1327. New York alleges none of that conduct here. The Bureau also cites *Atari Games v. Nintendo*, but *Atari* similarly addressed ***extra-patent conduct***—bad faith enforcement and leveraging a patent beyond its scope—that New York cannot allege here. 897 F.2d 1572, 1576-77 (Fed. Cir. 1990); Opp. 10.

B. The Bureau Fails to Allege Exclusionary Conduct

The Bureau argues that it does not "allege a duty to deal with a rival" and that instead "[t]his is a classic case about foreclosure and/or exclusionary conduct." Opp. 13-14. Neither assertion describes this case.

First, it is too late—after pre-complaint discovery, a trial, and two tries at a complaint—for New York to run from the anti-competitive duty to sell it proposes. New York has been clear throughout this litigation that the purpose of Forest selling twice-a-day Namenda IR at "full distribution" levels (P.I. Reply 20; Pl. Con. Law ¶ 11) would be to allow competitors to sell generic versions by state law substitution at the pharmacy. *See, e.g.,* Am. Compl. ¶ 3-4 (alleged

harm is "interfe[ing] with patients' ability to. . . ***switch" to "generic version[s]***") (emphasis added); ¶ 27 (alleging conduct "impede[s] the use of . . . ***generic drugs***") (emphasis added); p. 21 (challenging "Efforts to Stall the Effects of ***Generic Entry***") (emphasis added); Pl. Find. Fact at 4 (Defendants "required to ***allow generic competitors*** a fair opportunity to compete") (emphasis added).

Second, the authority New York cites regarding antitrust duties to deal—particularly for competitors' sake—confirms why this case should be dismissed. Antitrust encourages aggressive competition and is skeptical of rivals seeking to use the Sherman Act to gain competitive advantage. MTD 12-15, 19. Antitrust leaves little room for claims seeking to impose duties to sell products, so the Bureau is left to rely on the language in *Trinko* that "a refusal to cooperate with rivals" theoretically can violate the antitrust laws in "certain circumstances." Opp. 15 (citing *Trinko*, 540 U.S. at 408). But the Bureau fails to cite the next two sentences in *Trinko*, where the Court explains:

> We have been very cautious in recognizing such exceptions, because of the ***uncertain virtue of forced sharing*** and the difficulty of identifying and remedying anticompetitive conduct by a single firm. The question before us today is whether the allegations of respondent's complaint fit within existing exceptions or provide a basis, under traditional antitrust principles, for recognizing a new one.

540 U.S. at 408.[4] The Supreme Court declined to "recognize a new" duty to help rivals, and this Court should do the same.

Third, whether or not a duty to "fully distribute" a product to help competitors is cast as a duty to deal, the Bureau fails to allege any exclusionary conduct. New York alleges no exclusive contracts, tying, bundling, monopoly leveraging, predatory pricing, illegal procurement or

[4] The only exception in "certain circumstances" discussed in *Trinko* was the much-criticized essential facilities exception of *Aspen Skiing*—an exception New York concedes does not apply. P. Reply Con. Law ¶ 23.

enforcement of patents, or any other conduct that actually could block or exclude competition. That failure, among others, distinguishes this case from the D.C. Circuit's decision in *Microsoft*, which involved exclusive contracts, bundling, technical compatibility, and other conduct actually ***blocking*** and ***excluding*** competitors from competing. *See Microsoft*, 253 F.3d at 65-67, 70-71. Microsoft's conduct—unlike here—was so effective in foreclosing competition that it prevented any competitor from "***pos[ing] a real threat*** to Microsoft's monopoly." *Id.* at 70-71 (emphasis added). Here, New York alleges nothing to explain how generic competitors will not "pose a real threat" to Forest Labs' sales—they will take most of those sales away. MTD 3-5.

The Bureau's other cases similarly involved exclusive contracts (unlike here), product withdrawals (unlike here, where Plaintiff concedes that twice-a-day Namenda IR will remain available by specialty pharmacy distribution (Am. Compl. ¶ 111-17)), or new products that were not superior to the prior versions (unlike here, where New York's own medical witness testified there was no "market need" for the old version (Lah Hr'g 85:19-20, DX487), and "New York does not deny that Namenda XR may benefit some Alzheimer's patients"). Opp. 15-16 (citing *Dentsply* and *Abbott*).

C. The Bureau's Policy Arguments Do Not Justify Creating a New Sherman Act Section 2 Cause of Action for "Regulatory Gaming"

New York's opposition includes several policy arguments about what should not or "cannot be the law" (Opp. 1), how dismissing this case would "suggest that forced switches like Defendants' are always legal" (Opp. 1), and how "a dismissal could be interpreted as tantamount to a blank check for pharmaceutical companies" (Opp. 2). New York never alleges that Forest Labs violated the Hatch-Waxman Act or any of the complex FDA rules and regulations governing the approval and marketing of Namenda XR and IR, so instead New York argues that Defendants' conduct is "Regulatory Gaming."

New York's policy arguments do not provide a reason to convert Forest Labs' lawful patent and regulatory monopoly into an illegal monopoly. Nor do they justify converting Forest's decisions on how to practice its patents and distribute its FDA-approved products into exclusionary conduct. The Sherman Act is not a tool to patch holes in legislation or address lawful outcomes with which the Bureau disagrees. The Hatch-Waxman Act reflects a legislative balance, and a plaintiff should not be permitted to second-guess that balance when it disagrees with an outcome under the law.[5]

II. The Bureau Fails to State a Claim for Illegal Agreements in Restraint of Trade

New York's opposition is silent on the alleged Sherman Act Section 1 conspiracy between Forest Labs and unidentified health plans. *See* MTD 24 n.21. New York discusses only its claim regarding Forest's distribution agreement with specialty pharmacy provider Foundation Care. Opp. 24-25. This Court should dismiss that claim for the following reasons.

First, the Bureau tries to reinstate the now-"retired" "no set of facts" standard of *Conley v. Gibson*, and to limit *Twombly* to the allegation that an agreement exists at all. Opp. 6, 25. But the Supreme Court in *Iqbal* made clear that *Twombly* was not so limited—all claims and all elements of a claim must be pled plausibly. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

Second, the Bureau offers no basis for alleging that the distribution agreement between Forest and Foundation Care harms competition. Opp. 24. At best, the Bureau argues that a different agreement without a medical necessity requirement "might" reach *more* patients and

[5] The Bureau's effort to depict its case as enforcing "the policies and procedures that Congress enacted in the Hatch-Waxman Act, . . . which New York and other states embraced in their substitution laws" (Pl. Find. Fact ¶ 19), does not justify the creation of a federal antitrust duty. State substitution laws vary, and New York is in the minority of states to mandate generic substitution. MTD 16. New York could not have "embraced" the policies of Hatch-Waxman, because New York's mandatory substitution law was enacted in 1977, seven years before Hatch-Waxman was enacted in 1984. H. Grabowski & J. Vernon, Substitution Laws and Innovation in the Pharmaceutical Industry, 43 J.L. & Contemp. Probs. 43, 50 (1979) (Ex. 1). Even if Hatch-Waxman reflects any sort of state law consensus, it is unclear why the consensus is not based on the majority of states that did not require generic substitution when Hatch-Waxman was enacted.

therefore "would potentially" somehow be more procompetitive. Opp. 24. But even if that were the case, an otherwise procompetitive or competitively-neutral agreement does not violate the antitrust laws simply because "some other approach might yield greater competition." *See Trinko,* 540 U.S. at 415-16.

Third, Foundation Care sells Namenda IR only pursuant to Forest's explicit instructions, with no independent decision-making power. MTD 7-8; Pace Decl. Ex. 3 (Agreement Ex. C – "Fees"). Where a distributor does not exercise economic discretion or serve as a separate step in the distribution process, but rather implements the will of the manufacturer in return for payment, the distributor is not a "separate economic entity" and therefore cannot be held to have conspired with the manufacturer under the *Copperweld* doctrine.[6] The Bureau therefore cannot convert its failed Section 2 claims into Section 1 claims by labelling the Foundation Care distribution agreement a "conspiracy."

New York argues that Forest and Foundation Care disclaimed a full principal/agent relationship. Opp. 25. But the antitrust laws do not turn on such formalistic arguments. *See Fuchs*, 602 F.2d at 1031 n.5. Whether called an agent, independent contractor, vendor, or some other term, Foundation Care is not an independent step in the supply chain and not a potential competitor; therefore it cannot conspire with the entity providing its instructions. *See Bill's Birds*, 920 F. Supp. 2d at 365. The Bureau's Section 1 claims should be dismissed.

III. The Bureau Fails to State a Claim under the Donnelly Act

New York argues that its addition of a concerted conduct claim somehow renders the motion to dismiss its *unilateral* conduct claim under the Donnelly Act moot. Opp. 21-22. But the Court can and should dismiss the Bureau's unilateral conduct claim under the Donnelly

[6] *Bill's Birds Inc. v. Trademarketing Resources Inc.*, 920 F. Supp. 2d 357, 364-65 (E.D.N.Y. 2013) (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)).

Act—and the concerted conduct claim for the reasons discussed above. MTD 22.

IV. The Bureau Fails to State a Claim under New York Executive Law

New York cannot overcome the black letter rule that Section 63(12) "does not create any new causes of action," but only a remedy. *People v. Frink Am., Inc.*, 2 A.D.3d 1379, 1380-81 (N.Y. App. Div. 2003). This is true regardless whether the Bureau seeks to allege "illegal acts" or "fraud" under Section 63(12). *See People v. Direct Revenue, LLC*, 2008 WL 1849855, at *6-7 (N.Y. Sup. Ct. 2008) (dismissing Section 63(12) claim where underlying fraud claim not pleaded with particularity).

With respect to the potential "fraud" claim underlying New York's proposed section 63(12) claim, New York argues simply that the standard for fraud under 63(12) is somewhat less than the high standard usually applied to fraud. But New York cannot suggest that the standard is so low that fraud exists whenever the Attorney General claims it exists. But that is all it has done here—simply recited the word "fraud" without alleging who was defrauded, when, or how.

V. The Amended Complaint Should Be Dismissed with Prejudice

New York's claim that it "has not yet had the opportunity to take full discovery" (Opp. 4) is no reason to deny the motion to dismiss—in fact the extensive proceedings to date confirm that the Amended Complaint should be dismissed with prejudice.

While an antitrust plaintiff normally would not be entitled to any discovery pending its motion to dismiss, New York has had extensive discovery here. New York conducted a nearly seven-month investigation before it filed this lawsuit. On February 28, 2014, New York served the first of two document subpoenas on Forest Labs. Forest Labs produced over 1.7 million pages of documents over the course of twenty document productions,[7] [redacted]

[7] The production letters are attached to the Supp. Pace Decl. supporting Defendants' Motion to Seal.

[redacted] New York's complaint about the composition of Forest Labs' production (Opp. 8) is hollow; [redacted]

In addition to five days of hearing testimony from November 10-14, 2014, during which the Court heard from ***twelve live witnesses***, the parties deposed ***twenty-five*** witnesses and New York served ***three additional document requests*** upon Forest Labs. The depositions included testimony from Bureau-sponsored witness Mylan Inc. As of New York's Amended Complaint filed the evening of November 5, all but three of those depositions had been taken—one of which was of New York's belatedly disclosed economist, Dr. Ernst Berndt.

In light of the extensive pre-complaint discovery, additional proceedings, and New York's amendment to the Complaint, this Court should dismiss the Complaint with prejudice. *See Beauford v. Helmsley*, 740 F. Supp. 201 (S.D.N.Y. 1990) (Sweet, J.) (dismissal with prejudice following preliminary injunction denial in antitrust case); *Justice v. McGovern*, 2013 WL 1809634 (E.D.N.Y. Apr. 29, 2013) ("Plaintiff's Amended Complaint failed to address, let alone correct, the pleading deficiencies in his original Complaint."); *Sasmor v. Powell*, 2013 WL 1335838 (E.D.N.Y. Mar. 31, 2013) (dismissal with prejudice following denial of preliminary injunction); *Williams v. Calderoni*, 2012 WL 691832 (S.D.N.Y. Mar. 1, 2012) ("[L]eave to amend would be futile because plaintiff has already had two bites at the apple and they have been fruitless."); *Empire State Distrib. Ass'n v. Patterson*, 2010 WL 749828 (S.D.N.Y. Mar. 1, 2010) (dismissal with prejudice following denial of preliminary injunction).

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Respectfully submitted,

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