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 OPPOSITION TO
PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

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Pursuant to Federal Rule of Civil Procedure 65, Defendants Forest Laboratories, LLC and Actavis, plc[1] submit this memorandum and supporting fact and expert declarations in opposition to the Bureau's motion for a preliminary injunction.

INTRODUCTION

The Bureau asks this Court to grant unprecedented and extraordinary relief that would require Forest Labs to sell an older product, twice-a-day Namenda IR tablets, on a nationwide basis, in an unspecified volume, and for an unspecified period, all to assist competitors launching generic versions in July 2015. But the Sherman Act is not a tool for conscripting branded drug companies to manufacture older drugs to aid their rivals. No court has ever commandeered a manufacturer's means of production solely to help the manufacturer's competitors. There is no special Sherman Act for healthcare. *See Arizona v. Maricopa Cnty. Med. Soc'y*, 457 U.S. 332, 346 (1982) (Sherman Act "establishes one uniform rule applicable to all industries alike").

The Bureau fails to justify extraordinary injunctive relief. The Bureau cannot prove any irreparable harm to anyone, nor that the Bureau likely will succeed on the merits of its novel claim, nor that the balance of harms favors the Bureau. The Bureau asserts that Alzheimer's patients "will suffer needless disruption in their treatment plans" and that offering patients improved (and FDA-approved), once-a-day Namenda XR capsules "raises the risk of an adverse effect." P.I. Mem. 1, 17. These bald assertions, unsupported by data, are irresponsible, incorrect, and provide no basis for a preliminary injunction. Overwhelming undisputed evidence supports the benefits of taking one capsule of Namenda XR once a day. In fact, the FDA considered the "switchability" to once-a-day Namenda XR, and the FDA ***approved instructions*** for transitioning patients from Namenda IR one day to Namenda XR the next day.

[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").

The Bureau's assertion of irreparable harm to potential generic competition, or competitors, is equally meritless. [redacted] Dep. of David F. Stitt 289:21-290:15 (KO Ex. 1);[2] *see also* MTD Mem. 3, 12 ([redacted]).[3] Nothing Forest Labs has done, or may do in its future business judgment, can alter the fact that generic competitors readily may sell their products, and [redacted] upon expiration of the exclusivity period for twice-a-day Namenda IR tablets.

The Bureau also ignores that, even before Forest Labs'—undisputedly lawful—exclusivity for Namenda IR concludes in July 2015, Namenda IR ***will continue to be available*** to patients who need it in oral solution form [redacted]. By continuing to seek an injunction despite the availability of Namenda IR, the Bureau asks this Court not only to impose an unprecedented duty to sell but also to act as a monitor to ensure that Forest Labs sells the older version of Namenda ***at certain levels*** and ***through certain distribution channels***. The precedent the Bureau seeks in this case therefore is not only anticompetitive but also unadministrable.

The Bureau also fails to establish that it likely will succeed on the merits. It fails to identify any legal duty that would require a company to continue to manufacture and sell a product. In fact, "any firm, even a monopolist, may generally bring its products to market

[2] Exhibits in support of Defendants' Opposition to Plaintiff's Motion for Preliminary Injunction are attached to the Declaration of Kristen O'Shaughnessy ("KO").

[3] Memorandum in Support of Defendants' Motion to Dismiss (Dkt. No. 35) (filed Oct. 15, 2014) ("MTD Mem.").

whenever and however it chooses." *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 286 (2d Cir. 1979) (emphasis added). And "[n]o court should impose a duty to deal that it cannot explain or adequately and reasonably supervise." *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 415 (2004). The Bureau fails to show, or even plausibly allege, that Forest Labs is—or will be—an illegal monopolist or that its conduct is—or will be—exclusionary. Nor does the Bureau show any likelihood of success in proving that the relevant antitrust product market should be defined so narrowly as to consist of only Namenda.

Moreover, any balancing of competing harms overwhelmingly favors Defendants. As discussed further below, neither patients, nor doctors, nor generic competition would suffer any harm from the sale of once-a-day Namenda XR capsules. But Forest Labs would suffer great financial harm, including unnecessary manufacturing and marketing costs and lost opportunities to recover its massive R&D costs, from an injunction mandating the sale of older products.

The Bureau's Donnelly Act claim similarly fails, because the Act does not even apply to single-firm conduct, which is all the Bureau alleges here. Nor does the Bureau justify its manufactured "fraud" claim under the N.Y. Executive Law; that law does not provide a cause of action but rather a remedy only if a plaintiff has a separate, viable claim. The Bureau does not.

STATEMENT OF FACTS

A. Defendants Forest Laboratories, LLC and Actavis, plc

Forest Labs is a fully integrated, specialty pharmaceutical company that manufactures and sells Namenda IR (immediate-release) tablets, Namenda IR oral solution, and Namenda XR (extended-release) capsules—all memantine hydrochloride drugs used to treat moderate-to-severe Alzheimer's disease.[4] As explained by William J. Meury,[5] Executive Vice-President,

[4] Namenda Package Insert (Oct. 2013) (KO Ex. 3); Namenda XR Package Insert (Sept. 2014) (KO Ex. 4).

North American Brands at Actavis, Namenda IR and Namenda XR are not the only drugs used to treat Alzheimer's disease and [redacted] used to treat that disease. Decl. of William J. Meury ¶ 30 (describing Namenda competitors, *e.g.*, Aricept).

Forest Labs relies upon innovation to compete. *See* Decl. of Saami Zain Ex. 47 at 5 (Forest Labs 10-K) ("The pharmaceutical industry is highly competitive as to . . . research for new or improved products . . . ."). Decl. of Dr. Marco Taglietti, M.D. ¶¶ 5-6. In the first quarter of 2014, [redacted] *Id.* at 10. Economic expert Professor Pierre-Yves Cremieux[6] explains that branded manufacturers' willingness and ability to expend these resources are necessary to achieve medical breakthroughs. *See* Decl. of Pierre-Yves Cremieux ¶ 25 (overall cost of developing single approved new molecule, taking into account investment in compounds that are abandoned, estimated to exceed $1.3 billion in 2005 dollars). And Dr. Marco Taglietti,[7] Forest Labs' former Executive Vice President of Drug Development & Research, points out that R&D can take years only to result in a failed drug. Taglietti ¶ 8. [redacted] Namenda—the last new molecular entity approved by the FDA to treat Alzheimer's in the United States. Meury ¶¶ 6-8.

B. Forest Labs' Development of Namenda

[redacted] *See* Meury ¶¶ 6, 8; *see also* Taglietti ¶ 7 (testing required to prepare New Drug Application takes years—

[5] Prior to Actavis's acquisition of Forest Labs, Mr. Meury was Executive Vice President, Sales and Marketing for Forest Labs. Meury ¶ 1.

[6] Professor Cremieux is a Managing Principal of Analysis Group, Inc. and an Adjunct Professor in the Economics Department at the University of Québec at Montréal and at Yale's School of Management. Cremieux ¶ 6.

[7] Dr. Taglietti formerly was the President of the Forest Research Institute, where he oversaw the continued development of Namenda XR as well as Forest's research into other novel therapies. Taglietti ¶¶ 1, 3.

clinical component alone can take five years or more). Forest "demonstrated statistically significant improvement in cognition and global function for patients treated with Namenda XR 28 mg plus an [acetylcholinesterase inhibitor ("AChEI")[8]] compared to placebo plus an AChEI." Zain Ex. 20 at 1. Dr. Steven H. Ferris,[9] Professor at the Alzheimer's Disease Center at New York University Langone Medical Center, and Dr. Barry Rovner,[10] Professor of Psychiatry and Neurology at Thomas Jefferson University, note that Namenda XR was shown to improve outcomes in patients receiving it with AChEIs compared with patients receiving an AChEI alone. Decl. of Steven H. Ferris, Ph.D. ¶ 25; Decl. Barry Rovner, M.D. ¶ 32. Forest Labs has also conducted extensive research on the potential for Namenda XR to treat other conditions, including pediatric autism, depression, and neuropathic pain—which, like Alzheimer's, currently have no cure. *See* Compl. ¶¶ 62-63; Dep. of William J. Meury 133:3-17 (KO Ex. 5); Taglietti ¶ 25. In fact, the FDA requested that Forest Labs conduct studies evaluating whether memantine could be approved to treat pediatric autism. Taglietti ¶¶ 25-26.

Several leading Alzheimer's experts, including Dr. Barry Reisberg,[11] Professor at the NYU School of Medicine, and Dr. Barry Rovner confirm that Namenda has made a profound difference in the everyday lives of countless Alzheimer's patients. Decl. of Dr. Barry Reisberg, M.D. ¶ 24; Decl. of Barry Rovner, M.D. ¶ 39; Ferris ¶¶ 2(a), 25. Alzheimer's patients taking

[8] AChEIs are also used for the symptomatic treatment of Alzheimer's disease and include such drugs as Aricept, Cognex, Exelon, and Razadyne. Compl. ¶ 46.

[9] Dr. Ferris has been Principal Investigator and Director of the Alzheimer's Disease Center since its inception in 1990. Ferris ¶ 1.

[10] Dr. Rovner was the director of the Geriatric Psychiatric Inpatient Unit at Thomas Jefferson University Hospital for more than a decade. He has also been a principal investor for investigational drug trials for Alzheimer's and currently serves on the American Psychiatric Association's work group to develop practice guidelines for Alzheimer's. Rovner ¶¶ 7-9.

[11] Dr. Reisberg is Director of the Fisher Alzheimer's Disease Program at the New York University School of Medicine and Clinical Director of the NYU School of Medicine's Aging and Dementia Research Center. He has over 30 years of clinical experience in researching Alzheimer's disease and patient treatments. Reisberg ¶ 1.

Namenda more easily perform "common activities of daily living such as eating, walking, toileting, bathing, and dressing." Zain Ex. 10 at 2. "In real life terms, the availability and use of Namenda may translate into many people maintaining their ability to communicate with their family or independently dress and bathe themselves for longer periods of time." KO Ex. 6 at 1 (quoting Dr. George Grossberg, Director of Geriatric Psychiatry at St. Louis University School of Medicine). Patient care groups hailed the development of Namenda as "bring[ing] fresh hope to people with Alzheimer's." *Id.* (quoting William Thies, Ph.D., Vice President, Medical and Scientific Affairs for the Alzheimer's Association).

C. Forest Labs Has Patent and Regulatory Exclusivities for the Sale of Namenda IR Until July 11, 2015

In recognition of its innovation, Forest Labs has various "patent and regulatory exclusivities" covering Namenda. *See* Compl. ¶ 3; MTD Mem. 6-7. The patent laws and Hatch-Waxman Act[12] afford these exclusivities to incentivize research by allowing branded manufacturers to better recover the upfront costs of their innovations, including those for drug R&D. Compl. ¶ 20. Forest Labs has an exclusive license to U.S. Patent No. 5,061,703, covering Namenda IR tablets, and that patent expires on April 11, 2015. Compl. ¶ 59. The FDA extended Forest Labs' exclusivity by six months (to October 11, 2015) based on Forest Labs' studies using memantine to treat pediatric autism. Compl. ¶¶ 62-63.

[redacted]

[12] Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[redacted] Compl. ¶¶ 61, 63; *see* Decl. of David F. Solomon[13] ¶ 14. [redacted]

[redacted] ¶ 14. [redacted]

[redacted] ¶ 15.

D. Forest Labs Secures FDA Approval to Manufacture and Sell an Improved Version of Namenda, Once-Daily Namenda XR Capsules

Prior to 2007, Forest Labs undertook R&D of once-daily Alzheimer's therapy, the Namenda XR capsule. Taglietti ¶¶ 10-11. By June 2010, Forest Labs had received final FDA approval to manufacture and sell Namenda XR.[14] Compl. ¶ 68. The Bureau admits that Namenda XR's once-daily dosing represents an improvement in the Namenda brand. Zain Ex. 20 at 1; *see also* P.I. Mem. 30 n.67 (Bureau does not challenge XR's "clinical benefits").[15]

Dr. Alan Jacobs,[16] who has treated hundreds of Alzheimer's patients, and other Alzheimer's experts expect that the reduced pill burden of Namenda XR will improve treatment outcomes by permitting patients more easily to adhere to their treatment regimens. Ferris ¶¶ 32-33, 42; Decl. of Dr. Alan R. Jacobs, M.D. ¶¶ 31-32; Decl. of Dr. Bruce D. Kohrman, M.D.[17] ¶¶ 3, 27; Reisberg ¶ 30; Rovner ¶ 37. Once-daily dosing also decreases burdens on caregivers,[18]

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[13] Mr. Solomon was Senior Vice President of Corporate Development and Strategy at Forest Laboratories, and was responsible for the assessment of commercial opportunities, including licensing arrangements, intellectual property, and related due diligence. Solomon ¶¶ 1, 4.

[14] U.S. Food and Drug Admin., Drugs@FDA, Namenda XR (KO Ex. 13).

[15] Dep. of Kevin Walsh 8-210:3 (KO Ex. 7) [redacted]

[16] Dr. Jacobs is a board-certified neurologist engaged in the full-time solo clinical practice of neurology for the past ten years. He has seen and treated hundreds of Alzheimer's patients on a daily basis throughout his career in private practice and in academia. Jacobs ¶¶ 1, 7, 10.

[17] Dr. Kohrman has been engaged in the full-time clinical practice of neurology for the past 25 years. He sees and treats multiple Alzheimer's patients on a daily basis. He also has more than 14 years' experience in medical research. Kohrman ¶¶ 1, 5-6.

[18] The Alzheimer's Association estimated that in 2013, 15.5 million caregivers provided 17.7 billion hours of unpaid care valued at $220.2 billion and had $9.3 billion in health care costs from the strain of providing constant care. *2014 Alzheimer's Disease Facts & Figures*, Alzheimer's Association, at 33 (KO Ex. 8).

reduces patient anxiety about repeatedly taking their pills, and alleviates confusion about dosing among caregivers and patients. Ferris ¶¶ 34-36, 41-42, 46; Rovner ¶¶ 40-43. Dr. Bruce Kohrman, a neurologist with 25 years of experience, notes that once-a-day dosing eases the pill administration to patients. Kohrman ¶¶ 25-27. With twice-a-day Namenda IR, "[e]ach pill can be a burden, requiring the caregiver to assume the burden of administering the pill, often to a reluctant patient, and the caregiver may also be employed or otherwise unavailable to administer the second pill without considerable personal stress." Ferris ¶ 39; *see also* Reisberg ¶¶ 30-33; Rovner ¶¶ 40-42; Decl. of LuMarie Polivka-West[19] ¶ 17. Reducing the number of separate dosages, in turn, improves the chances that the patient will get all doses as intended and decreases the risk of sporadic or incorrect administration, estimated to be approximately 20% of all drug dosing.[20] Ferris ¶¶ 42, 46; Reisberg ¶¶ 30-31. Reducing caregiver burden reduces costs for in-home caregivers and long-term facilities. Reisberg ¶¶ 32-33; Rovner ¶¶ 43-44. Generic twice-daily Namenda IR tablets (just like branded Namenda IR) do not offer these benefits. In fact, studies show that the reduced cost and time benefits that once-daily medications offer justify care facilities selecting higher cost extended-release products.[21]

Additionally, unlike Namenda IR tablets, Namenda XR has been FDA-approved to be

[19] Ms. Polivka-West is Senior Vice President and Senior Director of Policy and Program Development with the Florida Health Care Association. Polivka-West Sec. I.

[20] Medication administration errors are a serious health care problem because "drug therapy cannot be successful unless prescribing and delivery, and administration are performed correctly." Kenneth N. Barker, et al., *Medication Errors Observed in 36 Health Care Facilities*, 162 Archives Internal Med. 1897, 1897 (2002) (KO Ex. 9). Studies have found a mean error rate of 19% in institutional facilities and of 28% in assisted living facilities. Heather M. Young, et al., *Types, Prevalence, and Potential Clinical Significance of Medication Administration Errors in Assisted Living*, 56 J. Am. Geriatrics Soc. 1199, 1203 (2008) (KO Ex. 10). Simply put, patients were not receiving the correct dose for every 4-5 doses being administered to them by professional caregivers.

[21] A study showed that cutting back from three doses to a single one saved the nursing facility 45 minutes per patient per month, even when the patient was already receiving medication three times a day. Irene Hamrick, et al., *Nursing Home Medication Administration Cost Minimization Analysis*, 8 J Am. Med. Dir. Assoc. 173, 175-76 (2007) (KO Ex. 11). Saving as little as 34.2 seconds per dose saves 66 minutes per ward per day of nursing time. Alan Cottney, *Improving the Safety and Efficiency of Nurse Medication Rounds Through the Introduction of an Automated Dispensing Cabinet*, 3 BMJ Quality Improvement Reps., at 1, 3 (Apr. 25, 2014) (KO Ex. 12).

sprinkled over applesauce for patients with difficulty swallowing. Taglietti ¶ 15; Jacobs ¶ 25; Kohrman ¶ 21. Forest Labs has also conducted research using Namenda XR to learn more about the use of memantine in combination with other Alzheimer's treatments. Meury ¶ 9. Namenda XR also has been shown to have efficacy as a two-drug combination therapy with other Alzheimer's medications, specifically, AChEIs donepezil, galantamine (*e.g.*, Razadyne), and rivastigmine (*e.g.*, Exelon). Zain Ex. 20 at 1; Taglietti ¶ 17; Meury ¶ 9. Based on these results, Forest Labs has developed a product that combines extended release memantine with an already once-a-day donepezil, the leading AChEI to further reduce pill burden for patients and caregivers from two pills to one. *See* Meury ¶ 10 (fixed dose "has been a constant request from physicians treating Alzheimer's patients"); Taglietti ¶ 19. The development of the once-a-day Namenda XR formulation was a necessary first step. Taglietti ¶ 19. In 2014, Forest Labs submitted a new drug application for a fixed dose combination of Namenda XR and donepezil. Compl. ¶¶ 49, 66.

E. Forest Labs Launches Namenda XR

In the lead up to the Namenda XR launch,[22] [redacted] KO Ex. 14. [redacted] *Id.* [redacted] *Id.*

In launching Namenda XR in June 2013, [redacted]

[22] The FDA approved Namenda XR on June 21, 2010. *See* Drugs@FDA, Namenda XR (KO Ex. 13). Forest Labs launched Namenda XR in June 2013. The Bureau seems to wonder why Forest Labs "did not bring Namenda XR to market" in June 2010. P.I. Mem. 14. In the lead up to Namenda XR's June 2010 FDA approval and through the June 2013 launch, [redacted] Meury Dep. 164:11-165:7 (KO Ex. 5).

[redacted]

[redacted].[23] Meury ¶ 10; Decl. of Jerry A. Hausman[24] ¶ 22. By launching Namenda XR, Forest Labs hoped to deliver these benefits to patients and caregivers. Taglietti ¶ 11.

After launching Namenda XR in June 2013, Forest Labs continued to sell Namenda IR tablets, IR oral solution, and Namenda XR capsules concurrently, Taglietti ¶ 29, allowing patients to transition from the older, twice-a-day form to the newer, once-a-day Namenda XR, to increase formulary access, and to continue educating patients, caregivers, and health care providers about Namenda XR. Several Alzheimer's experts confirm that the transition from Namenda IR to XR was easy and incident free. Jacobs ¶ 33; Reisberg ¶ 28; Rovner ¶¶ 6, 51; Kohrman ¶ 39. Patients likewise without difficulty or adverse medical effects may transition back from Namenda XR to IR. Jacobs ¶ 34; Reisberg ¶ 29; Rovner ¶¶ 6, 51; Kohrman ¶ 33.

F. Forest Labs Decides to Discontinue Namenda IR Tablets [redacted]

In light of Namenda XR's benefits compared to twice-a-day Namenda IR, [redacted] As noted by William Kane,[25] Vice President for Marketing-Internal Medicine at Actavis, [redacted] Decl. of William Kane ¶ 5; Meury ¶ 16-17. [redacted]

[23] Namenda XR Package Insert § 2.2 (Sept. 2014) (KO Ex. 4).

[24] Professor Hausman is the MacDonald Professor of Economics at the Massachusetts Institute of Technology.

[25] Prior to Actavis's acquisition of Forest Labs, Mr. Kane was VP of CNS Marketing for Forest Labs. Kane ¶ 1.

[redacted] *See* KO Ex. 15 at 534 (**Figure 1** below). [redacted]

[redacted]

[redacted] *See* KO Ex. 29 at 487, KO Ex. 30 at 506; Kane ¶ 8. [redacted]

[redacted]

[redacted] KO Ex. 30 at 494; *see also* Kane ¶ 9. [redacted]

[redacted]

See KO Ex. 15 at 537 (**Figure 2** below).

[redacted]

Figure 1 **Figure 2**

[redacted]

[redacted] *See* Decl. of Napoleon Clark[28] ¶¶ 3-7; *see, e.g.*, Decl. of Dr. E.M. (Mick) Kolassa[29] ¶ 13 [redacted]

[26] [redacted] (KO Ex. 16).

[27] [redacted] (KO Ex. 17).

[28] Mr. Clark is Executive Director of Marketing, Generics at Actavis. Clark ¶ 1.

[redacted]; *see also ISTA Pharm., Inc. v. FDA*, 898 F. Supp. 2d 227, 229-30 (D.D.C. 2012) (summarizing pharmaceutical company's transition from a twice-a-day product, to a once-a-day version, before generic entry); Zain Ex. 16 [redacted]; Zain Ex. 15 [redacted]. [redacted] *See* Cremieux ¶ 30.

[redacted] KO Ex. 19. At that time, Forest Labs projected that discontinuation could occur on August 15, 2014. KO Ex. 18. [redacted] Meury ¶ 25; KO Ex. 19.

On February 14, 2014, Forest Labs announced a plan effective August 15, 2014 to focus its manufacturing and marketing efforts on once-a-day Namenda XR and discontinue the sale of Namenda IR tablets. Zain Ex. 33 at 1. Forest Labs would then have additional capacity to manufacture some of its other products. Zain Ex. 46 at 10. [redacted] Meury Dep. 270:11-273:2 (KO Ex. 5); Cremieux ¶ 29. [redacted] Meury ¶ 15; Cremieux ¶ 26. Forest Labs communicated its plans to patients, caregivers, health care providers, and various interest groups. *See, e.g.*, Zain Exs. 35 (caregivers), 36 (health care providers).

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[29] Dr. Kolassa is founding partner of Medical Marketing Economics, LLC, a consulting firm in the field of health care market analysis. Kolassa ¶ 1.

[30] Meury Dep. 87:16-89:4 (KO Ex. 5) [redacted].

In June 2014, [redacted] Forest Labs announced that it would continue selling Namenda IR tablets through Fall 2014. Zain Ex. 40; Decl. of Robert Stewart[31] ¶ 10. [redacted] Meury Dep. 233:20-235:5 (KO Ex. 5); Kane ¶ 13; Meury ¶¶ 27-29.

ARGUMENT

I. THE BUREAU APPLIES THE WRONG STANDARD AND ASSUMES AWAY THE REQUIREMENTS FOR A MANDATORY INJUNCTION

A. The Bureau Improperly Seeks to Avoid the Standard for Mandatory Injunctions

The Bureau requests a mandatory injunction to force Forest Labs to manufacture and sell a product—but misapplies the lesser standard for prohibitory injunctions. *Tom Doherty Assocs., Inc. v. Saban Entm't, Inc.*, 60 F.3d 27, 33-34 (2d Cir. 1995); *Mastrovincenzo v. City of New York*, 435 F.3d 78, 89-90 (2d Cir. 2006) (citing *Tom Doherty*, 60 F.3d at 34). A mandatory injunction seeks to *compel* (rather than *restrain*) a defendant to perform an act or to engage in a specified course of conduct, precisely the type of injunction the Bureau requests. *Louis Vuitton Malletier v. Dooney & Bourke, Inc.*, 454 F.3d 108, 114 (2d Cir. 2006) ("A mandatory injunction . . . 'orders an affirmative act or mandates a specified course of conduct' . . . .").

The proposed injunction would not preserve the "status quo." The Bureau concedes that "[i]f the Court issues the preliminary injunction, Defendants can claim only one 'harm': that *they have been forced to continue to sell* a blockbuster drug . . . against their will." P.I. Mem. 43.

[31] Mr. Stewart is Chief Operating Officer of Actavis. Stewart ¶ 1.

[32] [redacted]

Thus, the injunction must be denied unless the Bureau meets the standard for a mandatory injunction. *See Cacchillo v. Insmed, Inc.*, 638 F.3d 401, 406 (2d Cir. 2011) (denying mandatory injunction that would require defendant to provide FDA support for compassionate use of drug); *Tom Doherty*, 60 F.3d at 35 (finding injunction mandatory where it would require defendant to license book); *Union Cosmetic Castle, Inc. v. Amorepacific Cosmetics USA, Inc.*, 454 F. Supp. 2d 62, 68 (E.D.N.Y. 2006) (denying mandatory injunction, noting that "plaintiffs' apparent interpretation of the term 'status quo' lacks a basis in law or common sense"); *Vantico Holdings v. Apollo Mgmt., LP*, 247 F. Supp. 2d 437, 451 (S.D.N.Y. 2003) (finding injunction mandatory where it would require defendant to vote in particular manner); *Lincoln Cercpac v. Health & Hosps. Corp.*, 920 F. Supp. 488, 495 (S.D.N.Y. 1996) (finding injunction mandatory where it would require health facility to reopen), *aff'd*, 147 F.3d 165 (2d Cir.).

While both mandatory and prohibitory injunctions are considered "extraordinary and drastic" remedies, *Munaf v. Geren*, 553 U.S. 674, 676 (2008), the movant requesting a mandatory injunction must meet an even higher standard. A mandatory injunction requires (i) a "strong showing" that the movant will incur irreparable harm without the injunction, and (ii) a "clear" or "substantial" likelihood of success on the merits.[33] *Doe v. New York Univ.*, 666 F.2d 761, 773 (2d Cir. 1981) (heightened standard for irreparable harm); *Tom Doherty*, 60 F.3d at 33-

[33] The Bureau incorrectly relies upon *Jacobson & Co. v. Armstrong Cork Co.*, 548 F.2d 438 (2d Cir. 1977), to argue that injunctive relief can be granted as long as the Bureau has raised "a serious question going to the merits to make them a fair ground for trial." P.I. Mem. 41 (citing *Citigroup Global Mkts., Inc. v. VCG Special Opportunities Master Fund Ltd.*, 598 F.3d 30, 35 (2d Cir. 2010)). This case was effectively abrogated by *Tom Doherty*, which held that a mandatory injunction requires a "clear" or "substantial likelihood of success." 60 F.3d at 35. Every Second Circuit decision since *Tom Doherty* has so held, and none apply *Jacobson*'s "serious question going to the merits" test when evaluating mandatory injunctions. *See, e.g.*, *New York Civil Liberties Union v. New York City Transit Auth.*, 684 F.3d 286, 294 (2d Cir. 2011) ("For mandatory injunctions . . . 'the movant must show a 'clear' or 'substantial' likelihood of success' on the merits."); *Rossini v. Republic of Argentina*, 453 F. App'x 22, 24 (2d Cir. 2011) (same); *Levola v. Fischer*, 403 F. App'x 564, 565 (2d Cir. 2010) (same); *Doninger v. Niehoff*, 527 F.3d 41, 47 (2d Cir. 2008) (same); *Yu Juan Sheng v. City of New York*, 181 F. App'x 38, 39 (2d Cir. 2006) (same); *Mastrovincenzo v. City of New York*, 435 F.3d 78, 89 (2d Cir. 2006) (same); *Sunward Elecs., Inc. v. McDonald*, 362 F.3d 17, 24-25 (2d Cir. 2004) (same).

34 (heightened standard for likelihood of success).

This higher standard also applies where the injunction will "provide the movant with substantially all the relief sought and that relief cannot be undone even if the defendant prevails at a trial on the merits." *Tom Doherty*, 60 F.3d at 34-35; *see Pazer v. N.Y. State Bd. of Law Examiners*, 849 F. Supp. 284, 286 (S.D.N.Y. 1994). Here, an order mandating that Forest Labs continue manufacturing and selling Namenda IR tablets until a "reasonable period" after generic entry in July 2015, P.I. Mem. 43-45, would provide the Bureau with "substantially all the relief sought" at trial and "cannot be undone" if Forest Labs prevails at trial—which likely would not take place before July 2015. *See Tom Doherty*, 60 F.3d at 34-35; *Lincoln*, 920 F. Supp. at 494 n.10 (finding "heightened standard" applied where "[i]t would be difficult or impossible" to provide defendant with "any meaningful remedy once it had been directed" to reopen hospital already closed); *see also* P.I. Mem. 1 (requesting order requiring Forest Labs to produce Namenda IR "until final resolution of this litigation").

B. The Bureau Is Not Entitled to a Presumption of Irreparable Harm

The Bureau erroneously assumes a presumption of irreparable harm. P.I. Mem. 40. But because the Bureau moves in its *parens patriae* capacity (Compl. ¶ 9), no presumption applies. *See New York v. Kraft Gen. Foods, Inc.*, 862 F. Supp. 1030, 1033 (S.D.N.Y. 1993) (applying federal equity principles where Bureau sued under Clayton Act *parens patriae* capacity). The applicable federal injunction statute—Section 16 of the Clayton Act—applies federal equity principles, *including irreparable harm*.[34] Courts may not presume away the irreparable harm requirement in Sherman Act cases, even to a government plaintiff. *See United States v.*

[34] 15 U.S.C. § 26 (authorizing injunction "when and under the same conditions and principles as injunctive relief against threatened conduct that will cause loss or damage is granted by courts of equity . . . and a showing that the danger of ***irreparable loss or damage*** is immediate.") (emphasis added).

Microsoft Corp., 147 F.3d 935, 943-44 (D.C. Cir. 1998) (rejecting presumption).

Presumptions of irreparable harm are heavily disfavored and narrowly construed. *See Weinberger v. Romero-Barcelo*, 456 U.S. 305, 313 (1982) (statute should not be read lightly to replace traditional equity test). In *eBay Inc. v. MercExchange, LLC*, the Supreme Court eliminated the presumption of irreparable harm in patent cases, because "a major departure from the long tradition of equity practice should not be lightly implied." 547 U.S. 388, 391 (2006). The Second Circuit recently stated that *eBay* eliminates all presumptions of irreparable harm "in *any* type of case" absent explicit congressional intent (which is absent here). *See Salinger v. Colting*, 607 F.3d 68, 78 n.7 (2d Cir. 2010); *see also LSSi Data Corp. v. Time Warner Cable, Inc.*, 892 F. Supp. 2d 489, 501 (S.D.N.Y. 2012) (plaintiff must show irreparable harm because "the Second Circuit has repeatedly emphasized that [a] showing of irreparable harm is the single most important prerequisite for the issuance of a preliminary injunction").

The Bureau's reliance on state law does not help them. P.I. Mem. 40. First, the Bureau cites no authority to support the notion that a *state* statute such as the Donnelly Act or Executive Law § 63(12) can displace the *federal* equity principles mandated by Section 16 of the Clayton Act. The Donnelly Act does not in any event apply to the unilateral conduct alleged here. *See* MTD Mem. 23-24. Similarly, whether the Bureau may seek injunctive relief under Executive Law § 63(12) depends on whether the Donnelly Act applies (and it does not) because Executive Law § 63(12) is simply a remedies statute and does not create an independent cause of action. *See* MTD Mem. 24-25.

The only cases the Bureau cites (P.I. Mem. 40) to support a presumption—*Free Speech v. Reno*, 200 F.3d 63 (2d Cir. 1999), and *Prayze FM v. FCC*, 214 F.3d 245, 248 (2d Cir. 2000)—involved actions by the FCC where defendants already had been found to have violated a statute,

and the injunction would prevent future violations. Unlike *Free Speech* and *Prayze* (where the facts establishing liability were not in dispute), liability is substantially in dispute. *See United States v. Nutri-Cology, Inc.*, 1991 WL 1092506, at *1 (N.D. Cal. July 19, 1991) (finding no presumption of irreparable harm where statutory violation was "substantially disputed"). In any event, *Free Speech* and *Prayze* preceded *eBay* and *Salinger*. And they are inapposite because they involved the FCC—a regulator Congress has vested with plenary authority over the public airwaves. Of course, Congress has vested the Bureau with no plenary authority over pharmaceuticals. The normal rules for federal injunctions apply.

II. THE BUREAU FAILS TO MEET THE HEAVY BURDEN REQUIRED TO OBTAIN INJUNCTIVE RELIEF

A. The Bureau Has Failed to Show that Any Irreparable Harm Will Result [redacted]

The Bureau makes no showing—much less a "strong" one—that Forest Labs' [redacted] will irreparably harm consumers and generic competitors. P.I. Mem. 41-43. The Bureau relies on the speculation of two witnesses—a physician and an employee of MVP, a small health insurer—who offer only vague and uncorroborated evidence to support allegations of adverse effects or financial harm to patients or health care providers. But alleged injury cannot be either "remote []or speculative," but must be "actual and imminent." *In re Keurig Green Mountain Single-Serve Coffee Antitrust Litig.*, No. 1:14-md-02542, Dkt. No. 64 at 8 (S.D.N.Y. Sept. 19, 2014) (quoting *Grand River Enter. Six Nations, Ltd. v. Pryor*, 481 F.3d 60, 66 (2d Cir. 2007)); *see also, e.g.*, *Jackson v. Am. Plaza Corp.*, 2009 WL 1158829, at *6 (S.D.N.Y. Apr. 28, 2009) (holding alleged harm was "far too remote to establish probable irreparable harm"); *Kraft Gen. Foods*, 862 F. Supp. at 1035 (alleged irreparable harm "too speculative"); *N.Y. State Psychiatric Ass'n v. Blum*, 475 F. Supp. 67, 72

(S.D.N.Y. 1979) (finding no irreparable harm, particularly due to absence of affidavits from plaintiffs' patients indicating how they would be injured).

1. The Bureau Offers No Evidence of Harm to Patients

The Bureau's "Adverse Effects" Allegations Are Baseless. The Bureau asserts that Namenda IR patients will suffer "unnecessary disruption in their treatment—and the attendant risk of adverse effects." P.I. Mem. 41. These allegations are reckless. The Bureau's lone physician-witness, Dr. Lah, discredited the Bureau's speculation about patient harm. Dep. of James J. Lah M.D., Ph.D. 279:8-13 (KO Ex. 2). And Dr. Lah admitted he had not read the XR package insert showing that the FDA has ***approved*** instructions for safely transitioning patients from Namenda IR to Namenda XR the next day. Lah Dep. 141:25-142:17 (KO Ex. 2) (admitting that he did not look at the Namenda XR insert but "skimmed" the Namenda IR insert).[35] The FDA's Center for Drug Evaluation and Research approved this switching instruction after having reviewed the "Switchability from Namenda IR to Namenda XR in patients" in its Clinical Pharmacology and Biopharmaceutics Review of Namenda XR®.[36]

The Bureau speculates that if Namenda IR tablets become unavailable, patients will be "forced to switch" to Namenda XR. P.I. Mem. 4, 41. This is demonstrably false: Forest Labs' unquestionably lawful IR "patent and regulatory exclusivities," Compl. ¶ 3, permit it to discontinue production of Namenda IR tablets. In addition, patients can choose to take the Namenda IR oral solution [redacted] In any event, the Bureau is wrong that switching from IR to XR would result in a "disruption" of patients' treatment and "adverse effects." P.I. Mem. 41. Tens of thousands of

[35] Namenda XR Package Insert § 2.2 (Sept. 2014) (KO Ex. 4).

[36] FDA's Center for Drug Evaluation and Research, Clinical Pharmacology and Biopharmaceutics Review of Namenda XR® at pp. 4-5; Ferris ¶ 29; *see also* Taglietti ¶¶ 23-24.

Alzheimer's patients have done this switch, and the Bureau cites no adverse effects. Hausman ¶ 14 n.20; *see also* Reisberg ¶¶ 28-29, Kohrman ¶ 4. At his deposition, the Bureau's Dr. Lah had "***no foundation or basis*** on which to conclude that . . . individual patient[s] will have greater adverse effects going to XR from IR. It's a potential concern, not a known concern." Lah Dep. 279:8-13 (KO Ex. 2) (emphasis added). Dr. Lah "know[s] of no published data regarding potential adverse effects that may result from switching patients . . . ." Decl. of James J. Lah, M.D., Ph.D. ¶ 33 (Dkt. No. 25) (filed Sept. 30, 2014). Dr. Lah also is unaware of any clinical trials showing that a switch from IR to XR, or from XR to IR, will harm patients. *See* Lah Dep. 24:4-25:2 (KO Ex. 2).

Dr. Lah testified that he knows of ***no efficacy reasons*** why a patient should not switch from twice-a-day Namenda IR to once-a-day Namenda XR. Lah Dep. 225:8-16 (KO Ex. 2) (no basis to challenge FDA's finding that Namenda XR is effective); *id.* at 279:8-13. And Dr. Lah admitted he has not received any reports describing patient decline after a "reverse switch" from Namenda XR to Namenda IR, nor is he aware of any data regarding potential adverse effects of switching from Namenda XR to Namenda IR. *See* Lah Dep. 62:2-5; 24:9-13. (KO Ex. 2). Empirically many patients "reverse commuted" from XR to IR in the Summer of 2014 due to a shortage of XR. Cremieux ¶ 44; Hausman ¶ 19. There is no evidence that switching from IR to XR causes adverse effects. Jacobs ¶ 34; Reisberg ¶ 29; Rovner ¶¶ 6, 51; Kohrman ¶ 33.

Although Dr. Lah recounted an anecdotal report of cognitive decline in one patient, he could not remember the patient's identity or whether he had performed any cognitive testing on the patient. *See* Lah Dep. 48:18-49:6, 51:25-52:4, 53:22-54:3 (KO Ex. 2). And even with this patient, Dr. Lah's medical judgment was ***not*** to switch the patient back from Namenda XR to Namenda IR. Lah Dep. 56:14-15 (KO Ex. 2). Dr. Lah claimed there may have been others who

reported a cognitive or functional decline but he could not remember any details, including whether any such patients were assessed on a standardized test to see if they had in fact declined as a result of a transition from Namenda IR to XR. Lah Dep. 58:14-61:23. Dr. Lah also admitted any alleged decline a patient may have experienced could be consistent with the disease's ordinary progression. *See* Lah Dep. 290:6-23 (KO Ex. 2).

On the other hand, medical experts and N.Y.-licensed physicians specializing in Alzheimer's disease confirm that there is no evidence that patients will suffer "adverse effects" as a result of switching from two-tablet, twice-a-day Namenda IR to one capsule, once-a-day Namenda XR. Dr. Jacobs testifies that he has converted "about two dozen" patients from Namenda IR to XR "without issue or adverse effect." Jacobs ¶ 5. Drs. Rovner, Kohrman, and Reisberg—all of whom have transitioned patients from IR to XR—agree that switching patients from twice-a-day IR to once-a-day XR presents no safety risks. Rovner ¶¶ 6, 51; Kohrman ¶ 36; Reisberg ¶ 28. Dr. Ferris explains that while titration (gradual increase in dose) is required when a patient *first takes* memantine—for both IR and XR—no titration is required to *switch* from IR to XR, and no adverse effects will follow from a failure to titrate. Ferris ¶¶ 21, 28-29.

Patients and caregivers also will not suffer any administrative disruption in switching to the newer, once-a-day Namenda XR capsule. Forest Labs has ensured that if patients switch from Namenda IR to Namenda XR, they may do so seamlessly, particularly with regard to health plan coverage. *See* Meury ¶ 13. Forest Labs spent considerable resources educating patients, caregivers, and health care providers about the improved, once-a-day version to ensure that the new version is included in health plan formularies. *See* Meury ¶¶ 10, 12. The Bureau therefore cannot remotely show irreparable harm to patients from Forest Labs' conduct. *See, e.g.*, *Lincoln*, 920 F. Supp. at 495-96 (finding that defendant's "considerable efforts to smooth the transition"

from old services to new counseled against irreparable harm finding).

Once-a-Day XR Has Undisputed Advantages Over Twice-a-Day IR. The Bureau admits that Namenda XR is more convenient than Namenda IR. *See* P.I. Mem. 16 ("[s]ome patients may benefit"). Namenda XR, unlike Namenda IR, is a once-daily drug that can be administered to patients any time of the day. Once-daily dosing reduces the risk of a missed dose, reduces the burden on caregivers administering the drug and the patient's anxiety in taking medication, and ultimately can reduce costs.[37] *See* Polivka-West ¶¶ 3, 32-34 (explaining that long-term care facilities seek to minimize pill burden because, among other reasons, even the smallest error in pill administration could "expos[e] the facility not only to governmental fines and sanctions but also to onerous private lawsuits"); *id.* ¶¶ 39-41 (explaining from her personal experience as a caregiver to her late mother, who suffered from Alzheimer's disease, that once-a-day dosing "unquestionably" would have benefitted her and her mother who suffered from Alzheimer's disease). Taglietti ¶ 14; Kane ¶ 10. And, for patients with difficulty swallowing, the contents of a Namenda XR capsule can be sprinkled on applesauce—a crucial benefit for elderly patients. Meury ¶ 9; Taglietti ¶ 15; Jacobs ¶ 25; Kohrman ¶ 21; Polivka-West ¶ 41.

Dr. Lah readily acknowledges the various therapeutic benefits of taking one capsule of Namenda XR once a day and that some patients and caregivers may prefer it over twice-a-day Namenda IR. *See* Lah ¶ 22 ("Namenda XR, because it only has to be taken once a day, may be preferred by some patients or caregivers."); Lah Dep. 136:15-18 (KO Ex. 2). He agrees that fewer doses are better than more doses (Lah ¶ 15) and acknowledges that once-a-day dosing is

[37] *See* Patricia M.L.A. van den Bemt, et al., *Medication Administration Errors in Nursing Homes Using an Automated Medication Dispensing System*, 16 J. Am. Med. Informatics Assoc. 486, 486, 490 (2009) (KO Ex. 20) (finding statistically significant correlation between number of dosages administered per patient per day and errors in administering dosages even in nursing homes using automated distribution systems designed to minimize such errors); Andreas Hagendorff, et al., *Pill Burden in Hypertensive Patients Treated with Single-Pill Combination Therapy—An Observational Study*, 30 Adv. Ther. 406, 414-15 (2013) (KO Ex. 21) (reporting that "93.6% of physicians strongly agreed or agreed" that pill burden in chronically ill patients is a challenge for physicians).

easier to follow than twice-a-day, *see* Lah Dep. 138:13-17 (KO Ex. 2). Dr. Lah points out that swallowing tablets may be hard for some patients (Lah ¶ 19), and for those patients, taking a pill once a day is better than twice a day. *See* Lah Dep. 139:5-8 (KO Ex. 2). Dr. Lah also admits that for some patients who experience "sundowning"—where a patient becomes agitated or confused late in the day, *see* Lah Dep. 169:16-20 (KO Ex. 2)—it can be difficult for caregivers to administer medicine. Lah Dep. 173:16-18 (KO Ex. 2); *see also* Polivka-West ¶ 37 (during sundowning, "pill administration [becomes] even more problematic because caregivers were already exhausted at the end of a long day"); Rovner ¶ 41-42. Dr. Lah also agrees that fewer pills generally leads to greater compliance with treatment, Lah Dep. 137:6-138:17 (KO Ex. 2), and he generally prefers once-a-day over twice-a-day dosing, *see* Lah Dep. 169:9-12 (KO Ex. 2); *see also id.* at 300:2-6 (patient convenience is a factor).

Defendants' medical experts—Dr. Jacobs, Dr. Reisberg, Dr. Ferris, Dr. Rovner, and Dr. Kohrman—also confirm these advantages of once-a-day Namenda XR. Jacobs ¶¶ 3-4, 30-32 (Namenda XR is the "first choice for patients being put on an NMDA receptor antagonist for the first time, given its preferential once-a-day dosing"); Reisberg ¶¶ 2, 30-33 (once-daily formulations are better for patients with trouble swallowing and increases compliance, especially for dementia patients); Ferris ¶¶ 2, 32-42 (Namenda XR is an improvement over Namenda IR for patients and caregivers); Rovner ¶¶ 4-5, 44-47 (once-daily dosing reduces patient and caregiver costs and increases compliance); Kohrman ¶¶ 3, 24-28 (once-daily dosing increases compliance).

Moreover, marketplace data also overwhelmingly shows that patients, caregivers, and health care providers prefer once-a-day Namenda XR over twice-a-day Namenda IR.[38] Hausman ¶¶ 7-10. In addition, doctor preference for Namenda XR is clear from the Namenda XR

[38] [redacted] Hausman ¶ 9.

conversion rate (*i.e.*, the share of total memantine-based prescriptions accounted for by Namenda XR), which reached 40% in July 2014. Hausman ¶ 14. The undisputed feedback from patients, caregivers, and health care providers eliminates any basis to suggest irreparable harm here.

By shifting limited resources away from Namenda IR tablets, Forest Labs can continue to innovate with Namenda XR. For example, many Alzheimer's patients take another drug, AChEI, in addition to Namenda. Jacobs ¶¶ 26, 31; Rovner ¶ 28. Forest Labs has developed a product that combines Namenda XR with an AChEI (donepezil) that would further reduce the number of separate dosages—an innovation not possible with older, twice-a-day Namenda IR. Taglietti ¶¶ 17-19; Meury ¶ 9. This benefit further undermines the Bureau's empty irreparable harm claim. *See, e.g.*, *Eli Lilly & Co. v. Premo Pharm. Labs., Inc.*, 630 F.2d 120, 137 & n.78 (3d Cir. 1980) ("[D]evelopment and perfection of new drugs frequently requires the devotion of years of research time and expenditure of millions of dollars. . . . [T]his type of an investment of human and capital resources is . . . socially beneficial . . . ."); *see also Berkey Photo*, 603 F.2d at 281-82 (weighing research disincentives against creating innovation predisclosure requirement).

Both Namenda XR and Namenda IR Oral Solution Offer a Therapeutic Alternative to Namenda IR Tablets. The injunction should also be denied because choices are—and will continue to be—available. *See, e.g.*, *Lincoln*, 920 F. Supp. at 495-96 (no irreparable harm where defendant closed hospital facility and referred patients to replacement facility with same services); *Warren Pearl Constr. Corp. v. Guardian Life Ins. Co. of Am.*, 2008 WL 5329962, at *3 (S.D.N.Y. Dec. 9, 2008) (denying injunction where there was no evidence that replacement policy would adversely impact plaintiffs). But the Bureau and its witness, Dr. Lah, assume: "Neither we nor our patients will have a choice . . . . Until at least July 2015, the only version of Namenda, and indeed, the only drug available in this class of drug, will be Namenda XR." Lah ¶

29. Dr. Lah later admitted that this is incorrect. Lah Dep. 139:19-140:23 (KO Ex. 2).

Indeed, Dr. Lah concedes that twice-a-day Namenda IR is available in oral solution form, which has the same active ingredient as Namenda IR tablets, and is just as effective as the tablets. *See* Lah Dep. 186:16-25, 191:12-20 (KO Ex. 2). In fact, Dr. Lah admits that, for patients who refuse to take pills, the oral solution offers advantages over the tablets. *See* Lah ¶ 19 ("Swallowing may be a problem for patients in the late stages of Alzheimer's disease, and a liquid form of a medication may be easier to swallow at that stage than a tablet (or capsule)."); Lah Dep. 186:6-11 (KO Ex. 2). [redacted] Meury ¶¶ 27-28; Kane ¶¶ 12-13. Thus, [redacted] Namenda will be available—in addition to the new, once-a-day Namenda XR capsules—before competitors launch their generic versions of Namenda IR in July 2015. [redacted] Solomon ¶¶ 12, 14-15.

2. The Bureau Fails to Show Irreparable Harm to Generics

The Bureau also relies upon vague irreparable "harm to competition and the public." P.I. Mem. 42. But the Bureau cites ***no cases*** to support its position that a generalized "harm to competition" can satisfy the heavy burden required for a mandatory injunction. *See GPA Inc. v. Liggett Grp.*, 862 F. Supp. 1062, 1067 (S.D.N.Y. 1994) (evidence of lost future profits "fails to persuade the Court of the likelihood of irreparable injury"); *Topps Chewing Gum, Inc. v. Major League Baseball Players Ass'n*, 641 F. Supp. 1179, 1191 (S.D.N.Y. 1986) (calculable "loss of market share" or "lost profits" not irreparable injury). But the Bureau does not really allege harm to competition—there will be none as the evidence the Bureau relies upon demonstrates

that Forest Labs projected [redacted] Zain Ex. 30 at slide 28. What the Bureau is really alleging is harm to competitors; but "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, 485 (1977) (citing *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962)); *see also* MTD Mem. 13-14. The Sherman Act certainly does not protect firms that seek to use the antitrust laws as a shield against innovation and competition. *Berkey Photo*, 603 F.2d at 281 ("[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.").

Moreover, the Bureau's conclusions about the effect of Forest Labs' FDA-approved launch and marketing of once-a-day Namenda XR on generic competitors are unsupported and unsupportable. The Bureau's theory of competitive harm is that Forest Labs' transition to once-a-day Namenda XR will "demolish[]" generic manufacturers' "competitive significance" by "neuter[ing] the generic substitution laws." P.I. Mem. 32-33. But only 11 states have mandatory substitution laws requiring that a generic be substituted for a brand, and even those states make no guarantee a generic version—let alone an AB-rated equivalent version—will be dispensed when a brand is prescribed. MTD Mem. 17. 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. Creating a ***federal duty*** to sell older products, just in case a generic competitor may be able to take advantage of automatic substitution in a ***minority of states***, makes no sense.

a. Generic Competitors Will Take Over Half of Forest Labs' Namenda XR Business, Disproving Irreparable Harm

The Bureau misapprehends its alleged annihilation of generic competition. The Bureau

alleges that if Forest Labs' were to discontinue Namenda IR tablets, it "will *destroy* the market for the generic form of Namenda IR," "*prohibit* generic manufacturers from providing generic Namenda," "*exclude* generic competition," "*prevent* manufacturers of generic memantine from *engaging in effective price competition*," Compl. ¶¶ 4, 5, 6, 71 (emphasis added), and, "*devastate* generic competition," P.I. Mem. 32-33 (emphasis added).

But even the documents the Bureau relies upon confirm that Forest Labs will face extensive competition from generics—whether or not Namenda IR is discontinued before generic competitors launch in July 2015. First, the January 2014 Forest Labs analyst call shows how significant generic competition will be for Forest Labs—and certainly not "prevented"—even with pre-generic discontinuation of Namenda IR. On that call, Forest Labs' CEO, Brent Saunders, talks about "potentially doing a forced switch" to Namenda XR, Compl. ¶¶ 2, 87 & n.12, just as he explains:

- "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*. . . . [We will] have a *long, prolonged decline* . . . ."
- "[W]e will fight for new RX's, we 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."

Forest Labs, Inc. Earnings Call at 18, 19 (Jan. 21, 2014) (KO Ex. 22) (emphasis added).

Moreover, as detailed in Forest Labs' Motion to Dismiss (MTD Mem. 3-4, 12), an October 13, 2013 internal Forest Labs presentation that the Bureau has highlighted in this case (P.I. Mem., Zain Ex. 30, slide 28), shows that [redacted] In addition, the Bureau's statistics show that within one year of the sale of generic versions of a branded drug, the branded drug may lose as much as 90% of its sales to generic copies. Compl. ¶ 29. As a

result, some branded products are discontinued or otherwise phased out. Kolassa ¶ 7; *see* Meury Dep. 84:10-17 (KO Ex. 5) (promotion of brand typically declines after generic entry).

Even if the Bureau's allegations of harm to generics were well-pleaded (which they are not), it would not be "irreparable" harm, because any such harm could be remedied by money damages. *Tucker Anthony Realty Corp. v. Schlesinger*, 888 F.2d 969, 975 (2d Cir. 1989) ("A monetary loss will not suffice unless the movant provides evidence of damage that cannot be rectified by financial compensation.").

[redacted] Clark ¶¶ 16-18.

b. Further Eliminating Any Chance of Harm to Competition or Irreparable Harm, Third-Party Payers, Including the State of New York, Exert Substantial Pressure to Switch Patients to Generic Drugs

Additional proof of the opportunities for generic competition—and absence of any "foreclosure" by Forest Labs—comes from the enormous power of third-party payers, including the State of New York, pharmacy benefits managers, generic manufacturers, and pharmacists to switch patients to generics. Kolassa ¶¶ 31-50, 73-77; Decl. of Joseph Bova[40] ¶¶ 9, 12, 16, 20. The Bureau acknowledges that generic competitors compete for sales in a variety of ways, including price, obtaining insurance coverage that gives preferential treatment to generics over brands, and low-cost marketing opportunities. Compl. ¶¶ 24, 26; *see also* Clark ¶¶ 9-15; Kolassa

[39] [redacted]

[40] Mr. Bova has been a registered pharmacist for over 30 years and served as Chair of the New York Board of Pharmacy, from 2000 to 2001. Bova Appendix A.

¶ 73-77; *see also* Section C below.[41] [redacted]

[redacted] *See* Stitt ¶ 47; *see also* Bova ¶¶ 28-29; Kolassa ¶¶ 63-69.

Copayments and Formulary Coverage. The evidence is overwhelming that health plans provide substantial preferential coverage to generic drugs. Decl. of David F. Stitt ¶ 39 (Dkt. No. 25) (filed Sept. 24, 2014). Almost every plan has a formulary—*i.e.*, a list of drugs covered by the plan arranged by "tiers" with a corresponding level of co-pay—and health plans decide which drugs to include on their formularies. Stitt ¶ 6. Health plans use tiers and co-payments to encourage physicians to prescribe lower-cost drugs. Stitt ¶ 7; *see also* Kolassa ¶¶ 16, 37-38; Bova ¶¶ 3-6, 12-14; Cremieux ¶ 13. Health plans set co-pays for Tier 3 drugs higher than co-pays for Tier 1 to incentivize physicians and patients towards lower-cost, Tier 1 drugs. Stitt ¶ 9; *see also* Bova ¶¶ 12-14; Kolassa ¶ 37. Plans likely will place generic Namenda IR tablets on Tier 1 (low co-pay) to encourage prescriptions for generic Namenda IR. *See* Stitt ¶¶ 12, 34.

Significant co-pay difference can be more than sufficient to shift patients from a branded drug to a non-AB-rated generic. Kolassa ¶¶ 16, 37-38, 47-49, 55; Bova ¶ 14. Because "[p]atient utilization is higher when out-of-pocket costs are lower," Cremieux ¶ 48, health plans will remove drugs (*e.g.*, branded Namenda IR tablets) from their formularies to shift patients to lower-cost drugs, Bova ¶ 20; Kolassa ¶ 39.

Pharmaceutical manufacturers (of brands and generics) seek lower tier positioning because that "translates to greater sales." Cremieux ¶ 49. Manufacturers "provid[e] discounts and rebates to health plans and managed care organizations" to affect their formulary position.

[41] Dep. of Mark Devlin 169:17-25 (KO Ex. 23) [redacted].

Cremieux ¶ 48; Kolassa ¶ 40. Nothing—certainly nothing that Forest Labs has done—can stop generics from obtaining optimal formulary positioning by offering discounts for generic Namenda IR tablets.

Utilization Management Tools. Health care plans use "utilization management" tools, such as "step edits" and "prior authorizations," to encourage the use of generics. Stitt ¶ 21. In a "step edit," the insurer forces the plan member to try one drug before it will cover a competing treatment. Stitt ¶ 17. "Prior authorizations" require insurers to approve a planned treatment before the insurer will reimburse for the treatment. Stitt ¶ 17. Using these tools, health insurers *greatly influence* the medications that pharmacies dispense. Kolassa ¶¶ 41-46; Bova ¶ 16.

Mr. Stitt contends that MVP might not apply its utilization controls to move patients to generic Namenda IR tablets in 2015. Stitt ¶¶ 44-48. This is simply not credible based on the cost-cutting and profit-maximizing opportunities generic Namenda IR will offer MVP: [redacted] Stitt Dep. 266:2-16 (KO Ex. 1). [redacted] *See* Cremieux ¶ 57; Kolassa ¶ 57.

Insurers Pressure Physicians. Some insurance plans utilize physician withholds, physician report cards, and similar techniques to pressure physicians to prescribe medications consistent with health plan business goals. Kolassa ¶ 28. Physicians who do not meet health plan prescription benchmarks may suffer financial penalties. Kolassa ¶¶ 27-28. These measures incentivize the use of generic drugs. Kolassa ¶¶ 27-30.

Pharmacists Influence Prescribing Decisions. Pharmacists have a profit motive to dispense generics. Kolassa ¶ 26. A pharmacist can work with the patient's doctor to change a prescription to a lower-cost drug. Bova ¶¶ 15, 18. As Mr. Bova explains, these communications happen daily and result in substantial patient savings. Bova ¶¶ 23-24.

c. The Bureau Fails to Establish that Information Barriers Will Prevent Significant Generic Competition and that Patients, Caregivers, and Health Care Providers Ignore Price

The Bureau suggests that physicians and patients are blinded by "information barriers" regarding generic options that generic competitors are powerless to overcome. P.I. Mem. 33-35. The Bureau also suggests that patients and physicians are indifferent to price. *See id.* But the realities of health care competition and the Bureau's own witness refute those notions.

Physicians and Patients Are Well Informed of Generic Options. The Bureau contends that generics "generally" do not market to physicians and patients, and that generics "typically" lack incentives to undertake "substantial marketing." P.I. Mem. 34. But in today's health care landscape, "[t]he information disconnect claimed by Mr. Stitt and the Antitrust Bureau simply does not exist." Kolassa ¶ 20.

For example, electronic prescription writing (or "ePrescribing")—which allows physicians to see generic options, patient co-pays, and insurance coverage when prescribing medication[42]—"has grown substantially, and now represents the large majority of all prescriptions." Kolassa ¶ 23. Brian Bamberger,[43] a consultant with over 25 years of experience in the healthcare information industry, notes that the wide-spread use of ePrescribing has

[42] U.S. Dep't Health & Human Servs., Health Information Tech., *How Does ePrescribing Work?* (Oct. 20, 2014) (KO Ex. 24) ("E-Prescribing refers to a prescriber's ability to electronically send prescription information directly to a pharmacy . . . . Many e-Prescribing systems can also . . . ***inform you of generic alternatives***, and supply you with patient eligibility information and the authorization requirements of your patient's drug plan.") (emphasis added); Kolassa ¶ 23 ("The ePrescribing interface allows third party payers to provide doctors (and staff at the doctor's office) with . . . preferred alternative therapies on the computer screen at the time the prescription is written.").

[43] Mr. Bamberger is the Practice Lead of the Life Sciences at Point of Care Partners. Bamberger ¶ 1.

eliminated the alleged information barrier relied upon by the Bureau. P.I. Mem. 32-36; Decl. of Brian Bamberger ¶¶ 6-8, 9 (as of 2013, 73% of physicians use ePrescribing). The federal government (for Medicare Part D plan providers) and the State of New York (for all physicians) ***mandate*** ePrescribing.[44] The Bureau's Dr. Lah admits he uses ePrescribing and includes the brand and generic name for Namenda in his "favorites" list. Lah Dep. 207:11-19 (KO Ex. 2).

Patients are also well informed. Health plans routinely communicate with insureds to encourage them to lower their costs by talking to their doctors about generic alternatives. Kolassa ¶ 32. Information about generic alternatives also is readily accessible on the internet and numerous smartphone and tablet applications. Kolassa ¶¶ 58-61.

Moreover, generic manufacturers utilize a variety of cost-effective advertising techniques to promote awareness of their products, including press releases, emails, and wholesaler advertisements. Kolassa ¶ 73; Clark ¶¶ 3-13. Payers and government entities also assist generic manufactures by widely publicizing the availability of generic drugs. Kolassa ¶ 20.

As Dr. Lah Admits, Doctors Respond to Opportunities for Patient Savings. Relying on an FTC paper from the 1970s, the Bureau claims that physicians lack the "financial incentive" to "consider price when deciding which drug to prescribe." P.I. Mem. 33-34. That assertion defies reality. The Bureau's own physician-witness, Dr. Lah, rejects the Bureau's claim. Lah Dep. 27:19-21 (KO Ex. 2) ("I do care what the drug costs."); *id.* at 27:24-28:1 (Q. "Why do you care?" A. "Because it has an impact on my patients and their families."); *id.* at 28:2-6 ("I believe that other practitioners likely have similar concerns about drug costs.").

The testimony of Drs. Jacobs and Kohrman belies the Bureau's contention that

[44] CMS, Adopted Standard (KO Ex. 25) ("[S]ponsors who participate in the Part D program are required to support and comply with electronic prescribing."); Bamberger ¶ 9 (e-prescribing mandatory for all N.Y. prescriptions starting March 2015).

physicians do not consider costs. "Physicians routinely take prescription drug costs into account when determining a prescription drug routine for Alzheimer's patients and their caregivers. . . . This includes being sensitive to cost-constraints that guide decisions about treatments." Jacobs ¶ 40. And, "[i]nsurance coverage can have a great impact on what drug is ultimately prescribed." Kohrman ¶ 44, 47 (discussing co-pay incentives); Kolassa ¶¶ 37-38, 47-49. Indeed, Dr. Jacobs believes "being sensitive to cost-constraints that guide decisions about treatments" is part of the "Hippocratic oath." Jacobs ¶ 40. Further, Drs. Kohrman, Jacobs and Rovner confirm that to help manage drug costs they would be free to select lower-cost therapeutic alternatives, including generic Namenda, regardless of whether branded Namenda IR remained available. Jacobs ¶ 43 (whether the branded Namenda IR formulation remains available "would not change [his] ability as a physician to prescribe a generic twice-a-day, instant release memantine hydrochloride formulation when it becomes available"); Kohrman ¶ 41 (confirming he is free to prescribe generic upon entry); Rovner ¶ 49 (same).

d. Informing the Centers for Medicare and Medicaid Services that Forest Labs Planned to Discontinue Namenda IR Tablets Has Absolutely No Bearing on Generic Entry

The Bureau contends without support that Forest Labs informed the Centers for Medicare and Medicaid Services ("CMS") that it planned to discontinue Namenda IR tablets in order "to make it more difficult for Namenda IR tablets to be sold to Medicare patients." P.I. Mem. 19. After Forest Labs notified CMS of its plans, CMS removed Namenda IR tablets from the Formulary Reference File ("FRF"), effective January 2015. However, as former CMS Director of Finance and Operations Dr. Babette Edgar[45] notes, the FRF is not an exclusive drug list for

[45] Dr. Edgar is a principal at BluePeak Advisors and advises health plans on Medicare compliance. She was formerly Director of the Division of Finance and Operations at CMS, with responsibility for formulary benefit design of the Part D benefit. Edgar ¶¶ 2-3.

Medicare Part D Plan formularies, and Part D Plan Sponsors[46] are free to cover drugs that are not on the FRF. Decl. of Dr. Babette Edgar ¶¶ 12-13.

The Bureau is wrong to speculate that a Part D Plan Sponsor "may not cover Namenda tablets starting in January 2015," P.I. Mem. 20, if Namenda IR tablets are not on the FRF. Many major Part D Plan Sponsors, including Express Scripts, Humana, and Empire BlueCross BlueShield will include Namenda IR tablets on their 2015 formularies notwithstanding the FRF. Decl. of Mark Devlin[47] ¶¶ 3, 11-12, 15; Edgar ¶ 20 & n.21.

Dr. Babette Edgar further explains that Plan Sponsors may build their formularies using drugs not on the FRF. Edgar ¶¶ 19-21. Thus, the absence of Namenda IR from the FRF has had no impact on coverage for Namenda IR, and many Part D Plan Sponsors have included Namenda IR tablets on their January 2015 formularies. Edgar ¶¶ 18-20.

B. The Bureau's Claims Are Without Merit, and the Bureau Fails to Show a Clear or Substantial Likelihood of Success

The Bureau fails to carry its burden to show a "clear" or "substantial" likelihood of success on the merits of its novel theory that Forest Labs should be compelled to sell its older, twice-a-day Namenda IR tablets contrary to its business interests in focusing on the newer, once-a-day Namenda XR capsules.[48]

1. The Bureau's Claims Are Not Clearly Likely to Succeed for All the Reasons Discussed in Defendants' Motion to Dismiss

As discussed in the Defendants' Motion to Dismiss, Doc. No. 35, the Bureau's Sherman Act Section 2 claim fails as a matter of law: ***First***, as the Bureau admits, Forest Labs has patent

[46] Medicare beneficiaries obtain the Medicare Part D drug benefit through plans administered through private insurance companies ("Part D Plan Sponsors"). Edgar ¶ 8.

[47] Mr. Devlin is Senior Vice President of Managed Markets at Actavis. Devlin ¶ 1.

[48] Even if the lower standard for prohibitory injunctions applied, the Bureau's claims fail even to raise "serious questions going to the merits" to justify an injunction. *Citigroup Global Mkts.*, 598 F.3d at 35 & n.4.

and regulatory exclusivities until July 2015. Compl. ¶ 3. Forest Labs has no duty to practice its patent over twice-a-day Namenda IR tablets and may use its lawful exclusivity (including price and output decisions) as it wishes. 35 U.S.C. § 154(a)(1) ("Every patent shall contain . . . a grant to the patentee, his heirs or assigns, of the right to exclude others"); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1204 (2d Cir. 1981) ("Simply stated, a patent holder is permitted to maintain his patent monopoly through conduct permissible under the patent laws."); MTD Mem. 8-11. ***Second***, the Bureau fails to allege any exclusionary conduct under the Sherman Act. Even a monopolist "may generally bring its products to market whenever and however it chooses," *Berkey Photo*, 603 F.2d at 286, and the antitrust laws contain no duty to help competitors by manufacturing and selling older products. MTD Mem. 12-16. ***Third***, the Bureau challenges the [redacted] of twice-a-day Namenda IR tablets ***only*** because Forest Labs launched a new product the Bureau believes was not sufficiently innovative, but the antitrust laws do not permit courts to weigh innovation. MTD Mem. 22-23.

The Bureau's Donnelly Act claim also fails as a matter of law because the Act does not prohibit single-firm conduct. MTD Mem. 23-24. The claim under Executive Law § 63(12) fails as a matter of law because § 63(12) is only a remedies statute that requires a separate viable claim—and the Bureau fails to allege one—and because the Bureau cannot repackage its claim as a "fraud" theory. MTD Mem. 24-25. Defendants hereby incorporate by reference each of these arguments about the merits of the Bureau's claims as they confirm that the Bureau has failed to show it is substantially likely to succeed on the merits with its novel claims.

2. *Aspen Skiing, Trinko,* and *Adderall* Confirm that the Bureau Is Not Likely to Succeed on the Merits

Conspicuously, the Bureau devotes over ten pages to arguing that *Aspen Skiing* and its progeny *do not* apply in this case but, just in case they do, the Bureau's claims fit within the

Sherman Act "outer boundary" created by this authority. P.I. Mem. 31-40. The Bureau seeks to avoid relying on this authority at the "outer boundary" of antitrust, P.I. Mem. 32, presumably because the Bureau does not even allege the rare "sole exception" to the right to refuse to deal discussed in *Aspen Skiing*, *Trinko*, and *Adderall*, namely, a duty that may arise when a monopolist terminates a prior voluntary course of dealing with a competitor. *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985) (highly criticized ruling requiring owner to deal with competitor with which it had prior, profitable course of dealing); *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 409 (2004) ("*Aspen Skiing* is at or near the outer boundary of § 2 liability"); *In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 134 (2d Cir. 2014) ("Today, 'the sole exception to the broad right of a firm to refuse to deal with its competitors' comes into play only 'when a monopolist seeks to terminate a prior (voluntary) course of dealing with a competitor.'") (quoting *In re Elevator Antitrust Litig.*, 502 F.3d 47, 52, 53 (2d Cir. 2007) (per curiam)).

Even assuming the Bureau's theory could be recast as a duty to deal with customers, the Bureau's novel claims still would have no clear likelihood of success. *See* MTD Mem. 14-15. 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. And courts have rejected attempts to create a duty to deal with customers. *See United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919); *cf. Cacchillo v. Insmed, Inc.*, 638 F.3d 401, 403, 406 (2d Cir. 2011) (denying mandatory injunction requiring drug company to supply plaintiff with discontinued experimental drug because company had no contractual duty to do so).

The Bureau's argument only exposes that the real theme underlying the Bureau's claim is an "essential facilities" theory. That is, the Bureau argues that Forest Labs should be ordered to

sell twice-a-day Namenda IR tablets through July 2015 because branded Namenda IR is some sort of "essential facility" necessary for the sale of competitors' products. But viewed this way, the Bureau's claims are even more clearly meritless. The Supreme Court in *Trinko* disavowed the essential facilities doctrine in affirming the dismissal of a competitor's antitrust claims. *Trinko*, 540 U.S. at 410-411 (finding refusal to assist rivals not a recognized antitrust claim "even if we considered to be established law the 'essential facilities' doctrine crafted by some lower courts," and stating: "We have never recognized such a doctrine . . . and we find no need either to recognize it or to repudiate it here."); *see also RxUSA Wholesale, Inc. v. Alcon Labs., Inc.*, 661 F. Supp. 2d 218, 229 n.6 (E.D.N.Y. 2009) ("In reversing the Circuit Court on other grounds, the Supreme Court in *Trinko* noted that it had never recognized the essential facilities doctrine . . . ."), *aff'd*, 391 F. App'x 59, 61 (2d Cir. 2010).

3. The Bureau Fails to Show It Is Clearly Likely to Succeed in Showing that Forest Labs Engaged in "Coercive" or Exclusionary Conduct

The Bureau fails to allege any exclusionary conduct to substantiate a Section 2 violation. It does not allege tying arrangements, exclusive dealings, predatory pricing, monopoly leveraging, or any other conduct that could exclude competition under Sherman Act Section 2. The Bureau admits that, where a decision to "change products" is not coercive, "courts have found [the decision] to be lawful." P.I. Mem. 28. Here, Forest Labs' transition to once-a-day Namenda XR cannot plausibly be considered coercive, because, among other reasons:

(1) ***Between now and July 11, 2015,*** Forest Labs has lawful "patent and regulatory exclusivities" that allow Forest Labs to sell or not sell Namenda IR as it wishes. Compl. ¶ 3; *SCM*, 645 F.2d at 1204 ("patent holder is permitted to maintain his patent monopoly through conduct permissible under the patent laws");

(2) ***After July 11, 2015,*** patients will be free to choose, and physicians will be free to prescribe, any of the many available generic versions of twice-a-day Namenda IR tablets—[redacted] (*see above* Section II.A); and

(3) Even before the July 2015 launch of generic versions of twice-a-day Namenda IR tablets, [redacted] branded Namenda IR will continue to be available: Namenda IR oral solution in general distribution [redacted] Meury Dep. 233:20-235:5 (KO Ex. 5); Kane ¶ 13; Meury ¶¶ 27-29.

Moreover, none of the authorities relied upon by the Bureau supports a conclusion that Forest Labs' transition to once-a-day Namenda XR was exclusionary under the Sherman Act.

Berkey Photo*'s Dicta Concerning Tied Products Does Not Support the Bureau's Novel Theory.* The Bureau mischaracterizes *Berkey Photo* as supporting its claim. P.I. Mem. 28; MTD Mem. 15-16, 19-20. The Bureau's novel claims depend on an interpretation of dicta in a footnote of the *Berkey Photo* opinion, in which the court notes it was not ruling on a situation in which, "upon the introduction of the [new camera], Kodak had ceased producing [the old model of] film . . . thereby compelling camera purchasers to buy [the new] camera." 603 F.2d at 287 n.39. This dicta is not the law, and in any event, does not support the Bureau's claims.

In *Berkey Photo*, the Second Circuit rejected a competition challenge to Kodak's launch of a new camera and held that "any firm, even a monopolist, may generally bring its products to market whenever and however it chooses." *Id.* at 286. The dicta mentioned above was part of the court's discussion of potentially leveraging monopoly power in one market to gain advantages in another market, and it is irrelevant here. *See id.* at 284 ("[I]t is improper, in the absence of a valid business policy, for a firm with monopoly power in one market to gain a competitive advantage in another by refusing to sell a rival the monopolized goods or services he needs to compete effectively in the second market."); *see also Virgin Atl. Airways Ltd. v. British Airways PLC*, 257 F.3d 256, 272-73 (2d Cir. 2001) (discussing *Berkey Photo*'s monopoly leveraging principles); *see also* Himes & Zain at 4 n.16 (KO Ex. 26) ("This particular theory of monopoly leveraging [in *Berkey Photo*] is no longer viable after [*Trinko*]. *Trinko* rejected

monopoly leveraging except where the elements of attempted monopolization in the second market are demonstrated."); *see also Twin Labs., Inc. v. Weider Health & Fitness*, 900 F.2d 566, 570-71 (2d Cir. 1990) (rejecting applicability of principles announced in *Berkey Photo* to essential-facilities claim because "*Berkey Photo* involved a 'tying' claim").

The Other Cases Relied upon by the Bureau Similarly Fail to Establish that Transitioning to Improved, Once-a-Day Namenda XR Is Exclusionary Conduct. The remaining cases relied upon by the Bureau also do not support the Bureau's novel theory. *Abbott Labs. v. Teva Pharms. USA, Inc*. involved claims that the defendant (1) fraudulently obtained patents (unlike here, where Defendants complied with all applicable rules and regulations), (2) engaged in sham enforcement of the patents to ***actually exclude*** generic competition while new products were developed (unlike here, where the patents are valid, and no other conduct actually excluded competition), and (3) committed additional forms of exclusionary conduct, including pulling inventory of its older products off store shelves to reduce customer choice (unlike here, where no such conduct occurred or is even alleged). 432 F. Supp. 2d 408, 418, 421, 424-25, 426 (D. Del. 2006). The *Abbott* ruling has been criticized[49] and was not followed in the two most recent pharmaceutical "product switching" cases, which involved Prilosec.[50]

The Bureau's reliance on *Xerox Corp. v. Media Sciences Int'l, Inc.*, 511 F. Supp. 2d 372 (S.D.N.Y. 2007), is similarly misplaced. There, Media Sciences alleged that Xerox's sole purpose in redesigning its color printers and patenting the compatible replacement solid ink

[49] *See, e.g.*, Guy V. Amoresano, *Branded Drug Reformulation: The Next Brand vs. Generic Antitrust Battleground*, 62 Food & Drug L.J. 249, 253-56 (2007) (KO Ex. 27) (criticizing *Abbott* for following balancing test instead of *Berkey Photo*); M. Sean Royall et al., *Antitrust Scrutiny of Pharmaceutical "Product Hopping,"* 28 Antitrust 71, 74 (2013) (KO Ex. 28) ("Are courts or juries truly in a position to sit in judgment on the merits, including potential therapeutic benefits, of one FDA-approved drug formulation versus another?").

[50] *AstraZeneca AB v. Mylan Labs. Inc.*, 2010 WL 2079722, at *6 (S.D.N.Y. 2010) ("[T]he alleged conduct—introducing new products—is generally considered pro-competitive"); *Walgreen Co. v. AstraZeneca Pharms. L.P.*, 534 F. Supp. 2d 146, 151 (D.D.C. 2008) ("Courts . . . are not tasked with determining which product among several is superior. Those determinations are left to the marketplace.").

sticks was "wholly predatory," to exclude Media Sciences, the only other ink stick competitor, from the market. *Id.* In support, Media Sciences alleged that there was *no benefit* to the redesign because "the only benefit" to consumers of the redesigned printer channel was already being served by key plates in former models. *Id.* at 387. Here, the Bureau openly concedes, and undisputed evidence overwhelmingly shows, that taking one capsule of Namenda XR once a day has clear advantages over the older, twice-a-day Namenda IR. P.I. Mem. 16 (agreeing that "[s]ome patients may benefit from the ability of patients to take Namenda once a day instead of twice") (citing Lah ¶¶ 15, 22). Moreover, in *Xerox*, counterclaimant Media Sciences' product was rendered utterly useless by the product modification. 511 F. Supp. 2d at 381 ("One of two producers in the market will have been driven out and no competitors will be able to enter . . . ."). Here, the opposite is true. [redacted] when generics begin selling, [redacted]

The Bureau's other out-of-circuit cases are similarly distinguishable. *Glen Holly Entm't Inc. v. Tektronix Inc.*, involved an *agreement* by two competitors to discontinue the only competing product, unlike here, which involves single-firm conduct and several remaining competitive alternatives. 352 F.3d 367, 372 (9th Cir. 2003) ("The [district] court correctly noted also that the antitrust laws 'do not preclude any manufacturer from independently discontinuing a product line any more than they preclude a manufacturer from independently raising prices . . . .'"). *Free FreeHand Corp. v. Adobe Systems, Inc.* involved Adobe's acquisition of its only competitor in an alleged unlawful merger and its subsequent discontinuance of its competitor's product. 852 F. Supp. 2d 1171, 1182 (N.D. Cal. 2012). And *Microsoft* similarly does not support the Bureau's position because that case (unlike here) involved exclusive contracts, tying,

technical compatibility, or other conduct actually ***excluding*** and ***preventing*** competitors from competing. *United States v. Microsoft Corp.*, 253 F.3d 34, 64-67, 70-71 (D.C. Cir. 2001) (holding Microsoft violated Section 2 through "exclusive dealing contracts" and "integrating IE into Windows," which had "effect of significantly reducing usage of rivals' products").

4. The Marketplace Acceptance of Namenda XR Further Refutes Any Claim of Coercion or Anticompetitive Conduct

Berkey Photo and several other courts have made clear that marketplace acceptance of a new product eliminates any antitrust basis (novel to begin with) to challenge the transition to that product. *Berkey Photo*, 603 F.2d at 287 ("If a monopolist's products gain acceptance in the market, therefore, it is of no importance that a judge or jury may later regard them as inferior, so long as that success was not based on any form of coercion."); *Walgreen*, 534 F. Supp. 2d at 150-52 ("New products are not capable of affecting competitors' market share unless consumers prefer the new product, regardless of whether that product is superior, equivalent, or inferior to existing products."); Philip R. Areeda & Herbert Hovenkamp, 3 Antitrust Law § 706d at 164-66 (rev. ed. 1996) (advising that § 2 antitrust remedies should not be applied to monopolists who introduce new products under patents or, presumably, other official grants of exclusivity).

The "coercion" alleged by the Bureau cannot be shown where, as here, the marketplace has accepted the defendants' new product. [redacted] *See* Statement of Facts. [redacted] Hausman ¶¶ 7-10. Even before Forest Labs announced it was transitioning to Namenda XR, patients were converting from IR tablets to XR at a rate of

15.3%. Hausman ¶ 14. [redacted]

Taglietti ¶ 10; Reisberg ¶ 2(e). These undisputed facts show not only marketplace acceptance of Namenda XR, but also Forest Labs' valid business reasons for changing its focus from its old, two tablet, twice-a-day product to the new, one capsule, once-a-day version. *See Berkey Photo*, 603 F.2d at 284 ("We accept the proposition that it is improper, *in the absence of a valid business policy*, for a firm with monopoly power in one market to gain a competitive advantage in another by refusing to sell a rival the monopolized goods or services he needs to compete effectively in the second market.") (emphasis added) (citing *Eastman Kodak Co. v. S. Photo Materials Co.*, 273 U.S. 359, 375 (1927)); *Xerox Corp.*, 511 F. Supp. 2d at 389 ("Of course, if Xerox presents evidence that the modifications improved the product *or otherwise served valid business reasons*, then the Court or a jury may have to weigh these justifications against the alleged anticompetitive effect.") (emphasis added); *Corsearch, Inc. v. Thomson & Thomson*, 792 F. Supp. 305, 329 (S.D.N.Y. 1992) (finding that the president of the defendant company articulated "*valid business reasons* for termination of Corsearch and other resellers, thus meeting the test applied in *Berkey* and *Aspen*") (emphasis added).

A similar situation involving a business decision based on market data to discontinue one product in favor of another is found in *Kraft Gen. Foods, Inc.* In that case, the court denied the State's request for an injunction that would have prohibited defendant from discontinuing a cereal brand. 1993 WL 302644, at *1 (S.D.N.Y. July 30, 1993). The court denied the injunction for lack of irreparable harm and opined that Nabisco "might reasonably decide that it would maximize its overall RTE cereal sales by discontinuing sales of unpopular brands, and concentrating its resources on maximizing sales of the more popular Nabisco brands." *Id.* at *3.

The court further observed:

> The value of the Nabisco RTE cereals is best preserved by permitting Kraft to pursue a marketing strategy that maximizes the sale of Nabisco RTE cereals generally, rather than by forcing Kraft to continue to promote and sell unpopular brands solely to preserve the possibility of transferring to a new entrant the Nabisco RTE cereal business exactly as it existed on November 12, 1992 . . . .

Id. Like the defendant in *Kraft*, Forest Labs had valid business reasons for its previously announced plan to discontinue Namenda IR tablets so that it may instead focus on producing its new and patient-preferred product, Namenda XR.

5. The Bureau's Proposed Product Market Is Fatally Deficient

The Bureau's alleged single-molecule product market is implausible and unsupported by the facts. *See White Directory of Rochester, Inc. v. Rochester Tel. Corp.*, 714 F. Supp. 65, 69 (W.D.N.Y. 1989) (denying injunction where court could not reasonably determine relevant product market). The relevant product market is the "area of effective competition." *Tampa Elec. Co. v. Nashville Coal Co*, 365 U.S. 320, 327-28 (1961). If the defendant does not have monopoly power in a "relevant product market," then the plaintiff cannot prove a Section 2 violation. *United States v. E. I. DuPont de Nemours & Co.*, 351 U.S. 377, 394 (1956). The relevant market is defined by "the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962). In defining the product market, the court should consider "such practical indicia as industry or public recognition of the submarket as a separate economic entity." *Id*. Products in the same market "need not be identical" and can be used concomitantly. *AD/SAT, Div. of Skylight, Inc. v. Associated Press,* 181 F.3d 216, 227 (2d Cir. 1996) (citing *DuPont*, 351 U.S. at 404). Courts reject overly narrow product markets gerrymandered to suit a plaintiff's case. *See, e.g.*, *City of New York v. Grp. Health*, 649 F.3d 156 (2d Cir. 2011) (finding alleged

market "legally insufficient because it [was] defined by the [plaintiff's] preferences").

Courts are skeptical of "single-molecule" product markets. *See, e.g.*, *Bayer Schering Pharma v. Sandoz, Inc.*, 813 F. Supp. 2d 569, 576 (S.D.N.Y. 2011) (rejecting single-molecule market because "'proposed market makes no rational or economic sense and is far too narrow'"); *Am. Sales Co. v. AstraZeneca*, 2011 WL 1465786, at *4 (S.D.N.Y. Apr. 14, 2011) (dismissing monopolization claim with "single anti-heartburn drug" product market); *Ally Gargano/MCA Adver., Ltd. v. Cooke Properties, Inc.*, 1989 WL 126066, at *21 (S.D.N.Y. Oct. 13, 1989) (Sweet, J.) ("Few are the instances in which products and services have attributes so unique that the relevant market can reasonably be restricted to the output of a single producer.").

The Bureau proposes a single-molecule, memantine hydrochloride market (*i.e.*, ***only*** Namenda IR and Namenda XR), improperly excluding cholinesterase inhibitors ("CIs") that also treat Alzheimer's patients and compete with Namenda IR and Namenda XR. Compl. ¶¶ 46, 49. The Bureau's own Dr. Lah confirms that memantine and CIs belong to the same category as being symptomatic Alzheimer's treatments. Lah Dep. 282:14-283:12; 250:15-251:13 (KO Ex. 2). IMS data confirms industry recognition of memantine and CIs in the same market. *See* Cremieux ¶ 44; *see also id.* ¶ 45 (IMS places Namenda and CIs Aricept, Razadyne, and Exelon in "Alzheimer's Drug Market"). Doctors often prescribe memantine and CIs for their patients as therapeutic alternatives, and demand for memantine ***changes*** based on the price of CIs. Cremieux ¶¶ 44-45. Thus, the Bureau's proposed single-molecule memantine hydrochloride product market "makes no rational or economic sense." *Bayer Schering*, 813 F. Supp. 2d at 576.

When the product market is properly drawn to include other symptomatic Alzheimer's treatments, Namenda IR and Namenda XR together [redacted] Meury ¶ 30, and Forest Labs' purported monopoly power disappears. *See*

Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 26-27 (1984) (holding that 70% share does not "generate the kind of market power that justifies condemnation of tying"); *United States v. Aluminum Co. of Am.*, 148 F.2d 416, 424 (2d Cir. 1945) ("[I]t is doubtful whether sixty or sixty-four percent would be enough, and certainly thirty-three per cent is not."); *see also* MTD Mem. 12 (low barriers to entry weigh against even attempted monopolization claim).

C. The Balance of Harms Weighs in Favor of Forest Labs

The balance of harms in this case weighs heavily against an injunction that would force Forest Labs to manufacture and sell its older product to assist its competitors. As described above, the Bureau fails to show harm to consumers—there are only benefits—or cognizable harm to generic competitors. *See* Section II.A. On the other hand, as a result of the injunction, Forest Labs would face harm that "would not be trivial." *Clauson v. Eslinger*, 455 F. Supp. 2d 256, 259-60 (S.D.N.Y. 2006) (denying mandatory injunction). Courts have denied preliminary injunctions where, as here, the defendant had invested considerable resources in developing and marketing a new product. *See, e.g.*, *Kind LLC v. Clif Bar & Co.*, 2014 WL 2619817, at *13 (S.D.N.Y. June 12, 2014) (balance of hardships favored defendant, which had invested approximately $13.9 million in its new products); *Becoming, Inc. v. Avon Prods., Inc.*, 2001 WL 930794, at *10 n.10 (S.D.N.Y. Aug. 15, 2001) ("Defendant has expended a substantial amount of money in developing its . . . product line, and it stands to lose a significant amount if the launch is delayed. This harm is far greater than any that Plaintiff will suffer . . . ."); *Programmed Tax Sys., Inc. v. Raytheon Co.*, 419 F. Supp. 1251, 1255 (S.D.N.Y. 1976) (balance of hardships "tips decidedly toward the defendant" where defendant invested more than $1 million advertising its product and would "lose the customer recognition it ha[d] built" if preliminary injunction were ordered). Forcing Forest Labs to manufacture and sell its older IR product would cost Forest

Labs a substantial amount of the revenue to which it is entitled after R&D, manufacture, and launch of its new, improved product, once-daily Namenda XR. Taglietti ¶ 11; Meury ¶ 8.

In addition, the expansive injunction the Bureau seeks would force Forest Labs to incur untold new costs and require it to dedicate unplanned resources (including manpower, materials, and capital) to manufacture and sell Namenda IR tablets. The precise amount of these costs cannot even be quantified given the unspecified nature of the injunction sought.

Finally, the Bureau asserts that it benefits from a presumption that it acts in the public interest. P.I. Mem. 44 (citing *Register.com, Inc. v. Verio, Inc.*, 356 F.3d 393, 424 (2d Cir. 2004)). The sole authority cited by the Bureau on this point, a draft opinion attached as an appendix to the majority ruling in *Register.com*, states only that the presumption applies when a private plaintiff attempts to *enjoin government action*. *Register.com*, 356 F.3d at 424. The public interest is served by denying the injunction here and preserving the right of innovators to invest in new products, exercise their lawfully obtained patent and regulatory exclusivities as they wish, and manufacture and sell their products "whenever and however [they] choose[]." *Berkey Photo*, 603 F.2d at 286.

CONCLUSION

For the foregoing reasons, Defendants request that this Court deny the Bureau's motion for a preliminary injunction.

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Respectfully submitted,

/s/ J. Mark Gidley

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