UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK	:	
by and through ERIC T. SCHNEIDERMAN, Attorney General,	:	**Case No.: 14-CV-7473 (RWS)**
Plaintiff,	:	**FILED UNDER SEAL**
v.	:	
ACTAVIS, PLC, and	:	
FOREST LABORATORIES, LLC.,	:	
Defendants.	:	

NEW YORK'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR PRELIMINARY INJUNCTION

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Plaintiff the State of New York, by its Attorney General, Eric T. Schneiderman, submits this memorandum of law in support of its Motion for a Preliminary Injunction against Defendants Actavis, plc ("Actavis") and Forest Laboratories, LLC ("Forest") (together "Defendants"), to enjoin them from discontinuing or otherwise restricting the availability of Defendants' drug Namenda until final resolution of this litigation, and requiring them to promptly notify physicians, caregivers and the public of any such order.

PRELIMINARY STATEMENT

The Attorney General of the State of New York brings this antitrust action to prevent Defendants from manipulating the pharmaceutical regulatory system and interfering with the treatment of Alzheimer's patients, all in an effort to unlawfully extend their monopoly and maintain inflated profits. The tactic that the Defendants seek to employ is what industry insiders (including Defendants' CEO)[1] call a "forced switch." In a forced switch, a pharmaceutical company that sells a drug facing imminent generic competition withdraws its drug from the market, forcing patients taking the drug to switch to a different form of the drug that has later-expiring patents—thus impeding the entry of lower cost generic drugs.

Defendants' scheme will cause irreparable harm. Alzheimer's patients will suffer needless disruption in their treatment plans. These same patients and other participants in the healthcare system, including the taxpayer-supported Medicare and Medicaid programs, will be saddled with significantly increased drug costs. These higher costs, of course, will translate into a windfall of hundreds of millions of dollars of extra profits for Defendants, which Defendants' CEO has publicly admitted is the reason for the forced-switch scheme.

[1] *See* Transcript of Jan. 21, 2014 earnings call, attached as Exhibit 1 to the Declaration of Saami Zain in Support of Plaintiff's Motion for Preliminary Injunction [hereinafter Zain Decl.], dated September [25], 2014 ("We believe that by potentially doing a forced switch, we will hold on to a large share of our base users . . .").

The drug involved here is Defendants' blockbuster drug for Alzheimer's disease, Namenda, Forest's most profitable drug since 2012 with sales of over $1 billion last year. Namenda will face lower-cost generic competition beginning in July 2015. But, rather than allowing patients with Alzheimer's disease to continue taking Namenda and switch to the less-expensive generic version when it becomes available, as contemplated by federal and state laws, Defendants instead hatched a scheme to interfere with that competition. Defendants' strategy is to discontinue or severely restrict patient access to Namenda before the entry of generic Namenda, to force patients to switch to Defendants' newer, virtually identical, extended-release version of Namenda, called Namenda XR. Once patients have switched to Namenda XR, the market for the lower-cost generic Namenda will be destroyed because of, in the Defendants' CEO's own words, the "barriers or obstacles"[2] that Defendants' strategy creates for generic competition. Because Namenda XR is protected from competition by patents for years longer than the original Namenda, Defendants intend to use the "forced switch" to reap many more years of monopoly profits than they would have earned otherwise.

Plaintiff New York satisfies all of the requirements for a preliminary injunction. To begin with, New York is likely to succeed on the merits of its claims. A claim of unlawful monopolization requires proof of monopoly power, plus the use of improper, exclusionary conduct to maintain it. Here, both elements are met. First, Defendants have monopoly power in the market for a class of drugs called NMDA antagonists, which currently includes only Namenda and Namenda XR. There are no other drugs that are reasonable substitutes for NMDA antagonists. In fact, the only other drug class approved to treat Alzheimer's patients is typically used *together* with Namenda, *i.e.*, the drugs are complements, not substitutes. Second,

[2] *See* Transcript of Jan. 7, 2014 analyst call at FRX-NY-01642564, attached as Zain Decl. Ex. 2.

Defendants' "forced switch"— to be accomplished by effectively withdrawing Namenda from the market without a legitimate business justification—constitutes unlawful exclusionary conduct. Exclusionary conduct is "conduct without a legitimate business purpose that makes sense only because it eliminates competition." *In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 133 (2d Cir. 2014) (internal citations omitted). Exclusionary conduct includes a product withdrawal that harms competition and has no procompetitive justification. *See, e.g.*, *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006).

The facts show that Defendants' forced switch significantly harms competition, and has no procompetitive justification. By forcing all patients taking Namenda to switch to Namenda XR before generic Namenda becomes available, Defendants' strategy creates "barriers or obstacles" that will devastate the ability of generic drugs to compete. In particular, the strategy effectively prevents sellers of generic Namenda from engaging in price competition at the pharmacy because pharmacists cannot automatically substitute lower-cost generic drugs for Namenda XR.

Forest has no plausible procompetitive business rationale for withdrawing its top-selling drug from the market. The strategy only makes sense as part of an effort to game the regulatory system and thwart competition from lower-cost generics. Indeed, in the short term, the withdrawal makes no business sense because it will cause significant lost sales to the business when some patients simply stop taking Namenda rather than switching to XR, leaving Defendants with fewer sales than they had before. Defendants, of course, are not concerned. They know that their scheme is profitable in the longer term because it will enable them to realize monopoly profits from their Namenda drugs for many years longer than they would have otherwise.

New York is likely to succeed on the merits of its claims at trial, but because the balance of hardships in this case tips so decidedly in favor of New York and the public, an injunction would be warranted even if New York merely showed "serious questions going to the merits to make them a fair ground for litigation." *Citigroup Global Mkts., Inc. v. VCG Special Opportunities Master Fund, Ltd.*, 598 F.3d 30, 35 (2d Cir. 2010) (internal citations omitted).

The balance of hardships in this case could not be more lopsided. If no injunction issues and Defendants withdraw Namenda from the market, then patients, others who pay health insurance premiums, and taxpayers will suffer significant and irreparable harm. Patients taking Namenda will be forced to switch drugs against their doctors' best judgment, disrupting the treatment plans of these highly vulnerable patients. Once generics are available, the "barriers" that Defendants' plan creates for generic competitors mean that patients are not likely to switch back—and, moreover, if they did then they would need to bear yet another treatment disruption. The vast majority of patients who do not switch back will have to bear the higher co-pays that apply to branded drugs. [redacted] And once the market is switched to Namenda XR, the opportunity for effective generic entry is lost for good, raising drug costs for government and commercial health plans that are ultimately passed on to consumers in the form of higher premiums and taxes.

In contrast to the hardship faced by the public, in the event of an injunction the Defendants will face no "hardship" at all. Defendants will merely have to continue to sell a blockbuster drug that they have already been selling for more than ten years—at monopoly prices and at a massive profit—for just a few more months. After generics enter and continuity

of supply for patients is guaranteed, Defendants would be free to withdraw Namenda from the market.

The public interest clearly favors an injunction. If Defendants are permitted to implement their illegal scheme to exclude generic competition, they will defeat the purpose of the key legislative compromises underlying federal and state laws governing generic competition—which grant brand name drug companies more than a decade of exclusivity, in return for quick and effective entry by generic drugs at the conclusion of the exclusivity period. Defendants are taking full advantage of the former while showing disdain for the latter. The public interest requires that Defendants' efforts to game the carefully designed legislative scheme to promote effective competition between branded and generic drugs be stopped.

STATEMENT OF FACTS

I. THE REGULATORY FRAMEWORK GOVERNING PHARMACEUTICAL COMPETITION AND ITS VULNERABILITY TO MANIPULATION

A. The Regulatory Framework

The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), governs the manufacturing, sale and marketing of pharmaceuticals in the United States. Pursuant to the FDCA, a company seeking to bring a new drug to market must submit a New Drug Application ("NDA") with the Food and Drug Administration ("FDA") and provide scientific data demonstrating that the drug is safe and effective. *See* 21 U.S.C § 355(b)(1). The process for obtaining FDA approval of an NDA can be costly and time consuming.

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch–Waxman Act, which was intended to facilitate competition from lower-priced generic drugs while also providing further incentives for pharmaceutical companies to invest in new drugs. *See, e.g.*, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S.Ct.

1670, 1676 (2012) (The Hatch-Waxman "process is designed to speed the introduction of low-cost generic drugs to market) (internal citations omitted). By creating benefits and incentives for both generic and branded pharmaceutical manufacturers, the Act attempts to balance the competing policy goals of encouraging innovation and expediting patient access to less expensive generic versions of more costly branded drugs. *See* H.R. Rep. No. 98-857, Pt. 1, p. 14–17 (1984).

Under the Act, a company seeking to market a generic version of a drug that has an NDA may obtain FDA approval by filing an Abbreviated New Drug Application ("ANDA"), and demonstrating its generic version is "bioequivalent" to the drug already approved. By permitting the generic to rely on studies submitted by the NDA applicant (i.e., branded drug manufacturer), the Act reduces development costs and speeds up FDA approval for generics.

As part of the legislative compromise underlying the Act and its amendments, the Act includes several provisions that grant branded drug manufacturers opportunities to lengthen the exclusivity period beyond the twenty-year patent term. For example, the Act allows a branded drug manufacturer to seek up to a five-year patent extension to compensate for time lost during the FDA regulatory approval process.[3] In addition, a branded manufacturer may obtain an additional six months of "pediatric exclusivity" after the expiration of the life of its patent, if the manufacturer conducts pediatric studies of its drug that meet certain requirements.[4]

A comprehensive set of state generic substitution laws also govern generic drug competition. Most states have generic drug substitution laws that allow—or require—a pharmacist filling a prescription for a branded drug to substitute a less-expensive, therapeutically

[3] *See* 35 U.S.C § 156.
[4] *See, e.g.*, 35 U.S.C. § 156; 21 U.S.C. § 355a.

equivalent generic drug, unless a physician directs otherwise.[5] State substitution laws are a critical element in facilitating lower-cost generic competition because they allow a pharmacist to provide a patient with a lower-cost generic drug without contacting the doctor to change the prescription. These laws thus enable generics to compete on price at the pharmacy and, if they offer lower prices, take business from higher-priced brands.[6] *See* Declaration of David F. Stitt, R.Ph.[7] ¶ 21. This competition results in vastly reduced drug costs for patients and health plans after generic entry—and still provides patients with the same therapeutic benefits as the brand.

Price competition at the pharmacy, facilitated by state generic substitution laws, is the principal means by which generics are able to compete in the United States. *See* FTC Amicus Br. 6-7; *see also* Stitt Decl. ¶ 22 ("[T]he substitution of AB-rated generic drugs for the branded equivalents, through the applicability of state generic substitution laws, is the only method by which generic drugs achieve significant sales.").

An important limitation of generic substitution laws is that they generally permit a pharmacist to dispense a less-expensive generic drug instead of the branded drug only if the FDA approves the generic drug as "AB-rated" to the branded drug. *See Abbott Labs.*, 432 F. Supp. 2d at 415; Stitt Decl. ¶ 21. To be "AB-rated" to a branded drug, the generic drug must not only have the same active ingredient, but also the same form, dosage, strength, and safety and efficacy profile.[8] This requirement, while intended to ensure therapeutic equivalence to the branded drug,

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[5] *See, e.g.*, N.Y. Educ. Law. § 6816-a.
[6] *See* Brief for Federal Trade Commission as Amicus Curiae at 6–7, *Mylan Pharms., Inc., v. Warner Chilcott Pub. Ltd. Co.*, No. 2:12-cv-03824-PD (E.D. Pa. Dec. 13, 2012) [hereinafter FTC Amicus Br.], attached as Zain Decl. Ex. 3; Brief for Intellectual Prop. & Antitrust Law Professors as Amici Curiae at 8, *Mylan Pharms., Inc., v. Warner Chilcott Pub. Ltd. Co.*, No. 2:12-cv-03824-PD (E.D. Pa. May 7, 2014) [hereinafter Professors' Amicus Br.], attached as Zain Decl. Ex. 4.
[7] David F. Stitt has been a registered pharmacist in New York since 1976 and is Director of Pharmacy at MVP Health Care. *See* Stitt Decl. ¶¶ 1–3.
[8] *See* U.S. Food & Drug Admin., Approved Drug Products with Therapeutic Equivalence Evaluations, Preface (32d ed. 2012), attached as Zain Decl. Ex. 5.

provides an opportunity for branded manufacturers to game the system. For example, if a brand manufacturer tweaks its branded drug in even a minor way, e.g., switching from tablet to capsule, it can prevent a generic drug from being AB-rated to the reformulated branded drug, thereby preventing the pharmacist from dispensing the generic in place of the reformulated drug (unless he asks the doctor for a new prescription). This strategy can be used by a brand manufacturer to create an obstacle to the ability of generics to compete on price, defeating the intent of the legislative scheme governing drug competition, and impeding the use of lower cost generic drugs.[9]

B. Efforts by Brand Manufacturers to Game the System to Impede Generic Entry

Generic drugs are usually priced substantially below their brand-name drug equivalents. According to an FDA study using average retail drug prices between 1999 and 2004, entry of multiple generic competitors can reduce prices to as little as 20% of the branded price—in other words, an 80% discount.[10] According to a 2013 study commissioned by the Generic Pharmaceutical Association, over the 10-year period 2003 through 2012, generic drug use has generated more than $1.2 trillion in savings to the U.S. health care system.[11]

Once exclusivity is lost and generic entry occurs, the brand name manufacturer can expect a sharp drop in revenue, as it must choose between either competing by significantly lowering prices or accepting dramatically lower sales volume. This event is sometimes referred to as the "patent cliff." Typically, as a result of price competition at the pharmacy facilitated by generic substitution laws, most consumers switch from the branded drug to the AB-rated generic

[9] *See* Rebecca S. Yoshitani & Ellen S. Cooper, *Pharmaceutical Reformulation: The Growth of Life Cycle Management*, 7 Hous. J. Health L. & Pol'y, 379, 389–405 (2007) (reformulation approaches include changing a drug's molecular structure, using a new delivery method, or finding a new method of use).
[10] U.S. Food & Drug Admin., Generic Competition and Drug Prices, attached as Zain Decl. Ex. 6.
[11] Generic Pharm. Ass'n, Generic Drug Savings in the U.S. at 1 (2013), attached as Zain Decl. Ex. 7. In 2012 alone, generic drugs saved the health system $217 billion. *Id.*

drug upon its introduction into the market. *See* Stitt Decl. ¶ 21. When the branded manufacturer's exclusivity ends and multiple generics enter the market (as would be the case here), a branded drug often loses more than 80% of its market share within six months.[12]

This tradeoff of longer exclusivity rights for branded manufacturers, in return for quick and effective generic entry after loss of exclusivity, is the fundamental premise behind the policies and procedures that Congress enacted in the Hatch–Waxman Act, and which the states embraced in their generic substitution laws.

Nevertheless, confronted with an imminent loss of profits, pharmaceutical companies often seek to blunt the impact of generic competition. One method, which was the subject of a recent Supreme Court case involving one of the Defendants here, is to enter into anticompetitive patent settlements with generic manufacturers that include payments to the generic firm in return for an agreement to delay generic entry. *FTC v. Actavis*, 133 S. Ct. 2223 (2013).

A second strategy increasingly pursued by pharmaceutical companies (and relevant here) is a "product extension" strategy.[13] For a drug that is about to go-off patent and descend the "patent cliff," the firm develops a "follow-on" version of the drug with a later patent expiration, and encourages patients and their physicians to switch to the new version. As explained above, because the generic of the original version of the drug will not be "AB-rated" to the "revised" branded drug, if physicians write prescriptions for the new version instead of the original then

[12] The Use of Medicines in the United States: Review of 2010 at 3 (2011), attached as Zain Decl. Ex. 8 ("Over 80% of a brand's prescription volume is replaced by generics within six months of patent loss").
[13] *See, e.g.*, *Abbott Labs*, 432 F. Supp. 2d 408 (branded drug company completing switches to new drug formulations in a manner strategically timed to thwart imminent generic competition); Michael Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 Fl. L. Rev. 1009, 1016 (2010) (using the term "line extension").

generic entry will be thwarted—even if, in practice, the cost savings offered by the generic far outweigh any advantage offered by the new version of the branded drug.[14]

Sometimes, these follow-on drugs may be truly better than the original version. In other instances, the new drugs offer little to no therapeutic advantage over the prior formulation, and the reformulation is merely an attempt to game the regulatory system and interfere with effective price competition between branded and generic drugs at the pharmacy.[15] Efforts to switch patients to a follow-on drug with little-to-no clinical benefit—solely for the purpose of interfering with generic competition and extending the monopoly life of a drug franchise—is sometimes referred to as "product hopping." *See, e.g.*, Professors' Amicus Br. 3–4.

Product hopping usually involves making a minor, non-therapeutic reformulation to a branded drug such as a change in form or dosage.[16] Then, the brand manufacturer takes steps to move patients from the original product to the reformulated one before generic entry. *Id.* The rewards for this strategy can be massive. As explained above, because the generic version of the original drug is not AB-rated to the reformulated product, state substitution laws will not allow the pharmacist to substitute the lower-cost generic for the reformulated one. Due to barriers that prevent effective competition between generics and branded drugs at the pharmacy when state generic substitution laws do not act to facilitate substitution, the branded firm will avoid—or dramatically reduce—the "patent cliff."[17] And once a brand manufacturer has successfully achieved a switch to a follow-on product, it can expect that most "switched" patients will not make a second switch back to the original product. *See* Argument Section II(B)(2), *infra*.

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[14] *See* Carrier, *supra* note 13, at 1018.
[15] *See* Professors' Amicus Br. 7; FTC Amicus Br. 9
[16] *See* Carrier, *supra* note 13, at 1016–17; Professors' Amicus Br. 3–4.
[17] *See* FTC Amicus Br. 9 ("As a practical matter, if a generic cannot be substituted at the pharmacy counter, the economically meaningful market for the generic product disappears.").

There are various tactics that a branded manufacturer may use to encourage physicians and patients to switch to its new follow-on drug. Commonly, the company will aggressively promote the follow-on drug and remove marketing effort behind the original drug.[18] The company typically will advocate to physicians that the new product is superior and should be prescribed instead of the original.[19] At the extreme end of the spectrum, the company may seek to *force* physicians and patients to make the switch. *See, e.g.*, *Abbott Labs.*, 432 F. Supp. 2d at 424 (denying motion to dismiss where branded manufacturer engaged in forced switch by, *inter alia*, removing previous versions of drug from market).

To effectively implement a product extension strategy, it is critical to switch patients to the new drug before a generic form of the original drug enters the market. Accomplishing the switch at this time ensures that the generics have no opportunity to compete for the switched patients by means of the mechanisms provided for by generic substitution laws. If the brand is successful in completing the switch prior to generic entry, generic competition is likely to be thwarted.[20] At that point, as explained by the FTC, "[t]he generic's only practical option is to go back to the drawing board and reformulate its own product to be bioequivalent to the brand reformulation and thus substitutable at the pharmacy." *Id.* And even this strategy may or may not be feasible—among other things, obtaining FDA approval for a "revised" generic drug may take significant time,[21] or the reformulated drug may have later-expiring patents that prevent a revised generic drug from being sold (as is the case here).

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[18] *See, e.g.*, *Walgreen Co. v. AstraZeneca Pharms. L.P.*, 534 F. Supp. 2d 146, 151–52 (D.D.C. 2008); Carrier, *supra* note 13, at 1025–27.
[19] Steve D. Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 Rutgers L.J. 1, 44 (2009).
[20] Stitt Decl. ¶¶ 37–39; FTC Amicus Br. 10.
[21] *See Abbott Labs.*, 432 F. Supp. 2d 408.

If generics enter the market before the "product switch" occurs, then the branded manufacturer still has the ability to compete on the merits by seeking to convince patients and doctors that the clinical benefits (if there are any) of the reformulated drug justify the extra costs. However, its opportunity to block the primary mechanism of generic competition—drug substitution at the pharmacy facilitated by generic substitution laws—will have been lost. For this reason, branded manufacturers employing a product-extension strategy often engage in aggressive efforts in a race to switch as many patients as possible prior to generic entry.

II. DEFENDANTS' LAUNCH OF NAMENDA AND EFFORTS TO IMPEDE GENERIC COMPETITION

A. Forest Launches Namenda and Obtains Extensions of Its Exclusivity

Alzheimer's disease is an irreversible, progressive brain disease affecting over five million Americans. There is currently no cure. However, drug treatments can temporarily alleviate some symptoms or slow down their progression in some patients. *See* Declaration of James J. Lah, M.D., Ph.D.[22] ¶ 12. One key treatment is Defendants' drug Namenda.

On October 16, 2003, the FDA approved Namenda Instant Release Tablets ("Namenda" or "Namenda IR") for the treatment of moderate-to-severe Alzheimer's disease.[23] Defendants brought Namenda IR to market in January of 2004.[24] As is its right under the Hatch–Waxman Act, Forest sought and received a five-year patent extension to compensate for the time spent obtaining FDA approval for Namenda tablets. As a result, the '703 patent will expire on April 11, 2015. [25] And, on June 18, 2014, Forest announced that FDA had granted its request for

[22] Dr. James J. Lah is a Doctor and Associate Professor of Neurology at Emory University, whose research focuses on the care of patients with Alzheimer's. Lah Decl. ¶¶ 1–4.
[23] FDA Approval Letter, Application No. 21-487 from Robert Temple, Dir., Office of Drug Evaluation I, Ctr. for Drug Evaluation & Research, to Doreen V. Morgan, Forest Labs., Inc. (Oct. 16, 2003), attached as Zain Decl. Ex. 9.
[24] Press Release, Forest Labs., Inc., Namenda(TM) (memantine HCl), First Drug Approved For Treatment of Moderate to Severe Alzheimer's Disease Now Available Nationwide (Jan. 13, 2004), attached as Zain Decl. Ex. 10.
[25] *See* U.S. Patent and Trademark Office, Patent Term Extensions, attached as Zain Decl. Ex. 11.

pediatric exclusivity, extending Forest's exclusivity rights for another six months.[26] Numerous generic manufacturers have challenged its patents, however, and Forest settled these lawsuits under terms that allow generic manufacturers to enter the market in July 2015.[27]

B. Forest Develops a Product Extension Strategy and Launches Namenda XR

Although Forest took full advantage of the benefits under the Hatch–Waxman Act (and its amendments) that allowed it to extend the patent life of Namenda, the company was less enthusiastic about accepting the second part of the legislative compromise—quick and effective generic entry. It began to prepare for the inevitable patent cliff for Namenda (by 2012, its most profitable drug) by pursuing a "product extension" strategy to reduce the impact of generics.[28]

To successfully retain substantial sales for its Namenda franchise after generic entry, Forest would have to accomplish two objectives: introduce (or identify) a follow-on product with a later patent expiration *and* successfully switch a large number of patients to the new product. And, for the reasons explained above, Forest also realized that it would need to achieve these goals before the generic form of Namenda became available in the market.

Forest developed two new follow-on drugs with patent expiration dates later than those of the original version of Namenda ("Namenda IR"). It reformulated Namenda as a once-a-day extended-release capsule ("Namenda XR"). Namenda IR is taken twice a day. And it developed a combination product that would include both memantine and donepezil (a drug typically used together with Namenda). The patents that cover Namenda XR expire several years after those

[26] Press Release, Forest Labs., Inc., Forest Obtains Six Months U.S. Pediatric Exclusivity for NAMENDA® and NAMENDA XR® (June 18, 2014), attached as Zain Decl. Ex. 12.
[27] For additional detail, *see* Compl. ¶¶ 60–61.
[28] *See* Zain Decl. Exs. 13–16 (comparing analogous drugs to Namenda, including those in which a conversion strategy was pursued, in order to plan for patent cliff).

covering the original Namenda IR.[29] And the patents that cover the new combination drug expire even later than the Namenda XR patents.[30]

In June 2010, the FDA approved Namenda XR for the treatment of moderate-to-severe Alzheimer's; however, Defendants did not bring Namenda XR to market until July 21, 2013.[31] At that time, generic competition for Namenda IR was imminent and Namenda XR was needed to accomplish the product extension strategy. Both versions of Namenda are currently available.

C. Forest Makes Conversion of Namenda Patients to Namenda XR the Highest Priority for the Namenda Business

Consistent with its product extension strategy—i.e., its effort to extend the life of its Namenda franchise beyond the "patent cliff"—[redacted][32] Forest also realized that, to be successful, its product switch had to be accomplished before less expensive generic versions of Namenda IR ("generic Namenda" or "generic memantine") tablets became available in the market. This is because, as explained above, when generic memantine becomes available, there will be effective price competition between generic and branded Namenda at the pharmacy, and many patients who have prescriptions for Namenda IR after generic entry will likely switch to generic memantine.

However, if Forest could get patients, physicians, and insurers to switch to Namenda XR prior to the entry of generic memantine, then Forest would be able to prevent manufacturers of

[29] *See* U.S. Food & Drug Admin., Orange Book: Approve Drug Products with Therapeutic Equivalence Evaluations, attached as Zain Decl. Ex. 17.
[30] *See* Press Release, Forest Labs and Adamas Enter into Licensing Agreement for Development and Commercialization of Fixed Dosed Combination of Namenda XR and Donepezil, (Nov. 14, 2012), attached as Zain Decl. Ex. 18.
[31] *See* FDA Approval Letter, Application No. 22-525 from Russell Katz Dir., Div. of Neurology Prods., Office of Drug Evaluation I, Ctr. for Drug Evaluation & Research, to Michael P. Niebo, Forest Labs., Inc. (June 21, 2010), attached as Zain Decl. Ex. 19; Press Release, Forest Labs.., Inc., Forest Announces U.S. Availability of New Once-Daily NAMENDA XR (June 13, 2013), attached as Zain Decl. Ex. 20.
[32] *See* Argument Section II(B)(3), *infra*.

generic memantine from engaging in effective price competition for these patients. This is because generic memantine tablets will not be AB-rated to Namenda XR, and therefore a pharmacist will not be able to substitute lower-priced generic memantine for Namenda XR under state substitution laws.[33] By ensuring that generic manufacturers cannot engage in meaningful competition for the sales to the switched patients, Forest's strategy makes it much more likely that Forest will retain these sales once generic memantine becomes available.

Forest, therefore, made it a top priority to convert patients from Namenda IR to XR as quickly as possible. Forest heavily emphasized the importance of switching patients from Namenda IR to Namenda XR in internal documents, sales training, and public statements. In June of 2013, for example, an executive made a speech at a Namenda XR launch event:

[redacted]

Forest's internal documents also emphasize the importance of accomplishing its product switch in advance of the entry of generic memantine. [redacted][35] [redacted].[36] Defendants' CEO stated it clearly in a January analyst call: "We're very focused on our

[33] *See* Stitt Decl. ¶ 38.
[34] Zain Decl. Ex. 21 at FRX-NY-01573603-04. [redacted] Zain Decl. Ex. 22 at FRX-NY-01574212. Zain Decl. Ex. 23 at FRX-NY-01686842.
[36] Zain Decl. Ex. 24 at 4.

Namenda conversion . . . if you kind of look at the timing of IR, IR will go generic in July of 2015. And so the sweet spot for a switch would be in the fall, and so that's kind of how we're thinking about it."[37]

Since 2013, Defendants have undertaken an aggressive marketing campaign aimed at converting as many IR patients to XR as possible prior to Namenda IR losing exclusivity. [redacted][38] [redacted][39]

D. Forest Decides to *Force* Patients to Switch to Namenda XR

As Forest sought to accomplish the switch from IR to XR, [redacted]

Patients and their physicians are reluctant to switch from Namenda IR to Namenda XR for several reasons. *See* Lah Decl. ¶¶ 11, 22, 25. First, the benefits of a switch from Namenda IR to Namenda XR are marginal. *See* Lah Decl. ¶ 15 ("In my experience, compliance has not been a problem. A twice-daily regimen is easy to follow . . . ."). Some patients may benefit from the ability of patients to take Namenda once a day instead of twice, but this is a marginal benefit for most patients, especially those are already taking multiple medications. *See* Lah Decl. ¶¶ 15, 22.

[37] Zain Decl. Ex. 2.
[38] *See* Zain Decl. Ex. 25; Zain Decl. Ex 26 [redacted].
[39] Zain Decl. Ex. 23 at FRX-NY-01686845.
[40] *See* Zain Decl. Ex. 27 at FRX-NY-01618169–70.

Second, for many, if not most, patients (and their physicians), the benefits of the change of administration are outweighed by the risks of changing the medical routine of a highly vulnerable patient. As one physician explains:

> For Alzheimer's patients, stability is key: this is a very vulnerable group of patients. Any small change in medication raises the risk of an adverse effect. As Namenda is typically prescribed in the mid to later phases of Alzheimer's disease, the patients taking Namenda are at a stage in the disease when they are especially vulnerable. Even a small change in a patient's condition can require him or her to be moved to a care facility.

See Lah Decl. ¶ 24. Given the potential risks, without studies that show that a new medication has meaningful benefits over a patient's current medication, physicians frequently will not switch an Alzheimer's patient from a medicine on which they are doing well. *See id.* ¶ 25.

[redacted][41] Plainly, if physicians and patients had the choice, a large number of them would choose to stay on the original formulation. [redacted][42]

Accordingly, Forest began to consider whether it should *force* physicians and patients to switch to Namenda XR, whether they liked it or not. [redacted][43]

[41] *See* Zain Decl. Ex. 28 at FRX-NY-01566763.
[42] Zain Decl. Ex. 27 at FRX-NY-01618168.
[43] *See* Zain Decl. Exs. 13–16, *supra* note 28.

[redacted][45]

Forest has considered two approaches to the "forced switch": completely discontinuing Namenda, or "technically" leaving the drug on the market, but severely restricting patient access by engaging in what it calls "limited distribution." It has internally predicted that the real-world impact of both strategies is essentially the same. *Id.* In a presentation contained in an email between two executives dated June 26, 2013 and titled "Namenda IR to XR Conversion Project," the author notes that, with respect to Forest's conversion strategy, "[e]ither [a withdrawal or limited distribution] approach is unprecedented—would be operating in uncharted territory."[46] The presentation also notes that "Prescribers, patients, caregivers may be confused or dissatisfied with either withdrawal or limited distribution scenario and may choose to discontinue Namenda treatment." *Id.*

[redacted][47] In a January earnings call, its CEO,

[44] *See* Transcript of the Examination of William Meury at 280, attached as Zain Decl. Ex. 29.
[45] *See* Zain Decl. Ex. 30 at 28–31.
[46] Zain Decl. Ex. 31 at 4.
[47] Zain Decl. Ex. 32 at FRX-NY-01566920.

Brenton Saunders, explained that the purpose of the "forced switch" is to protect the company's Namenda revenues from declining too quickly after generic entry and the ensuing "patent cliff":

> [I]f we do the hard switch and we convert patients and caregivers to once-a-day therapy versus twice a day, it's very difficult for the generics then to reverse-commute back, at least with the existing Rxs. They don't have the sales force. They don't have the capabilities to go do that. It doesn't mean that it can't happen, it just becomes very difficult and is an obstacle that will allow us to, I think, again go into to a slow decline versus a complete cliff.[48]

E. Forest Commences Its Anticompetitive Scheme to Impede Generic Competition

On February 14, 2014, Forest began the "forced switch" by publicly announcing that it intended to discontinue Namenda IR tablets on August 15, 2014.[49] On the same day, Forest notified the FDA that it would "be discontinuing the sale of Namenda Tablets effective August 15, 2014."[50] Defendant also published open letters to physicians and caregivers on its website announcing its plans to discontinue Namenda IR and urging caregivers to speak with their loved ones' "healthcare provider[s] as soon as possible to discuss switching to NAMENDA XR."[51]

Forest also took an unusual step to make it more difficult for Namenda IR tablets to be sold to Medicare patients—the drug's largest customer base—by arranging the Center for Medicare and Medicaid Services ("CMS") to remove Namenda from its Formulary Reference File ("FRF").[52] On Feb. 5, 2014, a Forest employee wrote an email to the EVP for Sales stating:

> I propose that we have a letter to CMS and also place a call to the agency. We need to ask CMS to REMOVE [Namenda] IR from the Formulary Reference File. That way, the plans won't see it when they create their own formularies . . . .[53]

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[48] *See* Transcript of Jan. 21, 2014 earnings call, attached as Zain Decl. Ex. 1.
[49] *See* Press Release, Forest Labs., Inc., Forest Laboratories to Discontinue NAMENDA® Tablets, Focus on Once-Daily NAMENDA XR® (Feb. 14, 2014), attached as Zain Decl. Ex. 33.
[50] Zain Decl. Ex. 34.
[51] Zain Decl. Ex. 35–36.
[52] *See* Zain Decl. Ex. 37, 38.
[53] Zain Decl. Ex. 39 at FRX-NY-01596407.

The letter was approved and sent. If the drug is not on the FRF, health plans are less likely to include it in their formularies and, thus, many health plans may not cover Namenda tablets starting in January 2015. *See* Stitt Decl. ¶¶ 29–31.

On June 10, 2014, Forest announced that it was delaying the discontinuation of Namenda from August 15 to "the Fall of 2014."[54] As of the date of filing this motion, Defendants have not set a new firm date for discontinuing Namenda IR.

F. Defendants' Strategy Is a Moving Target

[redacted] Forest's website continues to represent to the public that it intends to discontinue Namenda IR. [redacted].[55] [redacted].[56] New York issued a subpoena for information on any changes in Forest's plans for Namenda, but has not received anything.

[54] *See* Press Release, Forest Labs., Inc., Forest Laboratories Announces Intention to Continue Marketing Both NAMENDA® TABLETS and Once-Daily NAMENDA XR® Into the Fall of 2014 (June 10, 2014), attached as Zain Decl. Ex. 40.
[55] *See* Transcript of the Examination of Mark Devlin at 150, 184, attached as Zain Decl. Ex. 41.
[56] *See* Transcript of the Examination of William Meury at 223–234, attached as Zain Decl. Ex. 29 [redacted]

New York should not need to guess at Forest's strategy. [redacted][57]

G. Expected Impact of Defendants' Conduct

Defendants' forced switch—whether implemented through discontinuance [redacted]—will result in dramatically increased profits for Defendants, and dramatically higher drug costs paid by insurers and patients who would otherwise have chosen the less expensive generic. *See* Stitt Decl. ¶ 36 (Defendants' forced switch will lead MVP to "incur

[57] *See* Zain Decl. Ex. 30 at 28–31; Zain Decl. Ex. 31 at 13-14; Defendants may also argue that they market a liquid form of Namenda IR that they do not intend to discontinue. They fail to disclose that the liquid form is difficult to administer, its dosing is less reliable, and it is rarely prescribed. *See* Lah Decl. ¶ 17–18. It cannot compensate for discontinuing the Namenda IR Tablet.

substantially higher costs for its member [sic]" and hurt patients who will end up paying higher co-pays for the brand). An executive at New York-based health plan MVP stated:

> I believe that if Actavis is permitted to accomplish the "forced switch" of patients from Namenda to Namenda XR, it will hurt patients, impose significant costs on MVP, and harm the economics of the health care delivery system. *Id.* ¶ 56

To date, more than 40% of existing patients have converted from Namenda IR to Namenda XR in anticipation of the lack of availability of Namenda IR.[58] The number of converted patients continues to increase as Defendants emphasize the imminent unavailability.

ARGUMENT

I. APPLICABLE LEGAL STANDARD

"The purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held." *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981). New York asks the Court to delay Defendants' planned discontinuation of (or any other restrictions on patients' access to) Namenda IR, thus preserving the status quo until the case reaches a final determination. A party seeking a preliminary injunction must show that he "is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. NRDC, Inc.*, 555 U.S. 7, 20 (2008). "A movant . . . need not show that success is an absolute certainty. He need only make a showing that the probability of his prevailing is better than fifty percent. There may remain considerable room for doubt." *Abdul Wali v. Coughlin*, 754 F.2d 1015, 1025 (2d Cir. 1985).

[58] *See* Press Release, Forest Labs., *supra* note 55, attached as Zain Decl. Ex. 40.

In the Second Circuit, if a balancing of the hardships tips decidedly in the plaintiff's favor, the plaintiff need only show that there is "a serious question going to the merits to make them a fair ground for trial." *Red Earth LLC v. United States*, 657 F.3d 138, 143 (2d Cir. 2011). New York meets the standards under either the "likely to succeed" test or the "serious question" test. Accordingly, this Court should grant the injunction.[59]

II. NEW YORK IS LIKELY TO PREVAIL ON THE MERITS

New York alleges that through the use of a forced switch, Defendants have violated Section 2 of the Sherman Act by unlawfully maintaining their monopoly in the market for NMDA antagonists—a class of drugs that includes only Namenda IR and Namenda XR. "The offense of monopoly under § 2 of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell*, 384 U.S. 563, 571 (1966)

A. Defendants Have Monopoly Power in the Market for NMDA Antagonists.

New York is likely to establish at trial that the relevant product market consists of NMDA antagonist drugs. A relevant market "is composed of products that have reasonable interchangeability for the purposes for which they are produced—price, use and qualities considered." *United States v. E. I. Du Pont de Nemours & Co.*, 351 U.S. 377, 404 (1956). A single product constitutes a relevant market where there are no reasonably interchangeable substitutes. *See Eastman Kodak Co. v. Image Tech. Servs.*, 504 U.S. 451, 481–82 (1992). In pharmaceutical markets, courts have held that a single drug and its generic substitutes can

[59] Plaintiff may seek an injunction under state and federal law. *See* N.Y. Exec. Law § 63(12); N.Y. Gen. Bus. Law § 342; *Georgia v. Pa. R.R. Co.*, 324 U.S. 439 (1945) (states may sue for injunctive relief under 15 U.S.C. § 26).

constitute a relevant market. *See, e.g., In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618 (E.D. Mich. 2000), *aff'd*, 332 F.3d 896 (6th Cir. 2003).

Currently, five drugs are approved to treat Alzheimer's disease: Aricept, Cognex, Exelon, Razadyne, and Namenda. *See* Lah Decl. ¶ 5. All except Namenda are acetylcholinesterase inhibitors ("AChEIs") and work in the same basic manner.[60] Namenda, however, is an NMDA antagonist and functions differently from AChEIs.[61] Currently, the various forms of Namenda are the only available NMDA antagonists. *Id.* ¶ 7. In practice, doctors commonly prescribe an AChEI first; Namenda is prescribed in addition to an AChEI or alone when the disease has progressed to a moderate stage and AChEIs become ineffective. Lah Decl. ¶ 10. There is little clinical support for the use of Namenda for early Alzheimer's patients.[62] Doctors do not consider AChEIs to be reasonable substitutes for Namenda. *See* Lah Decl. ¶ 7 ("To the best of my knowledge, there are not therapeutic substitutes for Namenda currently on the market") and ¶ 10 ("Almost all of my patients who take Namenda also take a CI [AChEI]. The two drugs are not interchangeable; rather, they seem to have the greatest beneficial effect when they are used together"). Instead, the two classes of drugs are complements: 70% of Namenda patients also take an AChEI.[63]

In addition, Defendants' own withdrawal strategy illustrates that AChEIs are not substitutes for NMDA antagonists such as Namenda IR. If they were, Forest's withdrawal of Namenda IR from the market would drive Namenda patients to AChEIs, many of which are

[60] *See* Lah Decl. ¶ 6. AChEIs reduce the breakdown in the brain of a chemical called acetylcholine, a chemical messenger that transmits information between nerve cells. *See id.*
[61] *See* Lah Decl. ¶ 7; Zain Decl. Ex. 23 at FRX-NY-01686843 ("AChEIs work on the acetylcholine pathway while Namenda works on the glutamate pathway."). Essentially, Namenda works to prevent the overstimulation of glutamate, an amino acid that excites nerves, and in excess, is a powerful nerve-cell killer. *See* Lah Decl. ¶ 8.
[62] *See* Press Release, Forest Labs., Inc., Forest Laboratories Announces FDA Decision on Supplemental New Drug Application for Namenda(R) (Jul. 25, 2005), attached as Zain Decl. Ex. 42. Some physicians may prescribe it earlier, however, for use in conjunction with an AChEI, since the drugs work well together. *See* Lah Decl. ¶ 10.
[63] Zain Decl. Ex. 23 at FRX-NY-01686842.

much less expensive than Namenda XR because they are available as generics. *See, e.g.*, *FTC v. Whole Foods Mkt., Inc.*, 533 F.3d 869, 880–81 (D.C. Cir. 2008) (conventional supermarkets are inadequate substitutes for natural/organic supermarkets). [redacted][64] Defendants do not predict that a significant fraction of Namenda users will switch to AChEIs in response to discontinuation—if they did, it would completely undermine the purpose underlying the "forced switch" strategy. [redacted].[65]

There is nothing unusual in pharmaceutical cases about an antitrust market limited to a single class of drugs (as here), or even a single drug. Courts regularly find a single brand-name drug and its generics to be a relevant product market in cases where the challenged conduct involves a branded drug manufacturer's effort to exclude generic competition. *See, e.g.*, *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 377–88 (D. Mass. 2013) ("The fact that other drugs may be used to treat heartburn and related conditions is immaterial to the present inquiry."); *Cardizem CD*, 105 F. Supp. 2d at 680–81; *see also In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1319 n.40 (S.D. Fl. 2005). Here, as in *Nexium* and *Cardizem CD*, the price or availability of AChEIs (or any other drug) will not be sufficient to counteract the effects of Defendants' efforts to exclude generic competition. Accordingly, NMDA antagonists—including Namenda IR, Namenda XR, and in the future any AB-rated

[64] *See* Zain Decl. Ex. 30 at 23.

[65] [redacted] Zain Decl. Ex. 14 at FRX-NY-01575875.

generics that may enter—constitute the relevant market. Defendants possess monopoly power in that market because they have a 100% market share, and because patents and other regulatory requirements are entry barriers for potential competitors.

B. Defendants' Forced Switch Constitutes Exclusionary Conduct

As explained below, by implementing plans to discontinue (or severely restrict patient access to) Namenda IR and accomplish a "forced switch," Defendants are illegally maintaining (or attempting to maintain) their monopoly power through the use of exclusionary, coercive conduct rather than through lawful competition on the merits.

This subsection is organized as follows. In Subsection 1, we explain the applicable standard for evaluating Defendants' conduct under the antitrust laws under the facts presented here. If a monopolist withdraws a product from the market it is "exclusionary" and not lawful "competition on the merits" if the conduct (1) harms competition, and (2) has no legitimate business justification (or the proffered justification is outweighed by the harm to competition). In Subsection 2, we explain why Defendants' conduct here harms competition. And in Subsection 3, we explain why Forest's withdrawal of its top selling product has no legitimate business justification, and in fact makes no economic sense but for its exclusionary effect on competition.

1. A Product Withdrawal by a Monopolist is Exclusionary if It Harms Competition, and Has No Business Justification (or an Inadequate One)

a. The General Rule in Evaluating Conduct Alleged to be Exclusionary

Conduct by a monopolist that serves no legitimate business goal, and is adopted solely to harm competition, is exclusionary. *See Adderall XR*, 754 F.3d at 133 (Anticompetitive conduct includes "conduct without a legitimate business purpose that makes sense only because it eliminates competition." (internal citations omitted)); *Trans Sport, Inc. v. Starter Sportswear,*

Inc., 964 F.2d 186, 188–89 (2d Cir. 1992); *In re IBM Peripheral EDP Devices Antitrust Litig.*, 481 F. Supp. 965, 1008 (N.D. Cal. 1979) ("The law need not tolerate deliberate acts where the only purpose and effect is to use monopoly power to gain a competitive advantage."). Moreover, a purported justification that is a mere pretext is not sufficient.

Because the legitimate business justification must outweigh the anticompetitive effect to avoid liability, proffering a minor, immaterial efficiency justification for conduct, the principal purpose and effect of which is to harm competition, will not render such conduct lawful. *See, e.g.*, *United States v. Microsoft Corp.*, 253 F.3d 34, 58–59, 64–66 (D.C. Cir. 2001); *Xerox Corp. v. Media Scis. Int'l., Inc.*, 511 F. Supp. 2d 372, 388–89 (S.D.N.Y. 2007); *Abbott Labs.*, 432 F. Supp. 2d at 422. Rather, in such cases, a court may find liability if the anticompetitive effects of the conduct outweigh the procompetitive benefits of the business justification.[66] *Id.*

b. A Monopolist's Withdrawal of a Product from the Market to Impair a Rival's Ability to Compete Constitutes Exclusionary Conduct

Defendants in antitrust cases frequently argue that a monopolist's decisions regarding what products to sell, and what not to sell, are subject to a special rule making them immune from the antitrust laws. But in cases like the current one—where a defendant is withdrawing its product from customers for the purposes of harming competition—the general rule that prohibits monopolists from engaging in conduct that harms competition, for no legitimate business purpose, applies with full force.

Numerous courts have examined efforts by a monopolist to exclude competition by switching customers to a newly-developed product, where the practical effect of such move is to

[66] Further, a monopolist may not proffer purportedly procompetitive goals for exclusionary conduct, where those goals could have been achieved by means that would had less harmful effects on competition. *See, e.g.*, *Trans Sport, Inc. v. Starter Sportswear, Inc.*, 964 F.2d at 188–89 (2d Cir. 1992) (conduct that furthers competition but "does so in an unnecessarily restrictive way" may be exclusionary).

undermine the ability of the monopolist's rivals to compete (typically, in such cases, the rivals' products are dependent on the monopolist's product in some way). The case law is justifiably cautious about subjecting a monopolist's decisions regarding what products to sell to antitrust liability. Thus, where a decision by a monopolist to change products is *not* coercive, and does *not* interfere with consumers' free choice of market alternatives, courts have found them to be lawful. In particular, several courts have held that if the monopolist leaves the old product on the market (and thus allows customers to choose which version they prefer), its development of a new product does not violate the antitrust laws. *See, e.g.*, *Berkey Photo v. Eastman Kodak*, 603 F.2d 263, 287 (2d Cir. 1978) (Kodak's switch of film technology was lawful where Kodak left prior version on market and thus "the free choice of consumers [was] preserved"); *Allied Orthopedic Appliances Inc. v. Tyco Health Care Group LP*, 592 F.3d 991, 1000 (9th Cir. 2010); *Walgreen*, 534 F. Supp. 2d at 152.

In contrast, the cases hold that where the monopolist's original product is *withdrawn* from the market—leaving customers with no choice but the new product—the conduct is properly scrutinized under the antitrust laws. *Berkey Photo*, 603 F.2d at 287 n.39 ("the situation might be completely different if, upon the introduction of the 110 system, Kodak had ceased producing film in the 126 size, thereby compelling camera purchasers to buy a Kodak 110 camera"); *Xerox*, 511 F. Supp. 2d at 387 (discontinuing and redesigning printer models "to foreclose all other competition [for replacement solid ink sticks] and not to improve the product" may be exclusionary); *Abbott Labs.*, 432 F. Supp. 2d at 422 (because "[d]efendants allegedly prevented [consumer] choice by removing the old formulations from the market while introducing new formulations . . . an inquiry into the effect of Defendants' formulation changes . . . is appropriate); *Glen Holly Entm't v. Tektronix Inc.*, 352 F.3d 367, 374 (9th Cir. 2003)

(reversing dismissal of plaintiff's antitrust claims when "discontinuation of the only competing product on the market [left consumers with no] viable choice between market alternatives.") (citation omitted)); *Free Freehand Corp. v. Adobe Sys.*, 852 F. Supp. 2d 1171, 1182 (N.D. Cal. 2012) ("[I]t is reasonable to infer that Adobe's discontinuation of FreeHand and channeling of FreeHand users to Illustrator made it more difficult for potential competitors of Illustrator . . . to enter the market ").

Accordingly, where a monopolist is engaged in a product switch that harms its rivals, it has two choices. It may leave both versions of the product on the market and let consumers make a non-coerced choice, as the courts found was the case in *Berkey Photo* and *Walgreen*—and avoid antitrust challenge. Or it can withdraw the original product from the market, and defend its conduct under the antitrust laws—in which case the withdrawal will be unlawful if a court determines that there is no legitimate business justification, that the proffered business justification is pretextual, or that the purported benefits are outweighed by the anticompetitive effects. *Abbott Labs*, 432 F. Supp. 2d at 422; *Xerox Corp. v. Media Scis. Int'l.*, 511 F. Supp. 2d at 388—89.

An analogous case is *Abbott Labs*, 432 F. Supp. 2d 408. *Abbott Labs* concerned a challenge to Abbott's repeated reformulations of its cholesterol drug TriCor (fenofibrate). Plaintiffs alleged that Abbott made successive, non-therapeutic reformulations to TriCor and then discontinued older formulations prior to generic versions of those formulations becoming available. *See id.* at 415–18. The plaintiffs contended that through these reformulations and discontinuations, Abbott improperly impeded generic competition by preventing state substitution laws from operating to facilitate generic competition between TriCor and AB-rated substitutes. *Id.* Abbott moved to dismiss on the grounds that its conduct was lawful, arguing

that "any product change that introduces an improvement, however minor, is *per se* legal under the antitrust laws." *Id.* at 420.

The court denied Abbott's motion, concluding that an evaluation of the anticompetitive effects and procompetitive justifications of the conduct was required. The court held:

> [H]ere, according to Plaintiffs, consumers were not presented with a choice between fenofibrate formulations. Instead, Defendants allegedly prevented such a choice by removing the old formulations from the market while introducing new formulations. Hence, an inquiry into the effect of Defendants' formulation changes . . . is justified.

Id. at 422.[67]

Similarly, in *Xerox*, 511 F. Supp. 2d 372, a competitor alleged that Xerox, the sole manufacturer of solid ink printers at the time, engaged in exclusionary conduct to prevent other companies from selling replacement solid ink sticks for these printers. *Id*. at 378. Acts alleged to be exclusionary included discontinuing and redesigning printer models "to foreclose all other competition [for replacement solid ink sticks] and not to improve the product." *Id*. at 387. The court denied Xerox's motion to dismiss, noting that "Xerox points to no case establishing a *per se* rule that modification and patenting of a product can never constitute prohibited anticompetitive conduct even if its purpose is entirely predatory and it reduces consumer options." *Id.* at 388.

Analogous conduct occurred in *Microsoft*, 253 F.3d 34, where Microsoft was found to have violated the antitrust laws by, *inter alia*, withdrawing features from its Windows operating system in an effort to disadvantage competing sellers of browsers. *See id.* at 64–66.

[67] One factor that distinguishes the instant case from disputes involving similar strategies by pharmaceutical manufacturers is that New York does not challenge Forest's decision to *introduce* Namenda XR. In cases challenging the product reformulation itself, the defendant frequently argues that it has a legitimate business justification because the reformulation results in a superior product. In contrast, here New York does not challenge Forest's introduction of Namenda XR. Therefore Defendants' business justifications for (and any supposed clinical benefits of) Namenda XR are *not* the issue. Rather New York challenges Defendants' decision to *withdraw* Namenda IR, its forced switching of patients and Defendants' lack of a business justification for these actions.

Specifically, the court held that Microsoft's elimination of its Internet Explorer (IE) browser from the "Add/Remove Programs" utility in Windows (which would have permitted a user to disable Internet Explorer)" was exclusionary and not justified by any pro-competitive benefits. *Id.* at 66–67.

c. The "Refusal to Deal" with a Competitor Cases

In contrast to the conduct in this case—which involves withdrawing a product from *customers*—there is a separate line of cases involving challenges to a monopolist's refusal to deal with *competitors*. Antitrust courts are reluctant to intervene in these cases. But even a refusal to engage in business directly with a competitor can violate the antitrust laws "when the purpose of such refusal is to maintain a monopoly." *See N.Y. Jets LLC v. Cablevision Sys. Corp.*, 2005 U.S. Dist. LEXIS 23763, at *27–28 (S.D.N.Y. Oct. 17, 2005) ("While Cablevision is generally free to engage in business or refuse to engage in business with whomever it chooses, it may not do so when the purpose of such refusal is to maintain a monopoly"); *see also* Hovenkamp, Janis, Lemley & Leslie, IP & Antitrust at § 15.3, at 15-79 (2d ed.) ("While monopolists have no general duty to help their competitors, they do have an obligation to refrain from acts that have no purpose or effect except to exclude competition.")

In *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985), the Court affirmed a jury verdict concluding that a company had monopolized the market for downhill skiing by ceasing to offer joint skiing passes and taking other actions that "made it extremely difficult for [the competitor] to market its own multi-area [ski] package to replace the joint offering." *Id.* at 593. The Court focused on defendant's "failure to offer any efficiency justification whatsoever" and that it was "willing to forgo daily ticket sales" to its rival—even at retail price—seemingly "because it was more interested in reducing competition." *Id.* at 608–09.

The decision in *Aspen Skiing*—which involved a refusal to deal directly with a competitor—is considered to be "at the outer boundary" of antitrust liability. *See, e.g.*, *Adderall XR*, 754 F.3d at 134 (citing *Verizon Communs., Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 409 (2004)). As explained by the Second Circuit in *Adderall XR*, a refusal to deal with a competitor will only be unlawful where it involves '"[t]he unilateral termination of a voluntary (*and thus presumably profitable*) course of dealing suggest[ing] a willingness to forsake short-term profits to achieve an anticompetitive end' and the refusal to renew the ticket '*even if compensated at retail price*.'" (*Adderall XR*, citing *Trinko*, 540 U.S. at 409 (emphases in original)). Although this case law does not apply to refusals to deal with *customers*, as is the case here, we also consider this standard below in evaluating Defendants' conduct.

In summary, under the applicable legal standards, Defendants' product withdrawal is unlawful if it (1) harms competition, and (2) does not have any non-pretextual, legitimate business justification (or any such justification is outweighed by the anticompetitive effect). In addition, if Defendants' product withdrawal were analyzed under the case law involving a refusal to deal with a competitor, it would be unlawful if it involved the termination of a pre-existing course of profitable dealing. The next two Sections explain why these standards are met here.

2. Defendants' Forced Switch Harms Competition Because It Substantially Impairs Effective Price Competition by Generics

Defendants' withdrawal of Namenda IR from the market is a manipulative ploy that will devastate generic competition by preventing the operation of generic substitution laws, creating obstacles to effective price competition at the pharmacy, and eliminating the only economically viable means by which manufacturers of generic memantine can compete. It circumvents the primary mechanism that the legislative scheme sets for competition between branded and generic drugs. As noted, generic substitution laws permit pharmacists to substitute lower cost,

therapeutically-equivalent generic drugs for their branded counterparts without the cost and burden of obtaining physician consent. FTC Amicus Br. 7.

In this case, Defendants' "forced switch" denies generic manufacturers the ability to take advantage of AB-rated substitution at the pharmacy, thus demolishing their competitive significance. By forcing all patients to switch to Namenda XR—a product for which generic Namenda is not AB-rated—Defendants neuter the generic substitution laws, by preventing pharmacists from offering patients taking Namenda a lower-priced generic. Instead, to make such a substitution, the pharmacist would need to contact the doctor.

For several reasons related to the unique nature of pharmaceutical competition, if pharmacists are not permitted to dispense a lower-priced generic instead of the brand without the need to obtain a new prescription from a doctor, generics are unlikely to be able to make substantial sales. *See* Stitt Decl. ¶ 22; Lah Decl. ¶ 32. This is due to information barriers and other market practices that are obstacles to effective generic competition absent application of generic substitution laws. *See Microsoft*, 253 F.3d at 64 (finding liability because although defendant "did not bar its rivals from all means of distribution, it did bar them from the cost-efficient ones."); *Abbott Labs*, 432 F. Supp. 2d at 423 (concluding that because generics "cannot provide generic substitutes for the current TriCor formulation, which is alleged to be their cost-efficient means of competing . . . [Defendants'] restriction on competition, if proven, is sufficient to support an antitrust claim). First, it is unlikely that most physicians, on their own, will react to higher prices for Namenda XR by prescribing generic memantine to patients who have already switched to XR. *See* Lah Decl. ¶¶ 31-32, 34. In addition to a desire to avoid unnecessary changes in medications, physicians lack a financial incentive. As the FTC explains: "The physician—who selects the drug product but does not pay for it—has little incentive to consider

price when deciding which drug to prescribe."[68] This is why generic substitution laws "are designed to address the disconnect in the industry between prescribing doctors, who are not directly responsive to drug pricing, and paying insurers and consumers, who do not directly select the prescribed drug."[69]

Second, generic manufacturers generally do not engage in direct marketing efforts to encourage physicians and patients to switch patient prescriptions. *See* Lah Decl. ¶ 32 ("I generally don't receive marketing from generic manufacturers, and would have to undertake my own effort to learn when a product like generic Namenda is about to become available."); Stitt Decl. ¶ 38 ("Generic drug manufacturers do not typically promote the availability of a new generic drug to patients or physicians."). It would make no economic sense for generic manufacturers to do so. Significant marketing expenditures by a generic manufacturer would likely increase the price of that manufacturer's drug, and would not necessarily lead to greater sales by that manufacturer. As explained by the FTC, marketing by a generic "does not guarantee the sale of that product when the patient goes to the pharmacy" because the "pharmacy may stock a different company's generic." *See* FTC Amicus Br. 9. As a result, there are typically no incentives for generics to engage in substantial marketing, and that would be the case here.

Moreover, requiring generics to engage in significant marketing would undermine the premise behind lower-cost generic drugs: that they will not be promoted in the same way as brand drugs. *See* FTC Amicus Br. 9 (marketing directly to physicians is "a costly undertaking [that would undermine] the ability of generic companies to offer the lower price benefits that the federal and state regulatory framework was intended to foster."); Professors' Amicus Br. 8.

[68] FTC Amicus Br. 6; *see also* Lah Decl. ¶ 32.
[69] Carrier, *supra* note 13, at 107; *see also* Stitt Decl. ¶ 38.

Third, while patients are concerned about price, they are frequently unaware that comparable, lower-cost generic drugs are on the market (and as noted, it is infeasible for generic manufacturers to market to them). *See* Lah Decl. ¶ 32 (patients rarely ask about generics); Stitt Decl. ¶ 22 ("In my experience, generic drugs are not generally marketed or detailed to physicians or patients."); *see also* Stitt Decl. ¶ 38 ("I have doubts as to whether many patients or physicians will even be aware when generic Namenda becomes available. Generic drug manufacturers do not typically promote the availability of a new generic drug to patients or physicians.")

Finally, while insurers may be aware of competing generics and motivated to encourage switching, they face substantial challenges in doing so. Even where they engage in substantial efforts to encourage patients to switch, these efforts are frequently very costly, and not always successful. *See* Stitt Decl. ¶¶ 17–20. Indeed, in this case, the Director of Pharmacy at MVP—a New York-based health plan—explains in his declaration why utilization management tools are not likely to be used to effectively switch most members taking Namenda XR to generic Namenda. *See* Stitt Decl. ¶¶ 42, 45–48. Among other things, once a patient begins taking a drug like Namenda XR, health plans such as MVP are very unlikely to pressure them to switch. *Id.*

Defendants' own words confirm their recognition that the forced switch will hobble generic competition. During Forest's January 21st earnings call, CEO Brenton Saunders explained the difficulties faced by generics in the face of his company's "hard" switch: "[I]f we do the hard switch . . . it's very difficult for the generics then to reverse-commute back . . . They don't have the sales force, they don't have the capabilities . . . . It is an obstacle . . . ."[70]

Similarly, another high-level Forest executive, considering the likelihood that patients converted to Namenda XR would switch back to Namenda IR, observed that "anyone converted

[70] *See* Transcript of Jan. 21, 2014 earnings call, attached as Zain Decl. Ex. 1.

[to Namenda XR] is likely to stay converted."[71] On January 7, 2014, CEO Brenton Saunders again explained Forest's ultimate goal: "What we're trying to do is put up barriers or obstacles to go from a cliff to a steady decline, right, a steady managed decline over four or five years versus in three months a $1.6 billion product is $200 million."[72] Thus, the forced switch was intended to and will harm competition.

3. Defendants Have No Legitimate Business Reason for Forcing Patients to Switch To Namenda XR.

Because Defendants have no legitimate business justification for the decision to withdraw Namenda IR from the market, the forced switch is exclusionary and not lawful competition on the merits. *See, e.g.*, *Microsoft*, 253 F.3d at 58–59, 65; *Media Scis.*, 511 F. Supp. 2d at 388–89. There is no element of Defendants' plan that benefits consumers. And, in fact, except for the impact on generic competition, there is nothing about it that seems to benefit Defendants. Rather, Forest's decision to withdraw its most profitable drug from the market—for no medical reason—makes no economic sense apart from its exclusionary effect. And the few alternative justifications proffered by Defendants are purely pretextual.

A simple review of the financial impact of withdrawing Namenda from the market illustrates the lack of any legitimate business justification. [redacted] This term masks the real-world harm to patients, and the resulting financial loss to Defendants, arising from the fact that many patients taking Namenda IR will, for one reason or another, not make the switch to Namenda XR and will thus stop taking Namenda altogether. [redacted]

[71] Zain Decl. Ex. 43 at FRX-NY-01579195.
[72] Zain Decl. Ex. 2 at FRX-NY-01642564.

[redacted].[73] [redacted]"[74] Thus, in the short term, Defendants' conduct actually harms its own business (ignoring the exclusionary effects on competitors) and thus cannot be a legitimate business justification.[75]

Of course, [redacted]. [redacted]"[76] Thus, the only reason for the Defendants' conduct is to exclude competition from the market.

Forest has proffered several pretextual justifications for discontinuing Namenda. In response to interrogatories and questioning, Forest provided the following reasons for discontinuing Namenda: (a) to focus exclusively on Namenda XR; (b) to reduce caregiver and patient confusion; (c) to free up manufacturing capacity for other drugs; (d) to lessen administrative costs; and (e) to focus on greater innovation (new products). None of the reasons is supported by the evidence.[77]

First, it is absurd to suggest that a pharmaceutical company would cease selling its highest-earning product because it was not worth the extra "focus," or as a result of vague

[73] *See* Zain Decl. Ex. 30 at 31[redacted]; Zain Decl. Ex. 44 at 1[redacted]; Zain Decl. Ex. 45 at FRX-NY-01565787[redacted].
[74] Zain Decl. Ex. 30 at 29.
[75] *See* Hovenkamp, Janis, Lemely & Leslie, IP & Antitrust at §12.3, at 12-32 (2d ed.) ("If a design change makes no economic sense unless the exclusion of rivals is taken into account, it is reasonable to infer both that the purpose behind the design change was anticompetitive and, more importantly, that the anticompetitive effects of the design change predominated over any technical benefits."); *see also* Areeda & Hovenkamp, Antitrust Law ¶ 651b3, at 104–05.
[76] Zain Decl. Ex. 30 at 30.
[77] *See* Defendants' June 23, 2014 Interrogatory Responses, at 6-11, attached as Zain Decl. Ex. 46.

"administrative costs." Forest (and now Actavis) has no problem dedicating significant "focus" and resources to many other products that generate vastly lower sales than Namenda.[78] There is no evidence of any material efficiency from eliminating Namenda IR. In any event, Defendants have already eliminated all marketing dollars behind Namenda IR.[79]

Second, Defendants' reference to patient and caregiver confusion has it backwards. Rather, it is instead the discontinuation of a product that patients may have been using for years that is likely to generate confusion, as Defendants have acknowledged.[80]

Third, a Forest executive testified under oath that that "freeing up any of the manufacturing equipment for the Namenda [IR] tablets" would not "assist in . . . increasing . . . manufacturing production of XR" because the equipment used to manufacture Namenda IR *tablets* and Namenda XR *capsules* "is completely different equipment."[81] To the extent discontinuing Namenda tablets would free up manufacturing capacity, it would be for other *tablets* which used the same equipment. It is also nonsensical for Defendants' to try to save manufacturing costs by eliminating a product that the company has no difficulty manufacturing, with the result of forcing patients to switch to a product that is significantly more difficult to manufacture. [82]

Rather, Defendants' documents (and its CEO's public statements) confirm that the *highest* priority in the business plan for the Namenda franchise was to move patients from Namenda IR to Namenda XR as quickly as possible, to blunt the impact of generic entry.

[redacted]

[78] *See* Forest Labs., Inc., Annual Report (Form 10-K) (filed May 30, 2014), attached as Zain Decl. Ex. 47 (comparing net sales of Forest's "Key Marketed Products").
[79] *See* Zain Decl. Ex. 23 at FRX-Ny-16868642.
[80] *See* Zain Decl. Ex. 31 at 4.
[81] Transcript of the Examination of Kevin Walsh at 169, attached as Zain Decl. Ex. 48.
[82] *Id.* at 292 ("XR is a completely different animal, more difficult to make, needs more sophisticated equipment")

[redacted] Defendants cannot hide the fact that this is the real reason for the decision to undertake the "forced switch."

For these same reasons, although the "refusal to deal with a competitor" cases do not apply here, the facts of this case would satisfy even the more demanding standard set forth in those cases. Under those cases, a "refusal to deal" will violate the antitrust laws where it involves a termination of a pre-existing profitable course of dealing, and entails a sacrifice of short-term profits, solely to achieve long-term gains from exclusion of competition. *Adderall XR*, 754 F.3d 135.

That is exactly what happened here. Defendants have terminated a pre-existing course of dealing with patients (ten years of selling Namenda IR) and sacrificing short-term profits (refusing to sell Namenda IR at its ordinary prices and sacrificing profits due to "disruption") solely to achieve long-term anticompetitive ends (the exclusion of generic competition). *See Trinko*, 540 U.S. at 409 (noting that a key aspect of *Aspen Skiing* was the defendant's refusal to sell lift tickets "*even if compensated at retail price*"); *cf. Lorain Journal Co. v. United States*, 342 U.S. 143, 152–153 (1951) (upholding monopolization finding where defendant refused to accept profitable advertising from customers who dealt with a competitor).

This Court's decision in *N.Y. Jets* is illustrative. In that case, this Court denied a motion to dismiss a complaint filed by the New York Jets alleging that Cablevision engaged in exclusionary conduct to prevent the Jets from competing with Cablevision's stadium. One of the acts alleged to be exclusionary was that "Cablevision refused to allows the Jets to purchase airtime for local commercials on any of the non-broadcast networks carried on its cable system." *Id.* at *8–9. The court held that plaintiff's allegation of Cablevision's "refusal to accept

profitable advertising" from the Jets, if proven, could support a claim. 2005 U.S. Dist. LEXIS 23763, at *27–28.

Similarly, here, Defendants are refusing to sell Namenda, a product that for over a decade they considered profitable, at its ordinary price. They cannot explain their sudden change of heart, other than the imminent arrival of generic competition and their desire to interfere with it.

III. NEW YORK, ALZHEIMER'S PATIENTS, AND THE HEALTHCARE SYSTEM WILL SUFFER IRREPARABLE HARM IF THE COURT DOES NOT ISSUE A PRELIMINARY INJUNCTION

Where, as here, the government seeks injunctive relief for a statutory violation, there is a presumption of irreparable harm. *See Prayze FM v. FCC*, 214 F.3d 245, 248, 250 (2d Cir. 2000); *accord Free Speech v. Reno*, 200 F.3d 63, 65 (2d Cir. 1999). That rule applies here because the Attorney General brings this action in his law enforcement capacity seeking injunctive relief for violation of the Donnelly Act and New York Executive Law § 63(12), as well as in a *parens patriae* and proprietary capacity for injunctive relief under federal law. Moreover, "with respect to irreparable harm, doubts as to whether an injunction sought is necessary to safeguard the public interest . . . should be resolved in favor of granting the injunction." *Bon-Ton Stores v. May Dep't Stores Co.*, 881 F. Supp. 860, 866 (W.D.N.Y. 1994) (internal citations omitted).

Irreparable harm is, in any event, clear here, as explained in more detail in Section IV, *infra* (balance of equities). Irreparable harm exists "where, but for the grant of equitable relief, there is a substantial chance that upon final resolution of the action the parties cannot be returned to the positions they previously occupied." *Brenntag Int'l Chems., Inc. v. Bank of India*, 175 F.3d 245, 249–50 (2d Cir. 1999). That is true here because if Defendants make Namenda IR unavailable prior to generic entry and force patients to switch to Namenda XR, there will be no going back. The market will have irrevocably moved to Namenda XR without a chance for

generic forms of Namenda to compete, with adverse effects on patients, health care premiums, taxpayers and the health care system.

IV. THE BALANCE OF EQUITIES FAVORS NEW YORK SO STRONGLY THAT IT NEED ONLY SHOW SERIOUS QUESTIONS UNDER THE LAW TO OBTAIN AN INJUNCTION

Although New York has shown likelihood of success on the merits, the Court need not even reach that issue to grant the preliminary relief requested, because here the "balance of hardships tipping decidedly in the plaintiff's favor." *Citigroup*, 598 F.3d at 35.[83] New York and citizens nationally stand to suffer far more hardship without a preliminary injunction than Defendants would suffer with one. Therefore, an injunction should issue as long as New York has raised "a serious question going to the merits to make them a fair ground for trial," which it clearly has.

A. Absent an Injunction, Defendants' Conduct Will Cause Irreparable Harm to Patients and Other Participants in the Health Care System

1. Harm to Patients

The injunction will protect patients from irreparable harm in several ways. First, it will protect those patients whose doctors prescribed them Namenda IR but who will be forced to switch to Namenda XR as a result of Defendants' withdrawal of Namenda IR. Such patients will suffer harm as a result of the unnecessary disruption in their treatment—and the attendant risk of adverse effects. Lah Decl. ¶ 30. In addition, these patients will end up paying higher co-pays after generic entry. Stitt Decl. ¶ 36. After generics enter in July 2015, patients are highly unlikely to switch back to the immediate release form of Namenda, and even those that do switch back will again be harmed by the disruption of their treatment for a second time. Lah Decl. ¶ 24.

[83] *See also Jacobson & Co. v. Armstrong Cork Co.*, 548 F.2d 438, 444–45 (2d Cir. 1977) (granting a preliminary injunction where the plaintiff raised serious questions even though the court found it "questionable whether Jacobson has shown that it is likely to succeed on the merits at trial").

Second, the injunction will protect those patients who would have continued to take Namenda IR absent the withdrawal, but will forego NMDA antagonist treatment entirely when Forest discontinues Namenda IR. [redacted].[84] The failure of these patients to make the transition to Forest's preferred product (e.g., due to logistical difficulties) could pose a risk to those patients' health.

2. Harm to Competition and the Public

By discontinuing Namenda IR before generic entry, Defendants will irreversibly destroy generic competition in the NMDA antagonist market, with real-world costs for patients, other payors and taxpayers. Once patients have been forced to switch to Namenda XR, as explained above, there are significant obstacles to switching them back. The result will be that generics will be unable to compete effectively, even though they offer a therapeutically equivalent drug at a dramatically lower price.[85] The fact that multiple generics invested resources to develop their products—and were then shut out of the market—will also discourage businesses from investing in future generic drugs, thus threatening the availability of other generic drugs.

This thwarts the statutory and regulatory objective of reducing costs for pharmaceuticals. Patients pay less in copays for generics than they do for brand-name pharmaceuticals, and other payors—government and commercial health plans—incur much lower reimbursement costs. Those health plan savings may then be passed on to plan members, in the form of lower premiums, and (for government payor programs) to taxpayers. *See* Stitt Decl. ¶ 55; *New York v. St. Francis Hosp.*, 94 F. Supp. 2d 399, 421 (S.D.N.Y. 2007) ("The economic reality is that insurers forced to pay higher rates for health care services are likely to pass the increase to their

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[84] [redacted] *See supra* note 73.

See Stitt Decl. ¶¶ 38–41; comments by CEO *supra* note48.

policy-holders."). But if Defendants discontinue Namenda IR, and force patients to switch to XR—a drug for which there is no imminent generic competition—pharmacists will not be able to substitute a lower-cost generic, thwarting this carefully crafted regulatory design intended to control health care costs.

B. Defendants Will Suffer No Cognizable Harm from an Injunction

On the other hand, Defendants can claim no real hardship from the requested injunction. *See Jacobson*, 548 F.2d at 445 (enjoining the defendant under the "serious questions" standard). An enjoined party does not "suffer any real harm" from being forced to continue to sell a product at a profit. *See id.* If the Court issues the preliminary injunction, Defendants can claim only one "harm": that they have been forced to continue to sell a blockbuster drug, at monopoly prices, earning a huge profit—against their will. Defendants cannot seriously argue that continuing to supply the market with Namenda IR—an activity they have been doing by choice for over a decade—suddenly constitutes a hardship.

Of course, if the injunction issues, and Namenda IR patients are provided with the choice to switch to generics next July, then Defendants will have to compete on price with generics. Defendants might claim that this competition is a "hardship;" but having to compete with other firms in the market is what the antitrust laws require—not a cognizable "harm." Nor is it harm for Defendants to refrain from engaging in conduct that "seems clearly to be an effort to game the rather intricate FDA rules to anticompetitive effect." *Abbots Labs.*, 432 F. Supp. 2d at 422.

Finally, because New York seeks an injunction preventing Defendants from withdrawing Namenda from the market only until generic entry (plus a short period thereafter to ensure supply continuity), any hardship Defendants can possibly show is limited to the time between

now and July 2015.[86] If the injunction issues, Defendants remain free to withdraw Namenda IR from the market in a few months. If patients begin to switch to generics, Defendants may try to win them back by convincing them that Namenda XR is superior and worth the extra costs.

C. New York Has Raised Serious Questions with Respect to the Merits

New York has raised serious questions with respect to the merits. *See* Argument Section II, *supra*. The *Abbott Labs* decision already held allegations of similar conduct to state a claim. *See Abbott Labs.*, 432 F. Supp. 2d at 420, 434. The FTC has explained that the potential for anticompetitive product reformulation is "particularly acute" in the pharmaceutical industry.[87] It is beyond doubt that Defendants' conduct in withdrawing a widely used drug from patients—merely to increase profits—is harmful to the public and to patients. It also clearly violates the antitrust laws, and at the very least, raises a serious question going to the merits.

Because there are serious questions going to the merits and the balance of hardships tips decidedly in New York's favor, the Court should grant the preliminary injunction.

V. GRANTING AN INJUNCTION SERVES THE PUBLIC INTEREST

"Courts of equity may, and frequently do, go much farther both to give and withhold relief in furtherance of the public interest than they are accustomed to go when only private interests are involved." *United States v. First Nat'l City Bank*, 379 U.S. 378, 383 (1965) (internal citation omitted). Here, the State of New York seeks to enforce laws on behalf of the public. Courts regularly presume that government action taken in furtherance of a regulatory or statutory scheme is in the public interest. *See, e.g.*, *Register.com, Inc. v. Verio, Inc.*, 356 F.3d 393, 424 (2d Cir. 2004). Enforcing the antitrust laws serves the public interest in a competitive

[86] If Defendants truly believe that they will suffer hardship from supplying Namenda IR for a few additional months, New York would accept immediate generic entry as a satisfactory alternative.
[87] *See* FTC Amicus Br. 12; *see also* Professors' Amicus Br. 14.

marketplace. *See United States v. Siemens Corp.*, 621 F.2d 499, 506 (2d Cir. 1980). New York seeks to protect competition in the market for NMDA antagonists.

Additionally, a preliminary injunction will protect the public interest by safeguarding the fundamental compromise envisioned by the Hatch–Waxman Act, which carefully sought to reconcile the sometimes conflicting public policy goals of making affordable generic drugs available to consumers and protecting pharmaceutical companies' incentives to innovate. Defendants have shown disdain for the former while taking full advantage of the latter. Defendants eagerly accepted a five-year extension to their patent rights, took advantage of pediatric exclusivity, and used Hatch–Waxman's mechanism for delaying generic entry by suing would-be generic competitors, thus delaying their approval. *See* Statement of Facts Section II(A), *supra*. However, they now want to deny generics and the public their side of the bargain, even after Defendants have enjoyed more than a decade of exclusivity. This represents a betrayal of the Hatch–Waxman compromise, and violates the spirit of the Hatch–Waxman Act and the public policy underlying it. Public policy, accordingly, strongly supports the issuance of the requested injunction.

CONCLUSION

New York has met all the requirements for a preliminary injunction: it has demonstrated that it is likely to win on the merits of its antitrust claims (and at the very least raises serious questions); that New York and the public are likely to suffer significant, irreparable harm in the absence of the requested injunction; that Defendants, in contrast, will face almost no harm from an injunction; and the injunction will serve the public interest. Accordingly, New York's request for a preliminary injunction should be granted.

Dated: September 24, 2014
New York, New York

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