UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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THE PEOPLE OF THE STATE OF NEW YORK,

Plaintiff,

14 Civ. 7473

-against-

REDACTED OPINION*

ACTAVIS, PLC, and
FOREST LABORATORIES, LLC,

Defendants.

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* The initial opinion was filed under seal to protect any confidential information asserted by the parties. Redactions have been made as determined by the prior opinion of the Court, dated October 24, 2014.

Sweet, D.J.

The plaintiff, the People of the State of New York (the "State" or the "Plaintiff"), has moved pursuant to Rule 65 of the Federal Rules of Civil Procedure to preliminarily enjoin the defendants, Actavis, PLC ("Actavis") and Forest Laboratories, LLC ("Forest") (collectively, the "Defendants"), from engaging in antitrust violations by discontinuing the current sales of the Forest drug Namenda IR, used in the treatment of Alzheimer's disease, currently scheduled to take effect on January 1, 2015. Based on the findings of fact and conclusions of law set forth below, the motion is granted, and a preliminary injunction will issue.

This motion involves one piece of the complicated mosaic that is the health care sector in the United States. At issue is the competition between Forest, a manufacturer of branded and patented drugs to treat Alzheimer's disease, and manufacturers that produce generic equivalents, as well as the effect of that competition on consumers. This competition has been the subject of federal and state legislation and is of great importance to pharmaceutical companies, patients, physicians, pharmacists, insurers, health plans, and regulators.

The issue is significant because of the particular needs of patients afflicted by Alzheimer's, the process by which prescription drugs are created and sold, and the economic significance of Forest's Namenda drugs, which had annual sales of over $1.5 billion in last year.

The idiosyncrasies of competition in this market were captured by the State's expert, Dr. Ernst Berndt:

> I think the phrase goes, he who consumes doesn't pay, and he who buys is not held accountable. . . . So we have this multiplicity of prices. We have the price received by the manufacturer and we have the total revenues received by the pharmacy. And we have the reimbursement to the pharmacy and a copayment by the patient. Who the consumer is ultimately a bit ambiguous.

Tr. 368:1-7 (Berndt).

Able and skilled counsel have assisted the court with their presentations of the complicated and significant issues raised by the State's antitrust and state law violation claims. In addition, this excellent performance has been rendered under the difficult conditions imposed by the march of time and the controlling external events.[1]

[1] The calendar has also dictated the timing of the issuance of this opinion. While the issues are deserving of an exhaustive treatment, their significance requires resolution in time to permit the possibility of appellate review.

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Prior Proceedings

On February 28, 2014, the Antitrust Bureau of the Office of the Attorney General of the State of New York (the "Bureau") opened an investigation into Forest's business plans regarding the pharmaceutical product Namenda, a therapy approved to treat Alzheimer's disease by the Food and Drug Administration ("FDA").

The State filed an initial complaint on September 15, 2014, followed by an Amended Complaint ("AC") on November 5, 2014, alleging that Defendants violated federal and state antitrust laws by attempting to improperly maintain and extend a monopoly over the Namenda drug. The AC sought injunctive relief requiring Defendants to keep the original form of the drug, Namenda IR, available on the market and to prevent the Defendants from in effect requiring patients to switch a new patent-protected form, Namenda XR.

The AC contains allegations describing: the parties (AC ¶¶ 12-15); the regulatory framework and relevant federal regulations, including the Food Drug and Cosmetic Act, 21 USC § 301 et seq., the Drug Price Competition and Patent Term

Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, the Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (AC ¶¶ 16-20); state generic substitution laws (AC ¶¶ 21-27); and the effect of generic competition and brand name manufacturers' tactics to evade them (AC ¶¶ 28-43).

The AC also contains allegations with respect to: Alzheimer's disease and the relevant products (AC ¶¶ 44-45); and the relevant market (AC ¶¶ 46-63), including memantine that is branded and marketed as Namenda by Defendants; Namenda's recent annual sales in excess of $1.5 billion in the United States; the extension of the Namenda patent; and the anticipated entry of generic competition in July 2015. The AC further alleges that the Defendants have made efforts to stall the effects of generic entry in the market (AC ¶¶ 64-97), including the launch of Namenda XR in June 2013 and the effort to convert patients from Namenda IR to Namenda XR and the implementation and subsequent modification of a scheme to force patients to switch to the new formulation. The AC alleges the anticompetitive effect of the conduct of the Defendants (AC ¶¶ 98-104) and their conduct in exaggerating the imminence of the plan to force switches (AC ¶¶ 105-119).

Six causes of action are alleged: (1) monopolization in violation of Section 2 of the Sherman Act; (2) attempted monopolization in violation of Section 2 of the Sherman Act; (3) unreasonable restraint of trade in violation of Section 1 of the Sherman Act; (4) violation of the Donnelly Act, New York General Business Law Section 340 et seq.; (5) repeated or persistent illegality in violation of Section 63(12) of the New York Executive Law; and (6) repeated or persistent fraud, in violation of Section 63(12) of New York Executive Law.

The AC seeks: (i) a decree that Defendants violated the statutory provisions in the six causes of action outlined above; (ii) disgorgement of proceeds from illegal activity, repayment of monies gained from unjust enrichment, and payment of restitution and damages to injured parties; (iii) preliminary and permanent injunctive relief barring Defendants from discontinuing Namenda IR until generic memantine becomes available, barring Defendants from other violations of law and other equitable relief necessary to redress Defendants' purported violations of law; (iv) civil penalties, damages and restitution for violations of state laws, including the Donnelly Act; and (v) attorneys' fees.

The State moved pursuant to Rule 65 of the Federal Rules of Civil Procedure for a preliminary injunction. The motion was heard and evidence adduced from November 10 to November 14, 2014, and final arguments were heard and the motion was marked fully submitted on November 24, 2014.

Certain materials submitted to the Court have been designated confidential. In order to protect that confidentiality, a public version of this opinion will not be filed for twenty-four hours to give the parties an opportunity to request redactions.

Evidence

The following witnesses provided live or written testimony with respect to these proceedings:

Dr. Ernst Berndt ("Dr. Berndt")	Louis E. Seley Professor of Applied Economics at the Massachusetts Institute of Technology
Mr. Dan Blakely, R.Ph. ("Blakely")	Chief Executive Office of Foundation Care (an Actavis Vendor)
Mr. Napoleon Clark ("Clark")	Executive Director for Marketing – U.S. Generics at Actavis
Dr. Pierre Y. Cremieux ("Dr. Cremieux")	Managing Principal at Analysis Group
Mr. Mark Devlin ("Devlin")	Senior Vice President Managed Markets at Actavis
Ms. Babette Edgar ("Edgar")	Principal at BluePeak Advisors
Dr. Steven Ferris ("Dr. Ferris")	Gerald D. and Dorothy R. Friedman Professor of New York University's Alzheimer's Disease Center
Mr. Jason Harper ("Harper")	Director of Marketing at Mylan Pharms.
Dr. Jerry Hausman ("Hausman")	McDonald Professor of Economics at Massachusetts Institute of Technology
Dr. Alan Jacobs ("Dr. Jacobs")	Neurologist in private practice
Mr. William Kane ("Kane")	Vice President of Marketing Internal Medicine at Actavis
Dr. Bruce Kohrman ("Kohrman")	Neurologist in private practice
Dr. E. Mick Kolassa ("Dr. Kolassa")	Chairman and Managing Partner of Medical Marketing Economics
Dr. James J. Lah, MD, PhD ("Dr. Lah")	Associate Professor of Neurology at Emory University Medical Center Director of Emory Cognitive Neurology Program Associate Director of Alzheimer's Disease Research Center
Mr. William Meury ("Meury")	Executive Vice-President of Commercial Operations for the North American Brands Division at Actavis
Ms. LuMarie Polivka-West ("Polivka-West")	Vice-President and Senior Director of Policy and Program Development for the Florida Health Care Association
Dr. Barry Reisberg ("Dr. Reisberg")	Psychiatrist, Alzheimer's Disease Center of the New York University Langone Medical Center
Dr. Barry Rovner ("Dr. Rovner")	Professor of Psychiatry and Neurology at the Signey Kimmel Medical College of Thomas Jefferson University

Mr. Brenton Saunders ("Saunders")	Chief Executive Officer of Actavis (former Chief Executive Officer of Forest Labs.)
Mr. David F. Solomon ("Solomon")	Partner at Hildred Capital Partners, LLC (former Senior Vice President of Corporate Development and Strategy of Forest Labs.)
Mr. Robert Stewart ("Stewart")	Chief Operating Officer of Actavis
Mr. David F. Stitt, R. Ph. ("Stitt")	Director of Pharmacy at a New York-based health plan (MVP Health Care)
Dr. Marco Taglietti ("Dr. Taglietti")	Senior Vice President for Research & Development at Actavis
Mr. Kevin Walsh ("Walsh")	Senior Vice-President of Operations at Actavis

In addition to live witness testimony, the State presented 581 exhibits and the Defendants presented 835. One hundred fifty-one exhibits were referenced during the testimony of the witnesses.

Findings of Fact

I. The Parties

1. The State, by its Attorney General, brought this action in its capacity as parens patriae and also as an "indirect purchaser of Namenda." Amended Complaint ("AC") ¶ 9.

2. Defendant Actavis is a public limited company registered in Ireland and headquartered at 1 Grand Canal Square, Docklands, Dublin 2, Ireland. It manufactures and sells generic drugs. In July 2014, Actavis acquired Forest. Tr. 192:8-10 (Saunders). Forest is a Delaware limited liability company with an office at Morris Corporate Center, 400 Interpace Parkway, Parsippany, New Jersey and at various New York locations. It manufactures and sells a number of branded pharmaceutical products including memantine hydrochloride (HCL) drugs in the form of Namenda IR tablets, Namenda IR oral solution, and Namenda XR capsules. See Press Release, Forest Labs., Forest Laboratories to Discontinue NAMENDA Tablets, Focus on Once-Daily NAMENDA XR (DX499) (Feb. 14, 2014). Defendants' United States revenues from Namenda were approximately $1.6 billion in Forest's 2014 fiscal year, and total sales stand to grow

consistent with the epidemiological projection that the number of Americans living with Alzheimers will triple by 2050. Tr. 612:16-22 (Meury); Forest 10-K (PX48) at 56; Rovner (PX358) ¶ 20.

II. Background

A. Alzheimer's Disease

3. As Dr. Ferris testified, "Alzheimer's disease is a progressive, irreversible, incurable disease of the brain that is the most common cause of dementia worldwide." Ferris Decl. ¶ 11. "Current pharmacotherapies offer only symptomatic benefits." Ferris Decl. (PX276) ¶ 13. The disease afflicts more than five million people in the United States and is the sixth leading cause of death in United States. Ferris Decl. ¶ 11; see also Rovner Decl. (PX358) ¶ 20. As the population continues to live longer, the number of people living with Alzheimer's is expected to triple by 2050. Rovner Decl. (PX358) ¶ 20. The visible signs of Alzheimer's include problems with memory and other cognitive functions, social skills, planning, and judgment. Ferris Decl. (PX276) ¶ 11. Patients also develop neuropsychiatric problems including apathy, depression, agitation, and delusions. Ferris Decl. (PX276) ¶ 11; see also

Reisberg Dep. 173:16-24. As the disease progresses, patients become completely dependent on their caregivers as they gradually lose the ability to perform routine activities of daily living. Ferris Decl. (PX276) ¶ 11; Kohrman Dep. 130:25-131:10; Reisberg Hr'g 728:18:729:4. In the final stages of the disease, patients require skilled nursing and intensive supportive care. Ferris Decl. (PX276) ¶ 11; Reisberg Dep. 176:2-177:17.

4. New York in 2014 has about 380,000 people living with Alzheimer's disease, and 1 million non-professional caregivers who provide 1.1 billion hours of care at an unpaid value of $14.3 billion each year. See Alzheimer's Association, 2014 Alzheimer's Disease Facts and Figures, 10 J. Alzheimer's Assoc. e47 (2014) (DX360); Rovner Decl. (PX358) ¶ 21. This caregiving is draining emotionally and physically and becomes more difficult and prolonged because patients with advanced disability can survive many years. Rovner Decl. (PX358) ¶ 21. Most persons with Alzheimer's are cared for at home by spouses and adult children or by professional caregivers in long-term care-facilities. Rovner Decl. (PX358) ¶ 21. About one in seven people with Alzheimer's live alone. Rovner Decl. (PX358) ¶ 23.

5. In 2013, caregivers provided unpaid care valued at more than $220 billion and the burden of providing that care imposed more than $9 billion in additional health care costs on the caregivers themselves. Cremieux ¶ 19 (PX229); Polivka-West Hr'g 621:7-9, 24-25.

B. Number of Prescriptions

6. Although the record does not establish the total number of Namenda prescriptions, the latest estimates are that Namenda IR and Namenda XR each have 50% of the market, as defined below. Defendants' CEO has stated that there are hundreds of thousands of Namenda IR prescriptions. Tr. 242:7-12 (Saunders). A fair approximation of the number of prescriptions is in the neighborhood of 500,000. See Tr. 165:15-21 (Stitt).

C. Available Drugs

7. The FDA has approved five drugs to treat Alzheimer's disease: Aricept, Cognex, Exelon, Razadyne, and Namenda, four of which currently are on the market. Lah Decl. (PX85) ¶ 5. Cognex was withdrawn from the market in 2012 because it was toxic. Rovner Dep. 50:23–51:3; Ferris Dep.

96:20–98:14. All these drugs except Namenda are acetylcholinesterase inhibitors ("CIs") and work in the same basic manner. Tr. 53:1–5 (Lah); Lah Decl. (PX85) ¶ 6. CIs reduce the breakdown in the brain of a chemical called acetylcholine, a chemical messenger that transmits information between nerve cells. Jacobs Dep. 92:14–93:10; 102:6–19.

8. Namenda is an N-Methyl D-Aspartate ("NMDA") receptor antagonist and works differently from CIs. AC ¶ 47; Tr. 53:10–12; 63:18–64:1 (Lah); Lah Decl. (PX85) ¶ 7; Namenda Franchise Business Plan (PX24) at FRX-NY-01686843 ("CIs work on the acetylcholine pathway while Namenda works on the glutamate pathway."). As Dr. Jacobs explained:

> Neurons in the brain communicate by signaling each other. Some of these signals are transmitted through an influx of calcium into a molecule on the surface of neurons called the NMDA receptor. This influx of calcium is triggered when glutamate, an excitatory neurotransmitter, docks at the NMDA receptor, causing the calcium influx. When patients enter the moderate stage of Alzheimer's disease, there can be overexcitation of the NMDA receptor by glutamate.

Jacobs ¶ 24 (CD Ex. 11); see also Ferris Dep. 99:14-16 (CD Ex. 27). Namenda works by "partially blocking the NMDA receptor to

prevent overexcitation, which can cause toxicity to neurons in the brain." Jacobs ¶ 24 (CD Ex. 11).

9. Currently, the two forms of Namenda produced and sold by Forest, Namenda IR tablets and liquid solution, and Namenda XR capsules, are the only available NMDA receptor antagonists approved to treat Alzheimer's disease. Lah Decl. (PX85) ¶ 7. The active ingredient in both Namenda formulations is memantine HCL. Jacobs ¶ 24 (CD Ex. 11); AC ¶ 47.

D. Stakeholders in the U.S. Healthcare Industry

10. Defendants are one of the complex array of stakeholders comprising the healthcare industry in the United States. See Tr. 368:1-7 (Berndt).

11. Suppliers in this industry include academics and relatively small start-up companies that conduct the initial research necessary to develop medically-promising chemical compounds; large branded pharmaceutical companies such as Forest whose business focuses on developing the medically-promising chemical compounds into saleable patent-protected and FDA-approved medicines, and generic pharmaceutical companies such as Actavis and third-party witness Mylan Pharmaceutical ("Mylan")

whose business focuses on low-cost production of the branded companies' drugs once those medicines have lost patent-exclusivity. See Tr. 236:20-237:20, 246:12-247:06 (Saunders).

12. Depending on the nature of the drug being considered, several intermediaries stand between a supplier and the ultimate end-user, i.e., the patient.

13. One intermediary is the FDA. As the main federal regulator in the industry, the FDA determines which medications can be marketed, whether a drug requires a physician's prescription to be dispensed, and how that drug may be marketed.

14. Another set of intermediaries are physicians and other medical professionals. If the medication is a prescription drug, this group determines which drugs to prescribe, in consultation with their patients. See Tr. 727:3-17 (Reisberg). Pharmacists, either working in traditional brick-and-mortar or mail-order pharmacies, dispense the medications and process payment for the medications. See Kolassa Decl. (DX821) ¶¶ 33, 52.

15. Depending on a patient's morbidity, caregivers comprise yet another group of intermediaries. Caregivers,

whether family members, friends or professional caregivers, may administer or assist the patient in taking the medication.

16. The final group of intermediaries are the third party payors, entities that pay all or part of the costs of a prescription drug on behalf of patients. Kolassa Decl. (DX821) ¶ 31. These include insurance companies and health plans, such as third party witness MVP Health Care ("MVP"). Kolassa Decl. (DX821) ¶ 31; Stitt (PX122) ¶ 4.

17. Typically, third party payors employ several strategies to manage costs. They generate a drug formulary, a list of approved drugs that will be paid for by the health plan (in whole or in part) when an insured patient fills a prescription. Kolassa Decl. (DX821) ¶ 34. A health insurer's drug formulary typically explains what drugs are covered, as well as the level of cost sharing the health plan requires the patient to bear. Kolassa Decl. (DX821) ¶ 34. Pharmacies enjoy larger profit margins on generic versus branded medications. Kolassa Decl. (DX821) ¶ 26.

18. Third party payors sometimes engage pharmacy benefit management companies (PBMs) to assist them in managing

their prescription drug costs. Kolassa Decl. (DX821) ¶ 31 and fn. 27.

19. Third party payors may also require patients to pay a portion of the costs of a drug as a "co-payment" or "co-pay." Kolassa Dep. 156:7-12; Kolassa Decl. (DX821) ¶ 34. This is often accomplished through a tiered co-pay system imposed in conjunction with the formulary file. Kolassa Decl. (DX821) ¶ 37. A typical three-tiered system has tier 1 reserved for generic drugs, tier 2 for preferred branded drugs, and tier 3 for non-preferred branded drugs. Kolassa Decl. (DX821) ¶ 37. The co-pays increase with each tier. Kolassa Decl. (DX821) ¶ 37. Tier 1 co-pays for generic drugs are commonly $10 or less and are sometimes $0. Kolassa Decl. (DX821) ¶ 37. By contrast, tier 3 co-pays for non-preferred brands are commonly between $50 and $90. Kolassa Decl. (DX821) ¶ 37.

20. Step therapy is another third party payor cost savings tool that rejects insurance coverage for a drug until the patient attempts unsuccessfully to take a preferred, usually less costly, alternative for that drug. Kolassa Decl. (DX821) ¶ 41.

21. Finally, third party payors attempt to educate patients and doctors about low-cost alternatives to branded medications, and occasionally implement programs to incentivize doctors and pharmacists to prescribe low-cost drugs. Kolassa Decl. (DX821) ¶¶ 20-21, 28-28.

E. Competition and Regulation

22. 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 FDA and provide scientific data demonstrating that the drug is safe and effective. 21 U.S.C. 355(b)(1). The process for obtaining FDA approval of an NDA can be costly and time consuming. Berndt Decl. (PX64) ¶¶ 11-12; Tr. 339:13-18 (Berndt).

23. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, (the "Hatch–Waxman Act"), which was intended to facilitate competition from lower-priced generic drugs while also providing further incentives for pharmaceutical companies by extending

patent protection. Tr. 338:22-340:18 (Berndt); Berndt Decl. (PX64) ¶ 12.

24. By creating benefits, limits, and incentives for both generic and branded pharmaceutical manufacturers, the Hatch–Waxman Act attempted to balance the competing policy goals of encouraging innovation and expediting patient access to less expensive versions of branded drugs. Tr. 338:22-340:18 (Berndt); Berndt Decl. (PX64) ¶ 12; H.R. Rep. No. 98-857, Pt. 1, 14–17 (1984). The Act has been variously characterized as the "grand compromise" between pharmaceutical companies with patent exclusivity and generic manufacturers and as the "thumb on the scales" in favor of generics. Tr. 228:1-12 (Saunders); Tr. 339:19-22 (Berndt).

25. Under the Hatch–Waxman 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 that its generic version is "bioequivalent" to the drug that has an NDA. Tr. 338:19-340:9 (Berndt). By permitting the generic to rely on studies submitted by the NDA applicant (the branded drug manufacturer),

the Act reduces development cost and speeds up FDA approval for generics. Tr. 339:19-340:9 (Berndt).

26. As part of the legislative compromise underlying the Hatch–Waxman Act and its amendments, the Hatch-Waxman Act includes several provisions that grant branded drug manufacturers opportunities to lengthen their exclusivity period beyond the twenty-year term of a patent. 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 process. 35 U.S.C. § 156; Tr. 340:15-340:18 (Berndt); Berndt Decl. (PX64) ¶ 92. 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. 35 U.S.C. § 156; 21 U.S.C. § 355a; Berndt Decl. (PX64) ¶ 92. The Hatch-Waxman Act has twin goals: (i) to encourage generic entry when a branded firm's patent is invalid or not infringed; and (ii) to ensure that the branded firm's patent exclusivity, as well as the branded product's market exclusivity, are appropriately protected. The Hatch-Waxman Act, like the patent laws, incentivizes research by helping to preserve lawful patent and regulatory monopolies, which allows

branded firms to better recover the upfront costs of their innovations, including for drug research and development. AC ¶ 17; Cremieux Decl. (PX229) ¶ 12.

27. State generic substitution laws aim to encourage generic drug sales. New York, prior to the Hatch-Waxman Act enactment in 1984, enacted drug substitution laws that require a pharmacist filling a prescription for a branded drug to substitute a less-expensive, therapeutically equivalent generic drug, unless a physician directs otherwise. See N.Y. Educ. Law § 6816-a; Tr. 115:8-117:4 (Stitt); Tr. 342:13-343:14 (Berndt); Berndt Decl. (PX64) ¶¶ 45-47; Tr. 222:12-222:25 (Saunders). Eleven other states enacted similar legislation. See Tr. 467:16-20 (Berndt); Jesse C. Vivian, Generic-Substitution Laws, U.S. Pharmacist (DX731) (June 19, 2008) at 3 tbl. 2. There are 40 additional states that permit generic substitutions. Id.

28. State substitution laws operate to facilitate lower cost generics because they allow or require a pharmacist to provide a patient with a lower-cost generic drug without contacting the doctor to change the prescription. Tr. 797:19-798:20 (Kolassa). Generics compete on price at the pharmacy and take business from higher-priced brands. Tr. 115:8-117:4

(Stitt); Stitt Decl. (PX122) ¶ 21; Tr. 342:13-343:24 (Berndt); Tr. 897:13-22 (Cremieux). This competition results in reduced drug costs for patients and health plans after generic entry and still provides patients with the same therapeutic benefits as the brand. Tr. 113:16-114:20 (Stitt). 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. Berndt Decl. (PX64) ¶¶ 45-47; Tr. 342:18-22 (Berndt); Stitt Decl. (PX122) ¶ 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. Zain Decl. Ex. 5 (U.S. Food & Drug Admin., Approved Drug Products with Therapeutic Equivalence Evaluations, Preface (32d ed. 2012)); Tr. 342:2-12 (Berndt).

29. In permissive substitution jurisdictions, managed care organizations and other third party payors encourage generic substitution at the pharmacy, such that any heterogeneity between mandatory and permissive states is negated in practice. Berndt Hr'g 343:11-14 ("And so even though there is variability across states in the specifics of state

substitution laws, in practice there is relatively little heterogeneity.").

30. 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. Tr. 409:6-11 (Berndt); Stitt Decl. (PX122) ¶ 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."); [redacted]; Tr. 351:10-14; 353:1-8; 376:12-17 (Berndt).

31. 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. Tr. 376:12-17 (Berndt).

32. When the branded manufacturer's exclusivity ends and multiple generics enter the market, a branded drug often loses more than 80-90% of its market share within six months. Saunders Dep. 44:8–21; Tr. 802:5–8 (Kolassa), 376:12–17 (Berndt). Defendants' CEO saw this result of the statutory scheme as stacking the deck against Forest. Tr. 202:18–21 (Saunders) ("[T]he entire healthcare system is designed to benefit the generic companies and put up barriers and obstacles to the innovative companies, and so that's why you generally see the market shift 90/99 percent towards the generics."). This tradeoff of longer exclusivity rights for branded manufacturers like Forest, 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 New York and other states embraced in their substitution laws. Berndt Decl. (PX64) ¶ 12–19; Tr. 339:19–340:18 (Berndt).

33. According to a 2013 study commissioned by the Generic Pharmaceutical Association, over the 10-year period from 2003 through 2012, generic drug use has generated more than $1.2 trillion in savings to the U.S. health care system by reduction in price over the branded drug. Generic Pharm. Ass'n, Generic

Drug Savings in the U.S. (PX8) at 1 (2013). In 2012, generic drugs saved the health system $217 billion. Id. Once patent 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 sharp drop in revenue has been referred to in this litigation and in the industry as the "patent cliff." Tr. 192:18-193:1 (Saunders), 386:2-11 (Berndt).

34. This AB-rated requirement, while intended to ensure therapeutic equivalence to the branded drug, provides an opportunity for branded manufacturers to game the system through a practice termed "product hopping." Tr. 453:19-454:12 (Berndt). For a drug that is about to go-off the "patent cliff," the drug manufacturer 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. See Berndt Decl. (PX64) ¶ 41. As found above, the generic of the original version of the drug will not be "AB-rated" to the follow-on branded drug. Thus, if physicians write prescriptions for the follow-on version instead of the original, the generic entry is not dispensed even if, in practice, the cost savings offered by

the generic may outweigh any advantage offered by the new version of the branded drug.

35. Sometimes, these follow-on drugs may be better than the original version. Tr. 456:19-457:12 (Berndt). In other instances, the new drugs offer little to no therapeutic advantage over the prior formulation, and the reformulation is merely an attempt to manipulate the regulatory system and interfere with effective price competition between branded and generic drugs at the pharmacy. Tr. 453:19-454:12 (Berndt).

36. A branded manufacturer may use various tactics to encourage physicians and patients to switch to its new follow-on drug. Typically, the company will aggressively promote the follow-on drug and remove marketing effort behind the original drug, what has been termed a "soft switch." Berndt Decl. (PX64) ¶ 41; Tr. 221:5-9 (Saunders). A brand manufacturer that has successfully achieved a switch to a follow-on product can expect that most "switched" patients will not make a second switch back to the original product. Tr. 374:1-22 (Berndt).

III. The Development of the Namenda Franchise

A. The Success of Namenda IR

37. In June 2000, Forest obtained an exclusive license to U.S. Patent No. 5,061,703 held by Germany's Merz Pharma GmbH & Co. KGaA. In December 2002, Forest submitted an NDA to the FDA, seeking approval to market memantine HCL tablets (5mg and 10mg) branded as "Namenda" for the treatment of Alzheimer's. U.S. Food & Drug Admin., NDA 21-487 Approval Letter (DX782) (Oct. 16, 2003).

38. 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. 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. (PX10) (Oct. 16, 2003). Forest brought Namenda IR to market in January of 2004. Press Release, Forest Labs., Inc., Namenda(TM) (memantine HCl), First Drug Approved For Treatment of Moderate to Severe Alzheimer's Disease Now Available Nationwide (PX11) (Jan. 13, 2004). Forest sought and received a five-year patent extension as compensation for the time spent obtaining FDA approval for Namenda tablets. 35 U.S.C. § 156; Tr. 340:15–340:18 (Berndt); Berndt Decl. (PX64) ¶ 92. As a result, Forest's main patent for

Namenda IR, the '703 patent, expires on April 11, 2015. U.S. Patent and Trademark Office, Patent Term Extensions (PX12).

39. At the time of the launch of Namenda IR tablets in January 2004, Namenda IR was the first and only medication approved for patients with moderate-to-severe Alzheimer's disease. See Tr. 124:21-125:09 (Stitt). Clinical trials established that Namenda IR is both safe and efficacious as a monotherapy. Reisberg Dep. 156:19-157:19, 196:12-199:20 (discussing the studies); Press Release, Forest Labs., Namenda(TM) (memantine HCl), First Drug Approved for Treatment of Moderate to Severe Alzheimer's Disease Now Available Nationwide (DX484) (Jan. 13, 2004). Leading Alzheimer's experts confirm the salutary effect Namenda has made in the everyday lives of Alzheimer's patients. See Reisberg Decl. (PX352) ¶ 24; Rovner Decl. (PX358) ¶ 39. Alzheimer's patients taking Namenda more easily perform "common activities of daily living such as eating, walking, toileting, bathing, and dressing." Press Release, Forest Labs., Namenda(TM) (memantine HCl), First Drug Approved for Treatment of Moderate to Severe Alzheimer's Disease Now Available Nationwide (DX484) (Jan. 13, 2004). Namenda IR is administered twice a day. Lah Dep. 191:4-6.

40. In 2005, Forest introduced a liquid form of Namenda IR (often referred to as an "oral solution") for patients who have difficulty swallowing tablets, although any Namenda patient can take it. Meury Decl. (DX720) ¶ 7; Lah Decl. (PX85) ¶ 13; Lah Dep. (DX487) 192:10-13; see also Jacobs Dep. 104:23-105:9 (CD Ex. 41); Rovner Dep. 210:2-13 (CD Ex. 28); Reisberg Dep. 117:5-118:6; Solomon Decl. (DX718) ¶ 6. Namenda IR oral solution is an immediate-release product that has the same active ingredient as Namenda IR tablets and is as effective as the tablets. See Lah Dep. (DX487) 186:16-25, 191:4-23, 284:8:14. The oral solution originally was covered by the same FDA-approved label as the tablets. Namenda Package Insert (DX456) (Oct. 2013); Lah Dep. (DX487) 284:15-22. As of August 2014, the tablets and the oral solution are covered under separate labels. See Namenda Oral Solution Package Insert (Aug. 2014) (CD Ex. 47). Like Namenda IR tablets, the oral solution should be administered twice a day. Lah Dep. (DX487) 191:4-6; Jacobs Decl. (CD Ex. 11) ¶ 25; Ferris Decl. (CD Ex. 20) ¶ 15; Kohrman Decl. (CD Ex. 15) ¶ 21; Reisberg Decl. (CD Ex. 13) ¶ 25; Rovner Decl. (CD Ex. 18) ¶ 31; Meury Decl. (DX720) ¶ 9; Solomon Decl. (CD Ex. 16) ¶ 7.

41. In 2009 and 2010, Forest, as a resolution of patent litigation, entered into licensing agreements with ten generic competitors allowing for the sale of generic memantine ("generic Namenda" or "generic IR") tablets on July 11, 2015, three months before Forest's exclusivity ends, or earlier in certain circumstances. See also Solomon Decl. (DX718) ¶¶ 13-14; Press Release, Forest Labs., Forest and Merz Pharma GmbH & Co. KGaA Settle Namenda IR Patent Litigation (DX781) (July 22, 2010). Five generic manufacturers have obtained and currently maintain tentative approval from the FDA to market their generic versions of Namenda IR tablets as early as July 11, 2015. Solomon Decl. (DX718)¶ 14. Seven more generic competitors may begin selling their generic versions of generic Namenda IR tablets as early as October 11, 2015. Solomon Decl. (DX718) ¶ 16.

42. In 2009, Forest began a large program to evaluate whether memantine could be approved to treat pediatric autism at the FDA's "official request," known as a "Pediatric Written Request" ("PWR"). Taglietti Decl. ¶¶ 25-26; Taglietti Dep. (CD Ex. 42) 235:8-236:19; Solomon Dep. (CD Ex. 39) 227:20-237:8 (explaining full background of autism studies). On June 18, 2014, Forest announced that FDA had granted its request for

pediatric exclusivity, extending Forest's exclusivity rights for another six months. Press Release, Forest Labs., Inc., Forest Obtains Six Months U.S. Pediatric Exclusivity for Namenda R and Namenda XR (PX13) (June 18, 2014). This extended the patent exclusivity to October 11, 2015. Solomon Decl. (DX16) ¶ 15.

43. Forest invested almost $70 million in support of clinical studies for the treatment of pediatric autism. Taglietti Decl. (DX303) ¶ 25; Saunders Dep. (CD Ex. 38) 318:13-17. At that time, it was the "largest study ever done on autistic patients." Taglietti Dep. (CD Ex. 42) 237:3-7. In designing and running these clinical studies for pediatric autism, Forest "developed for the first time a network of over 185 clinical study sites for autism that had never existed before." Taglietti Decl. (DX303) ¶ 28.

44. Sales of Namenda IR for 2013 have exceeded $1.5 billion and 2012 had similar results. Kolassa Decl. (DX821) ¶ 5; Nikhil Nayak email re: FW: Namenda Manager's Meeting Draft Script (PX70) at FRX-NY-01634297.

B. Introduction of Namenda XR And Its Place In The Franchise

45. Between 2006 and 2014, Forest invested approximately [redacted] in R&D for an improved version of Namenda: a once-daily extended release capsule called Namenda XR. Meury Decl. (DX720) ¶¶ 5, 8. All currently marketed symptomatic treatments for Alzheimer's disease had already moved to once-a-day treatments before the introduction of Namenda XR. Ferris Dep. 107:16-109:9; Reisberg Dep. 165:23-166:8.

46. As Dr. Reisberg testified:

> [T]here is an exponential difference between being able to take a medicine once daily versus twice daily. And I think all of us have taken medications know this, that it's much easier to take a medicine once a day than twice a day. But these differences become very much compounded for my patients. So persons with Alzheimer's disease are frequently older, and older people take more medications than younger people. And persons with memory problems have difficulty taking medication.

Reisberg Hr'g 727:6-728:8; Reisberg Dep. 136:5-137:8. All Defendants' medical experts echoed Dr. Reisberg's statements. Kohrman Hr'g 740:1-9; Rovner Dep. 271:16-25; Ferris Dep. 317:17-318:11; Jacobs Dep. 217:20-219:15. Fewer pills generally lead to greater compliance with treatment. Lah Hr'g 95:5-7; Lah Dep. 137:13-138:24; Kohrman Decl. (PX315) ¶¶ 3, 24-28 (once-daily dosing increases compliance); Reisberg Decl. (PX352) ¶¶ 30-31;

Rovner Decl. (PX358) ¶ 37; Ferris Dep. 112:8-10; Jacobs Dep. 218:24-220:16.

47. "Many controlled clinical trials have also shown that 'extended-release agents are associated with improved tolerability, greater patient adherence to treatment, reduced total treatment costs, and better long-term clinical outcomes.'" Cremieux (PX229) ¶ 18. Some Alzheimer's disease patients experience "sundowning," which is the "tendency for some patients with Alzheimer's disease to become more confused, anxious, paranoid, [and] restless later in the day than earlier in the day." Rovner Dep. 245:8-14; Kohrman Hr'g 740:3-9; Polivka-West Dep. 120:10-121:6. As Dr. Lah testified, "sundowning may lead to agitation" which "may make it more difficult to get the patient the medication they need." Lah Hr'g 98:18-99:2; Lah Dep. 173:16-18; see also Rovner Dep. 247:21-248:2 (reporting that half of his sundowning patients have trouble taking medication at night); Rovner Decl. (PX358) ¶¶ 41-42; Ferris Decl. (PX276) ¶ 41; Hausman Hr'g 714:13-15 (acknowledging caregiver burden and difficulties associated with getting patients to take a drug in the afternoon).

48. Forest is the sole owner (through its subsidiary) or exclusive licensee of all patents covering Namenda XR listed in the Orange Book. See Food & Drug Admin., Orange Book: Approved Drug Products with Therapeutic Equivalence Functions (DX388) (2014). The FDA approved once-daily Namenda XR in June 2010. Meury IH Tr. (DX488) 160:22-24; Taglietti Dep. 166:20-22 (CD Ex. 42). The patents that cover Namenda XR expire in 2029, several years after those covering the original Namenda IR. Tr. 598:21–599:1 (Meury); U.S. Food & Drug Admin., Orange Book: Approve Drug Products with Therapeutic Equivalence Evaluations (PX18). Forest is in litigation with potential generic competitors over these patents [redacted]. Tr. 203:8–23 (Saunders).

49. In the summer of 2011, Forest worked with market research firm GfK Healthcare to learn more about caregiver burdens and preferences and obtain caregiver feedback regarding Namenda and a potential Namenda XR combination therapy. GfK Healthcare, 2011 Alzheimer's Disease Caregiver Study (CD Ex. 4) (Aug. 15, 2011). In late 2012, GfK surveyed physicians on behalf of Forest, in part, to gauge awareness of the upcoming Namenda XR. GfK Healthcare, 2012 Alzheimer's Disease Physician

Study (CD Ex. 3) (Dec. 20, 2012). Forest conducted further research in the spring of 2013. GfK Healthcare, Namenda Caregiver Research, Final Presentation (DX496) (May 2013).

50. In the 2013 survey, caregivers reported that they viewed Namenda XR as a "meaningful and welcome improvement" over the twice-a-day Namenda IR tablets. Id. at 6, 33 (emphasis added). Eighty percent of caregivers interviewed responded that they were likely to ask the patients' physicians about Namenda XR. Id. at 33.

51. Defendants obtained survey results that 90% of physicians support the switch from Namenda IR to Namenda XR. Tr. 34:18-22 (showing slide and citing 93% approval for discontinuation plan in opening statement). However, the 90% figure is based on a single question that sought a rating from 1 to 10, but first instructed the physicians to assume caregiver and patient satisfaction. Tr. 505:7-506:17. Other open-ended questions indicate that some doctors were outraged by the forced switch scheme. Tr. 513:17-18.

52. Forest did not bring Namenda XR to market until July 21, 2013. 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. (PX20) (June 21, 2010); Press Release, Forest Labs., Inc., Forest Announces U.S. Availability of New Once-Daily NAMENDA XR (PX21) (June 13, 2013). At that time, generic competition for Namenda IR was imminent, and Namenda XR was needed to accomplish the product extension strategy to protect its share of the market.

53. Forest spent approximately [redacted] educating patients, caregivers, health care providers, and pharmacists about Namenda XR, including Namenda XR's benefits and FDA-approved instructions for transitioning from Namenda IR to Namenda XR. Namenda XR Package Insert § 2.2 (Sept. 2014) (DX368); Meury Decl. ¶ 10 (DX720); Hausman Decl. ¶ 22 (PX287). After launching Namenda XR, Forest sold Namenda IR tablets, IR oral solution, and Namenda XR capsules concurrently. Taglietti Decl. ¶ 29 (DX303).

54. Namenda XR has the same therapeutic effect as Namenda IR but because of its one-a-day dosage it can reduce costs based on the number of pills administered by a caregiver, the time expended in pill administration. Tr. 59:12-13 (Lah).

55. Defendants are in the process of developing and/or marketing another future product, a Fixed Dose Combination ("FDC"), that combines Namenda XR with donepezil, the once-a-day CI, in one pill. Meury Decl. (DX720) ¶ 9; see Taglietti Decl. (DX303) ¶¶ 17-20; Meury Dep. 26:24-27:2. Defendants are currently seeking FDA approval for the FDC product. Saunders Hr'g 272:23-273:3.

IV. Defendants Have Monopoly Power

A. Medical Practice Demonstrates Memantine Is Its Own Market

56. In practice, doctors commonly prescribe a CI in the early stage of the disease. Tr. 54:12–18 (Lah); Tr. 732:21–733:4 (Reisberg). Namenda is prescribed in the moderate-to-severe stages, in addition to the CI, or alone if CIs cannot be tolerated due to side effects. Lah Decl. (PX85) ¶ 9; Tr. 54:19–55:1 (Lah); Tr. 732:21–733:4 (Reisberg); Tr. 760:1–6, 760:16–24 (Kohrman); Jacobs Dep. 92:14–93:10; 102:6–19 (explaining that all patients who clinically qualify to take a CI are prescribed one unless they have side effects, and explaining the differences between the functions of memantine and CIs); Jacobs

Dep. 102:6–19 (“[T]he cholinesterase inhibitor will be most effective when there is cholinergic deficiency at the same time that there is neurons around to utilize the return of acetylcholine and . . . memantine will be more effective any time the brain cells are leaking calcium”); Rovner Dep. 68:25–69:11 (“Q. They complement one another, would you say? A. They work in different ways, and tackle the problem from different directions, but they all have the same focus. Q. So they work with differing mechanisms? A. That’s right.”); see also “Namenda Franchise Business Plan” (PX68) at FRX-NY-01648216 (“As Aricept is indicated for mild patients it is usually initiated first. Namenda is usually added when the patient progresses to the moderate stage of the disease . . . .”).

57. Namenda IR is not indicated for use with mild-stage Alzheimer’s Disease patients. FDA “Highlights of Prescribing Information (PX109) (Sept. 2014). Using Namenda for early Alzheimer’s patients has little clinical support. Press Release, Forest Labs., Inc., Forest Laboratories Announces FDA Decision on Supplemental New Drug Application for Namenda® (PX43) (Jul. 25, 2005).

58. Doctors do not consider CIs to be reasonable substitutes for Namenda. Tr. 63:18–64:1 (Lah); Lah Decl. (PX85) ¶ 7 ("To the best of my knowledge, there are not therapeutic substitutes for Namenda currently on the market"), ¶ 10 ("Almost all of my patients who take Namenda also take a CI. The two drugs are not interchangeable; rather, they seem to have the greatest beneficial effect when they are used together"); Tr. 760:15–24 (Kohrman) ("[I]n the mild stage of the disease the typical way of approaching this is that . . . I will prescribe a cholinesterase inhibitor, calling it a CI . . . and if they progress into the moderate or moderate to severe stage, at that point continuing the cholinesterase inhibitor, I will add Namenda to that regimen"); Jacobs Dep. 106:7–23 ("I . . . start with a cholinesterase inhibitor, because I am usually seeing them earlier in the phase of their dementia syndrome, and then try to get them on both drugs because that's two different types of good band-aids to help them think better.").

59. Doctors do not switch patients from Namenda to a more affordable CI because they are not substitutes for one another. Tr. 63:18–64:1 (Lah) ("Q. Did you consider switching your patients on Namenda IR to a cholinesterase inhibitor? A. No. Q. Why not? A. That wouldn't make any sense. Q. Why not?

A. The drugs very different. So Namenda works by an entirely different mechanism than any of the cholinesterase inhibitors, so they're not equivalent drugs.")

60. Instead, the two classes of drugs are complements: 70% of Namenda patients also take an ACI. Tr. 609:9–19 (Meury); Namenda Franchise Business Plan (PX24) at FRX-NY-01686842; Forest Laboratories Management Discusses Q2 2014 Results, Earnings Call Transcript at 4 (PX485); Jennifer Rinaldo email re: Namenda and Carip Business Reviews (PX68) at FRX-NY-01648216; Tr. 883:11–14 (Cremieux).

61. Even in instances where memantine is prescribed without a CI, i.e., as a monotherapy, it is the severity of the CIs' side-effects that eliminates that class of drugs altogether as a viable therapy. Lah Decl. (PX85) ¶ 9; Tr. 54:19–55:1 (Lah); Tr. 732:21–733:4 (Reisberg); Tr. 760:1–6, 760:16–24 (Kohrman); Jacobs Dep. 92:14–93:10, 102:6–19.

62. Thus, whether prescribed alongside CIs or as a monotherapy, medical practice establishes that memantine is not a substitute for CIs.

B. Empirical Analysis Demonstrates Memantine Is Its Own Market

63. The economic evidence also establishes that CIs are not reasonable substitutes for Namenda. Tr. 346:16–348:8; 351:17–20: 352:3–5; Tr. 358:16–20 (Berndt); Berndt Decl. (PX64) ¶¶ 23–28; Tr. 359:15–361:2 (Berndt) (discussing PX331).

64. Dr. Berndt's study of the cross elasticity of demand between Namenda IR and a generic form of one of the CIs, donepezil, demonstrated little to no switching from Namenda to donepezil when the relative price of donepezil fell. Tr. 351:3–20 (Berndt); Tr. 346:16–351:15; 351:25–6; 352:7–22 (Berndt); Berndt Decl. ¶¶ 29–32. This pattern continued for a number of years after the relative drop in donepezil's price, in fact memantine's demand slightly increased following the donepezil relative price reduction, suggesting the two medications are complements rather than substitutes. Tr. 355:14–356:4 (Berndt). This finding establishes a low cross elasticity of demand between the two drugs, and supports the State's contention that memantine and CIs do not comprise one market of competing Alzheimer's drugs.

65. Dr. Cremieux's, Defendants' expert's, conclusion that cross elasticity of demand between memantine and donepezil

was substantial is not as persuasive as Dr. Berndt's. Dr. Cremieux's conclusions were based on a data sample of approximately less than 600 prescriptions from one employer. Tr. 362:11–363:11 (Berndt). By contrast, Dr. Berndt's conclusion was based upon the behavior of multiple payors, representing over one million prescriptions pulled from the entire U.S. market. Tr. 362:11–363:11 (Berndt). Moreover, Dr. Cremieux's dataset reflected changes to patients' copayments alone, while Dr. Berndt's data included both health plan and patient costs. Tr. 367:10-9 (Berndt).

66. Dr. Cremieux's other principal analysis is based upon a 2013 Forest study documenting "reversals," i.e., where a Namenda XR patient does not fill his prescription, and "rejections," i.e., where a Namenda XR patient's insurance company refuses to pay for Namenda XR. See DX093; Cremieux Dep. 165:15-168. Patient reversals are not useful proxies for substitutability. Substitutability assumes that changes in relative price result in changes in demand. Reversals in this data set, on the other hand, do not control for other non-price factors that may affect a patient's decision to refuse XR, such as an increase in negative side-effects when switching from CIs to memantine. Payor rejections are likewise ill-suited to a substitutability analysis. Defendants study shows that [redacted] of

those Namenda XR prescriptions that were rejected by payors were filled with another product. DX093 at slides 2, 6. Of this [redacted] group, about [redacted] were filled with Namenda IR, and roughly the remaining [redacted] were filled with a CI. [redacted] But an insurer refusal to pay for the Namenda XR is equivalent to a highly significant price increase on that drug since the patient sees his effective price shift from the co-payment to the full retail price of the drug. Therefore, the ratio of the two, the cross-elasticity, is too small to demonstrate substitutability.

67. To the extent that Dr. Berndt's and Dr. Cremieux's cross elasticity of demand analyses conflict, Dr. Berndt's relatively data-rich analysis is more credible.

C. Defendants' Business Strategy Demonstrates Memantine Is Its Own Market

68. In addition to medical practice and empirical evidence, Defendants' own withdrawal strategy illustrates that CIs are not substitutes for NMDA receptor antagonists such as Namenda IR. If they were, Forest's withdrawal of Namenda IR

from the market would drive Namenda patients to CIs, many of which are much less expensive than Namenda XR. Indeed, it is the complementary nature of CIs and memantine that gives Defendants' FDC product a comparative advantage. Meury Hr'g 566:4-23; see also Hausman Hr'g 664:11-665:6. Meury Decl. ¶ 9 (DX720); see Taglietti ¶¶ 17-20 (DX303); Meury Dep. 26:24-27:2. Defendants are experienced producers in the market that have premised their Namenda IR strategy on the absence of substitutes for memantine. Defendants' studies predict that approximately [redacted] or more of Namenda IR patients will switch to Namenda XR as a result of the intended discontinuation. Presentation titled "Namenda IR & XR Conversion Plan" (PX31). In January 2013, a Forest employee expressed confidence that discontinuing Namenda would likely be successful because, unlike other attempts to pursue similar product extension strategies, "there are no alternatives" to Namenda—"although of course patients could simply stop taking the drug." Presentation titled "Namenda IR & XR Conversion Plan" (PX31) at FRX-NY-01575875. This was so, even though donepezil (the generic version of Aricept) has been and continues to be priced significantly lower than Namenda XR. Tr. 892:8–25 (Cremieux).

69. Accordingly, NMDA receptor antagonists, including Namenda IR, Namenda XR, and any future AB-rated generics that may enter constitute the relevant product market ("memantine market"). Tr. 336:14–16 (Berndt). Defendants currently have all of the sales in that market. Tr. 344:9–19 (Berndt). Patents and other regulatory requirements presently prevent potential competitors from entering that market.

70. There is no dispute that the relevant geographic market is the United States.

V. Forest's Anti-Competitive Conduct

A. Defendants Strategies to Avoid the Patent Cliff

71. If Defendants maintain the status quo with respect to IR sales and distribution, generic memantine will have about 80% of the total memantine market within three months and 90% after twelve. Berndt Decl. (PX064) ¶ 63.

72. By Fall 2012, Forest was considering ways to convert patients from IR to XR prior to the availability of generic memantine. PX14–PX17. Forest 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:

> Our mission is to convert to Namenda XR and lift the franchise as a result of increased sales calls and combination therapy usage . . . . Make no mistake about it, this is a sprint. We need to convert as much IR business to Namenda XR as quickly as possible.

PX22 (Speech from Namenda XR launch event, June 2013) at FRX-NY-01573603–04. Another executive wrote in a draft speech:

> [T]he core of our brand strategy with XR is to convert our existing IR business to Namenda XR as fast as we can and also gain new starts for Namenda XR. We need to transition volume to XR to protect our Namenda revenue from generic penetration in 2015 when we lose IR patent exclusivity.

PX23 at FRX-NY-01574212.

73. In June 2013, Forest's senior marketing executives considered two alternatives to the typical soft switch approach described above: completely discontinuing Namenda IR; or "technically" leaving the drug on the market, but severely restricting patient access with "limited distribution." Presentation titled "Namenda IR & XR Conversion Plan" (PX31).

74. In a presentation attached to a June 26, 2013 email between two of Defendants' executives dated, the author notes that, with respect to Forest's conversion strategy, "[e]ither [a withdrawal or limited distribution] approach is unprecedented . . . [we] would be operating in uncharted territory." Namenda IR + XR Conversion Project (PX32) at slide 4. 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." Namenda IR + XR Conversion Project (PX32) at slide 4; see also PX14; Tr. 183:22–184:17 (Stitt) (describing differences between the Namenda IR hard switch and prior situations where there were substitutes for the discontinued drug: "So the unique thing here I think is that there's really no place for prescribers to, to go with a drug to treat that condition.").

75. On October 18, 2013, a Forest executive emailed his colleagues, announcing the decision to withdraw Namenda from the market: "Dear all: Forest has made the decision to discontinue sales of Namenda IR and transition all patients to Namenda XR." Saunders testified that he made the decision. Tr.

262:18–23 (Saunders). By doing the hard switch, Forest hoped to hold on to a large share of its base instead of losing them to competition. Tr. 219:12–16 (Saunders).

76. In a January earnings call, Saunders explained that the purpose of the hard switch was 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.

Tr. Of Jan. 21, 2014 earnings call, annexed to Zain Decl. as Ex. 1.

77. On February 14, 2014, Forest began the "forced switch" by publicly announcing that Namenda IR tablets would be discontinued on August 15, 2014. Press Release, Forest Labs., Inc., Forest Laboratories to Discontinue Namenda Tablets, Focus on Once-Daily Namenda XR (Feb. 14, 2014), annexed to Zain Decl. as Ex. 33. That same day, Forest notified the FDA that it would

"be discontinuing the sale of Namenda Tablets effective August 15, 2014." Zain Decl. Ex. 34. Forest 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." Patrick Boen letter to healthcare providers (PX37).

78. Forest's announcements of its plans for discontinuance were made to alert physicians and patients that Forest would be discontinuing IR so they could take appropriate actions. Tr. 616: 18–20 (Meury). Physicians interpreted the announcement as a warning to switch their patients from Namenda IR to Namenda XR. Tr. 61:8–19 (Lah) (viewing the announcement as forcing a "wholesale switch" of patients from Namenda IR to Namenda XR).

79. In its Form 10-K filing with the Securities and Exchange Commission for fiscal year 2013 (ending March 31, 2014), Forest made representations that it would discontinue Namenda IR on August 15, 2014. In Item 7, which relates to "Management's Discussion and Analysis of Financial Condition and Results of Operations," Forest's 10-K reads: "In February 2014,

the Company announced that it would discontinue the sale of Namenda tablets effective August 15, 2014."

80. Forest sought to convert the drug's largest customer base, Medicare patients, from XR to IR by having the CMS remove IR from its FRF. On Feb. 5, 2014, a Forest employee wrote an email to the Defendants' Executive Vice President 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.

Decl. Ex. 39 at FRX-NY-01596407. The letter was approved and sent. Amanda Seef-Charny email re: FW: Forest Laboratories to Discontinue Namenda® Tablets, Focus Once-Daily Namenda XR® (PX39). Defendants' expert pharmaceutical consultant witness testified that she has never in her consulting experience heard of a company sending such a letter. Edgar Hr'g 63:24–25. If the drug is not on the FRF, health plans are less likely to include it in their formularies and, thus, health plans may not cover Namenda tablets starting in January 2015. Stitt Decl. (PX122) ¶¶ 29–31.

81. As Forest sought to accomplish the switch from IR to XR, Forest executives began to express concerns that their efforts would be insufficient to switch a high enough number of patients from Namenda IR to Namenda XR prior to the market entry of generic memantine. William Meury email re: Namenda XR Weekly Performance Tracker – WE 8-9-13 (PX28) at FRX-NY-01618169–70.

82. Patients and their physicians are reluctant to switch from Namenda IR to Namenda XR. Lah Decl. (PX85) ¶¶ 11, 22, 25. The benefits of a switch from Namenda IR to Namenda XR are often marginal. Tr. 58:5–15 (Lah); Lah Decl. (PX85) ¶ 15 ("In my experience, compliance has not been a problem. A twice-daily regimen is easy to follow . . . ."). No studies have been done to show that Namenda XR is more effective than Namenda IR. Taglietti Dep. 181:7–16, 211:22–212:7. Being able to take Namenda once a day instead of twice, is not a significant benefit for patients already taking other twice-daily medications. Lah Decl. (PX85) ¶¶ 15, 22.

83. According to Polivka-West, most Alzheimer's patients are in a long-term care facility (Tr. 626:6–13)

(Polivka-West), and that the average patient in a long-term care facility takes nine pills per day. Tr. 641:5–22 (Polivka-West). She also testified that long-term care facilities generally dispense pills three times a day. Tr. 640:4–6 (Polivka-West). Thus, a patient that switches from Namenda IR to Namenda XR might go from nine pills a day to eight pills a day, Tr. 642:5–8 (Polivka-West), and given that pills are dispensed three times a day, it is possible that the patient is still going to have to take pills multiple times per day. Tr. 642:9–12 (Polivka-West).

84. Only half of all patients are willing to pay more money out-of-pocket to reduce their pill burden by half (e.g. going from eight pills per day to four). Tr. 642:13–643:17 (Polivka-West) & Pill Burden in Hypertensive Patients Treated with Single-Pill Combination Therapy: An Observational Study (PX349) at 414.

85. For some patients (and their physicians), the benefits of the change to Namenda XR are outweighed by the risks of changing the medical routine of a highly vulnerable patient. As Dr. Lah explained:

> 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.

PX85 (Lah Decl.) ¶ 24; PX64 (Berndt Decl.) ¶ 84 (discussing reasons why twice-daily Namenda may be preferred by some patients).

86. 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 the patient is doing well. Tr. 58:5–15 (Lah); Lah Decl. (PX85) ¶ 25; Rovner Dep. 106:18–25, Oct. 29, 2014 ("Q. And if the caregiver said I would rather just keep my husband or wife on the medication they're taking, they seem to be doing fine, what would you do? A. I would go along with that.").

87. As a result, despite aggressive marketing and pricing practices typical of a soft switch, Forest forecasted in late 2013 that only about [redacted] of patients using Namenda IR tablets could be voluntarily converted to Namenda XR prior to availability of generic Namenda IR. William Meury email re:

Namenda Financials (PX29) at FRX-NY-01566763. If physicians and patients had the choice, many would stay on the original formulation. As one Forest executive stated, "I could see doctors just being apathetic about it and if patient is fine and not complaining of any issues, why switch?" William Meury email re: Namenda XR Weekly Performance Tracker – WE 8-9-13 (PX28) at FRX-NY-01618168.

88. For Forest's plan to avoid the "patent cliff" to be successful Forest had to switch large numbers of patients from Namenda IR to Namenda XR. Tr. 412:15–20 (Berndt); Berndt Decl. (PX64) ¶¶ 76, 79. Forest also realized that, to be successful, its product switch had to be accomplished before less expensive generic versions of Namenda IR tablets became available in the market. Transcript of Forest Earnings Call, January 17, 2014 (PX3) at FRX-NY-01642564 (Saunders: "IR will go generic in July of 2015. And so the sweet spot for a [Namenda] switch would be in the fall [of 2014]"). Once generic memantine became available, generic and branded Namenda IR would be AB substitutable at the pharmacy, and most patients with prescriptions for Namenda IR would likely switch to generic memantine instead of Namenda XR. Tr. 375:21–376:5 (Berndt).

89. If, however, Forest could get patients, physicians, and insurers to switch to Namenda XR before the entry of generic memantine, Forest would be able to prevent manufacturers of generic Namenda IR from effectively competing for those patients. Generic memantine tablets would not be AB-substitutable for Namenda XR under state substitution laws. A pharmacist would have to call the prescribing physician in order to substitute lower-priced generic memantine for branded Namenda XR. Stitt Decl. (PX122) ¶ 38; Tr. 409:9–23 (Berndt).

90. Forest gave priority to converting patients from Namenda IR to Namenda XR as quickly as possible. In Defendants' CEO's words, "I think our view is that what we're trying to do is make a cliff disappear." Tr. 197:5–22. It was one of the three key elements in its strategy to protect the Namenda franchise sales stream. Tr. 201:9–18 (Saunders); Transcript of Forest Earnings Call, January 17, 2014 (PX3) at 8; Namenda Transition PowerPoint presentation, Dec. 2013 (PX363).

91. Forest's CEO stated during a January analyst call: "We're very focused on our 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." Transcript of Forest Earnings Call, January 17, 2014 (PX3) at 2. A document titled "Namenda Franchise Business Plan" dated September 2013 specifically explains that the sales target for "converting" Namenda patients must be achieved "prior to the Namenda LOE [loss of exclusivity] in 2015." FRX-NY-01686842 (PX24).

92. A separate presentation lists "Maximize XR Conversion leading up to IR LOE [loss of exclusivity]" as a key part of Forest's strategy for convincing health plans to pay for Namenda XR. Namenda XR FY15 Business Plan Managed Care (PX25) at 4. Forest agreed to pay [redacted] rebates to health plans to make sure they put Namenda XR on the same tier as Namenda IR so that members would not have an incentive to choose Namenda IR. Carolyn Myers email re: FW: Namenda (PX15).

93. The total promotional budget for the Namenda franchise in fiscal year 2014 was [redacted], with "[a]ll funds . . . allocated to drive conversion from Namenda to Namenda XR." Namenda Franchise Plan (PX24) at FRX-NY-01686845. Last year, Forest spent hundreds of millions of dollars detailing, i.e., visiting doctors to promote, Namenda XR. Tr.

231:14-17 (Saunders). Forest knew that once generic Namenda IR entered the market, it would be even more difficult and expensive to promote Namenda XR. Tr. 218:21-23 (Saunders).

94. Since 2013, Forest has undertaken an aggressive marketing campaign aimed at converting as many IR patients to XR as quickly as possible prior to Namenda IR losing exclusivity.

[redacted]

95. As found above, third party payors use formularies to influence the drugs doctors prescribe and patients take. To achieve formulary coverage for Namenda XR, Forest negotiated with health plans to obtain "preferred brand" status with top Part D plans nationally. See Hausman Decl. (PX287) ¶ 13, tbl. 1; Meury Dep. 22:3-25; Kane Dep. 276:25-277:4; Meury Decl. (DX720) ¶ 12; Devlin Dep. 118:25-119:5 (Forest negotiated to get XR on formularies after launch). The lower co-pay associated with "preferred brand" status lowers the

price to patients and can be crucial to a new drug's success because better formulary positioning results in substantially higher demand. See Hausman ¶ 12 (PX287); Hausman Hr'g 659:23-662:3 (testifying that formulary tier status can result in $350 to $1000 a year savings to a patient and provide "an incentive to switch"). For patients, because "nonpreferred" brands have higher co-pays, the negotiated "preferred brand" formulary position can result in patient savings of up to $40 per prescription, depending on the plan. Tr. 111:23-112:5 (Stitt). For other plans with three rather than four tiers, Forest achieved a tier status identical to Namenda IR in most cases. Devlin Dep. 127:19-148:10; PX242-PX251 (formularies for several health plans).

96. Forest discounted Namenda XR at a minimum of 5% discount from the wholesale acquisition cost ("WAC") of the Namenda IR tablets. Meury Decl. (DX720) ¶ 12; Kane Dep. 275:23-276:10. On average, the discount of XR is [redacted] off the average selling price of Namenda IR. See Meury Dep. 23:3-7. Where additional discounts apply, Forest positioned Namenda XR to be over [redacted] less expensive for health plans than Namenda IR tablets. Meury Decl. (DX720) ¶ 12.

97. Discounts that Forest offered ranged "anywhere from [redacted] percent." Devlin Dep. 120:10-18; Meury Hr'g 593:24-594:1 ("We have to negotiate . . . in some cases [redacted] discounts with health plans . . . ."). For example, one of the [redacted] providers "of the Medicare Part D benefit in the country" secured a discount of over [redacted]. Meury Hr'g 579:9-14. In 2014, managed care organizations paid approximately [redacted] less for Namenda XR than for Namenda IR. Meury Dep. 22:21-25. Meury testified that when the "tidal wave" of generics comes in 2015, [redacted] Meury Hr'g 594:6-9. The total discounts given by Forest exceed [redacted]. See Meury Hr'g 580:20-581:5.

98. During the same period, executives at Forest became aware that problems in the manufacturing and supply of Namenda XR presented a substantial risk that they would be unable to discontinue Namenda IR and effectively implement the proposed forced switch by August 15, 2014 because it would be unable to supply the market with sufficient Namenda XR. Stewart Decl. (DX717) ¶ 10; Meury Decl. (DX720) ¶¶ 22-23; Press Release, Forest Labs., Forest Laboratories Announces Intention to

Continue Marketing Both NAMENDA® TABLETS and Once-Daily NAMENDA XR® Into the Fall of 2014 (DX371) (June 10, 2014).

99. In June 2014, in light of manufacturing issues affecting the yield of production batches of Namenda XR, higher than expected demand, and other factors, Forest announced that it would continue selling Namenda IR tablets through Fall 2014. Press Release, Forest Labs., Forest Laboratories Announces Intention to Continue Marketing Both NAMENDA TABLETS and Once-Daily NAMENDA XR® Into the Fall of 2014 (DX371) (June 10, 2014); see Stewart Decl. (DX717) ¶ 10; Meury Decl. (DX720) ¶¶ 22-23.

100. Following improvements to the XR manufacturing process, Forest regained the ability to supply the market. Stewart Dep. (CD Ex. 37) 87:6-23; Stewart Decl. (DX717) ¶ 13. On November 5, 2014, in the Actavis 3rd Quarter Earnings Press Release the company confirmed: "The Company continues to enhance manufacturing efficiencies related to its once-daily dosing of Namenda XR, and is now producing product at capacities sufficient to support transitioning all Namenda IR twice daily tablet patients to its Namenda XR® once-daily product." See Press Release, Actavis Net Revenue Increases 83% to $3.7 Billion

in Third Quarter 2014; Non-GAAP EPS Increases 53% to $3.19 (Nov. 5, 2014).

B. Distribution through Foundation Care

101. Forest actively considered alternative plans to outright discontinuance of IR, including after the State began investigating the planned withdrawal in February 2014. According to Meury, Forest's plan for limited distribution was "on the table" in February 2014 when Forest announced its plan to discontinue Namenda IR as of August 15, 2014; he also testified that it was still "on the table" when Forest announced in June 2014 that the August date was extended to the Fall. Tr. 615:1–14 (Meury). However, neither the February nor June announcements mentioned any alternative plan. See Pill Burden in Hypertensive Patients Treated with Single-Pill Combination Therapy: An Observational Study (PX34); 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" (PX41) (June 10, 2014).

102. Forest began speaking with Foundation Care LLC ("Foundation Care") about a limited distribution plan [redacted]

[redacted]. Tr. 616:21–25. Established in 2004, Foundation Care is accredited by the Accreditation Commission for Health Care (ACHC) as a specialty pharmacy and by National Association of Boards of Pharmacy as a Verified-Accredited Wholesale Distributor (VAWD) through July 22, 2017. Master Service Agreement ("MSA") (DX607); Foundation Care Verified-Accredited Wholesale Distributors Accreditation (DX97). It is also recorded with the New York State Board of Pharmacy as a Non-Resident Establishment Registered Wholesaler of Drugs and/or Devices, valid through May 2017, DX101-DX103, and holds a controlled substance license from the New York Department of Health, valid through November 2015, N.Y. State Dept. of Health Controlled Substance License (DX99). Foundation Care is a "full-service retail pharmacy, so any product that's available from any store in the country can be made available through Foundation Care." Blakeley Dep. 17:18-24, 38:15-18 (CD Ex. 45). Foundation Care provides reimbursement coverage for most all commercial health care plans as well as Medicaid (Pharmacy and DEME) and Medicare (Part B & D). Foundation Care Overview and Capabilities Presentation (DX87) (Oct. 21, 2014).

103. [redacted] after the State filed its initial complaint in this action, Defendants signed a Master

Services Agreement ("MSA") and Work Order with Foundation Care, to distribute Namenda IR tablets directly to patients whose physician decides it is medically necessary. MSA (DX88) [redacted]; Blakeley Dep. 46:1-6, 29:13-15. On November 5, 2014, Forest publicly announced its distribution arrangement with Foundation Care ("limited distribution"). Press Release, Actavis, Actavis Net Revenue Increases 83% to $3.7 Billion in Third Quarter 2014; Non-GAAP EPS Increases 53% to $3.19 (DX721) (Nov. 11, 2014); Kane Hr'g 500:22-501:2.

104. Under the MSA, Defendants remain the sole supplier, or "vendor," and Foundation Care becomes the sole distributor, [redacted] of IR tablets. See MSA (DX88) [redacted]. Foundation Care will ship the Namenda IR tablets within two business days of receipt of a valid prescription and Medical Necessity Order Form [redacted] MSA, Work Order No. 1 § 2.7(a) (DX88); see also Stitt Hr'g 129:12-14.

105. Foundation Care is expected to dispense Namenda IR tablets to patients on the basis of a prescription and a

Medical Necessity Form from physicians. The Work Order's Medical Necessity Form requires basic information: patient information, physician information, and a prescription; as well as a physician certification that the "Namenda [IR] tablets are medically necessary." MSA, Work Order No. 1, Medical Necessity Form (DX607); Kane Dep. 295:1619 (CD Ex. 30).

106. Though there are currently "millions" of IR prescriptions in the market, Saunders Dep. 346:19–20, [redacted] Defendants' economics expert agrees. Cremieux Dep. 91:4–15 (referring to Forest's limited distribution plan as "largely eliminating the use of that product"). Defendants predict that less than 3% of patients will take advantage of the Foundation Care program. Press Release, Actavis Net Revenue Increases 83% to $3.7 Billion in Third Quarter 2014 dated November 5, 2014 (PX501) (stating "for select groups of patients, perhaps less than 3 percent, the continued utilization of the twice-a-day tablet dosing of Namenda® might be necessary for treatment").

107. Limited distribution could impose an undue burden on physicians and their staffs, who would have to fill out more paperwork to obtain the drug for their patients, with no financial incentive to do so.

108. Like discontinuance, limited distribution would create artificial roadblocks to patient access to Namenda IR. Tr. 61:8–19 (Lah). Defendants have instructed their specialty pharmacy distributor not to dispense Namenda IR to patients unless a physician has signed a form stating that the patient has a "medical necessity" for Namenda IR. Tr. 549:2–10 (Kane). Defendants designed those roadblocks to protect their profits. Tr. 244:23–245:2 (Saunders) ("Q. The reason that you are requiring the medical necessity form is a competitive reason; it's not a medical reason, right? A. I guess you could lump it into a competitive reason.")

109. Because Namenda IR and XR are pharmacologically the same drug, doctors may not be willing to sign such a form. PX85 (Lah Decl.) ¶¶ 29–31. Dr. Lah explained the reluctance that he and other physicians may feel as follows:

> Q. Would you be uncomfortable signing this form for most of your patients even though they might, even

> though you might prefer that they continue on IR instead of switching to XR? A. Yes.

Tr. 70:14–17. He continued:

> So I'm not sure I would be comfortable continuing to prescribe Namenda IR if it were required me to declare that it was medically necessary for an individual to stay on that drug, when another perfectly good drug, Namenda XR, which may also be perfectly safe and effective may also be available for that patient.

Tr. 72:11–16 (Lah).

110. A prescription does not indicate medical necessity for Namenda IR tablets given the availability of Namenda XR:

> And so when I prescribe a medication and indicate a specific version should be dispensed, then I am indeed declaring that it is medically necessary for that individual to have that version of the drug. But as a general matter, prescribing medications in my mind does not imply that level of medical necessity.

Tr. 106:2–7 (Lah); see also Tr. 733:17–23 (Reisberg) ("Q. And I believe you testified before that you don't see a medical need for Namenda IR tablets on the market, is that correct? A. What I said was that for some of my patients, finances are a concern. At the moment—two different issues here. Yes, at the present

time, I do not—right, I do not see any—any medical need for the IR tablets, that's correct.").

111. Defendants' survey data and testimony indicate that only 2.4% of patients would be able to obtain the drug under the "medical necessity" standard, consistent with the State's contention that physicians will be reluctant to certify that Namenda IR tablets are medically necessary for their patients. Tr. 535:14–16 (Kane) ("So based on the surveys, we have quantified that approximately 2.5% or so of patients would require Namenda [IR] tablets based on medical necessity"); Kane Decl. (PX282) Ex. A; Press Release, Actavis Net Revenue Increases 83% to $3.7 Billion in Third Quarter 2014 dated November 5, 2014 (PX501) (stating "for select groups of patients, perhaps less than 3 percent, the continued utilization of the twice-a-day tablet dosing of Namenda® might be necessary for treatment.").

112. The limited distribution of Namenda IR does not materially alter the nature and impact of the earlier hard switch strategy. Tr. 336:9-337:8 (Berndt). Both discontinuance and the limited distribution are functionally hard switches.

C. The Absence of Business Purpose

113. Defendants have not established a legitimate pro-competitive justification for their plan to limit IR distribution until generic entry. Tr. 337:2–4, 411:24–412:20, 415:12–416:20 (Berndt).

114. Defendants have stated that the very purpose of the limited distribution is to blunt generic competition and prevent the operation of state generic substitution laws. Tr. 228:13–15 (Saunders) ("Q. But you intend to fight back and try to blunt the force of those laws, right? A. That's the definition of competition.").

115. According to Saunders, generic substitution laws cause the deck to be "stacked against" Defendants, and "put the thumb on the scale for the generics." Tr. 227:5–9.

> [T]he market isn't designed for generics as a standalone versus innovator. It is the innovator, the generic, the pharmacy, the PBM, the managed care company all working against the innovator. The decks are stacked incredibly the other way. That's why we refer to it as a dog fight.

Tr. 223:25–224:4.

116. Defendants have stated that the company is fighting back against the state substitution laws by seeking to convert patients from Namenda IR to Namenda XR prior to generic entry, which would allow Forest to evade the application of these laws and thus have a better chance of protecting its sales. Tr. 223:25–224:4 (Saunders); Forest Laboratories F3Q 2014 Earnings Call Transcript (PX2) (Saunders: "if we do the hard switch and we've converted 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 [prescriptions]. 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. It is an obstacle that will allow us to, I think, again go into to a slow decline versus a complete cliff."). While Saunders discussed contemplated discontinuation of Namenda IR on numerous earnings calls with investors, he never suggested that this business tactic would result in any cost savings or other efficiencies. See generally April 29, 2014 transcript of earnings call (PX366); Forest Laboratories F4Q 2014 Earnings Call Transcript (PX82); Tr. of Jan. 21, 2014 earnings call (PX2); Forest Laboratories Management Discusses Q2 2014 Results, Earnings Call

Transcript at 4 (PX485); Tr. Of Jan. 21, 2014 earnings call, annexed to Zain Decl. as Ex. 1.

117. Under a conventional scenario, i.e., leaving the older drug on the market while competing on the merits to convince physicians that the newer one is better, it would take years to convince patients and physicians to switch to Namenda XR. Tr. 694:17–20 (Hausman). The forced switch limits access to Namenda IR in order to overcome what Saunders called the "inertia" that causes most patients and physicians to resist changing medicines, with the goal of impeding lower-cost competition and the result of driving up the average price for memantine. See Tr. 286:18–287:9 (Saunders), 376:3-17 (Berndt). This conflicts with the notion that patients should not be switched off of a drug that is working. Tr. 58:5–15 (Lah); Lah Decl. (PX85) ¶ 25; Polivka-West Dep. 90:2–7.

118. [redacted] Tr. 232:21–233:20 (Saunders); Tr. 411:24–412:5; 413:23–414:23; 415:12–416:5 (Berndt). Forest seeks [redacted] greater retention of sales after generic entry than it would have had absent a forced switch. TR:

233:21–23 (Saunders). As Dr. Berndt testified, [redacted] Tr. 411:12-412:20 (Berndt).

119. Defendants have referenced several pro-competitive for the limited distribution in conjunction with this litigation: [redacted] savings in inventory costs; savings due to greater "focus" and a reduction in manufacturing costs; benefits from "focus" on newer innovations; and distribution and other supply chain-related savings. Meury Hr'g 570:12-20; Meury Decl. (DX720) ¶ 14; Saunders Dep. 222:10-21; Saunders Dep. 66:13-17; Solomon Dep. 64:4-13, 203:7-17, 203:17-204:2; Meury Hr'g 569:17-21; Meury IH Tr. 270:11-272:24.

120. However, Defendants have not quantified most of the savings resulting from limiting distribution of Namenda IR. Tr. 234:25–235:4 (Saunders); Tr. 416:10–20 (Berndt). Defendants' economic expert has also not quantified any savings from discontinuing the widespread availability of Namenda IR. Cremieux Dep. 238:14-241:21.

121. Defendants' two senior management witnesses, Saunders and Meury, did not testify that the purported savings from the hard switch were considered when the strategy was adopted, nor do these explanations appear elsewhere in the documents produced by Defendants.

122. [redacted] Tr. 416:6–20 (Berndt); Berndt Decl. (PX64) ¶ 80–82 (pro-competitive rationales proffered by Defendants, including "focus," are not credible).

123. Presumably in part because of its announced discontinuance, [redacted] which addresses any concern that selling multiple drugs for the same indication reduces "focus." Tr. 221:5-9 (Saunders). While the oral solution is nominally on the market, Defendants do not promote it, and physicians do not prescribe it. Tr. 245:13–14 (Saunders); Tr. 58:16–59:1 (Lah); Tr. 732:9–12 (Reisberg); Jacobs Dep. 104:9–15; Rovner Dep. 102:18–20.

124. Since the launch of Namenda XR in mid-2013, [redacted] Tr. 605:16–606:4 (Meury). [redacted] Tr. 606:14–22 (Meury). Sales reps are told to promote Namenda XR, not IR. Tr. 606:14–22 (Meury). [redacted] Tr. 606:10–13 (Meury) [redacted].

125. Continuing to keep IR tablets available is highly unlikely to have any impact on Defendants incentive to innovate. Forest launched 8–9 new drugs in new therapeutic areas in the last five years without discontinuing or limiting distribution of any other drug. Tr. 894:3–895:5 (Cremieux).

VI. Effect of the Anti-Competitive Conduct

A. Damage to Competition

126. As found above, Namenda IR, Namenda XR, and in the future any AB-rated generics that may enter constitute the relevant product market, i.e., the memantine market. Tr.336:14–16 (Berndt). As found above, Defendants currently have all of the sales in that market. Patents and other regulatory requirements prevent potential competitors from entering that market. The first generic versions of Namenda IR are expected to enter the market in July 2015.

127. By implementing the limited distribution, Defendants game the generic substitution laws and prevent pharmacists from offering patients taking Namenda a lower-priced generic. As a result of the hard switch strategy, the pharmacist would need to contact the doctor in order to obtain approval for generic substitution. Tr. 409:12–23 (Berndt); Berndt Decl. (PX64) ¶ 50. If pharmacists are not permitted to dispense a lower-priced generic instead of the brand without needing to get a new prescription from a doctor, generics are unlikely to be able to make substantial sales. Stitt Decl. (PX122) ¶ 22; Lah Decl. (PX85) ¶ 32; Berndt Decl. (PX64) ¶ 50; Tr. 380:19–381:7, 381:11–15 (Berndt).

128. Generic products are typically not marketed to physicians or patients. Harper Decl. (PX496) ¶ 11; Tr. 62:24–63:1 (Lah); Jacobs Dep. 203:7–18 ("Q. What about from generic drug companies, do you get any marketing information or pens from those firms? . . . A. I don't remember ever getting—I don't know anything about generic companies honestly, never heard of one. Q. You can't name a single generic company? A. Not at all."); Tr. 759:8–25 (Kohrman) (no sales calls from generic manufacturers other than branded generics several years after entry).

129. For example, Mylan does not have any direct relationship with patients, does not talk to doctors, and does not do direct-to-consumer advertising. Moreover, "generic products . . . most efficiently will achieve sales through AB-rated substitution for the branded product at the pharmacy level." Tr. 327:1-14 (Harper). Generics compete on price and avoid marketing to physicians because the costs of such marketing severely impact their ability to offer the significantly lower prices upon which they compete. Tr. 299:24–300:3, 327:15–328:4 (Harper). In addition, "because the generic [firm] promoting the product would have no way to ensure that its generic product, rather than an AB-rated generic made by one

of its competitors, would be substituted for the brand by pharmacists, a substantial investment in marketing a generic product to physicians would not make sense as a practical matter." Tr. 328:5–11 (Harper).

130. Generic manufacturers do not generally market to health plans. As MVP's representative testified:

> Q. In your experience, do generic drug manufacturers engage in marketing?
>
> A. Not to the—I'm going to just answer no. But they may in journals put [advertisements] out. But I have never had a generic manufacturer call on me at the health plan. And I could have brand manufacturers coming in every day to sell their drugs.
>
> So I would say generic manufacturers don't market, and the—probably the most—I mean, the reason for that would be simple. Because if you're one of three and you get somebody to write a prescription and you didn't—and not indicate dispense as written, the benefit isn't necessarily going to accrue to you. You're only going to get, if there's three people out there, maybe a third of that business. So just the motivation behind marketing a generic product is limited when compared to a brand product.

Tr.117:5–19 (Stitt).

131. Generic manufacturers compete by selling products at a significant discount relative to their branded equivalents, and that discount typically increases as additional generic versions of a branded product enter the market. Tr. 376:12-17

(Berndt); Harper Decl. (PX496) ¶ 5; see Berndt Decl. (PX64) ¶ 17.

132. Price competition at the pharmacy, facilitated by state substitution laws, is the principal means by which generics are able to compete in the United States. See Berndt Decl. (PX64) ¶¶ 10, 22, 44–46; Stitt Decl. (PX122) ¶¶ 21–22; Tr. 116:4–117:4 (Stitt); Harper Decl. (PX496) ¶ 10; Tr. 299:12–23 (Harper); see also Tr. 409:6–11 (Berndt); Tr. 114:21–115:3 (Stitt); Tr. 897:3–22 (Cremieux); Brief for Intellectual Prop. & Antitrust Law Professors as Amici Curiae at 14, Mylan Pharms., Inc., v. Warner Chilcott Pub. Ltd. Co., 2:12-cv-03824 (E.D. Pa. May 7, 2014) (PX5) ("Under Hatch-Waxman and state substitution laws, generics can only compete cost-effectively through substitution on the new or old branded-drug version."). Generic Namenda will not be AB-rated to Namenda XR and generics will not be automatically substituted for Namenda XR (after entry in 2015) under New York's mandatory substitution laws. Tr. 115:19–25 (Stitt).

133. Non-AB-rated generic drugs, such as generic memantine, cannot compete effectively for sales of a branded drug in the same class, such as Namenda XR, even if the price of

the generics is much lower than the brand. For example, imposing utilization plans to shift people from Lipitor—the "biggest [drug] in history"—to generic simvastatin, a non-AB-rated generic in the same statin class, only resulted in 30% of patients switching from Lipitor to simvastatin. Tr. 815:13–817:5 (Kolassa).

134. If Defendants are permitted to execute the limited distribution, they would achieve significantly higher levels of conversion from Namenda IR to Namenda XR than they would have achieved absent the forced switch. Tr. 218:12–16 (Saunders). Before October 2013, Forest predicted that it could switch approximately [redacted] of Namenda IR patients to Namenda XR without a hard switch, but Defendants' hard switch strategy is expected to result in [redacted] of Namenda IR patients switching to XR prior to generic entry. Tr. 217:25–219:3 (Saunders); Presentation titled "Namenda IR & XR Conversion Plan" (PX31) at 31; Presentation discussing "Namenda Disruption Scenarios" (PX45) at 1; Meury email with subject line reading "Re: Namenda Financials" (PX46) at FRX-NY-01565787.

135. Forest has predicted that forcing a hard switch from Namenda IR to XR will generate over [redacted] in

additional sales of Namenda XR than it would have absent a hard switch. Tr. 221:10–15 (Saunders).

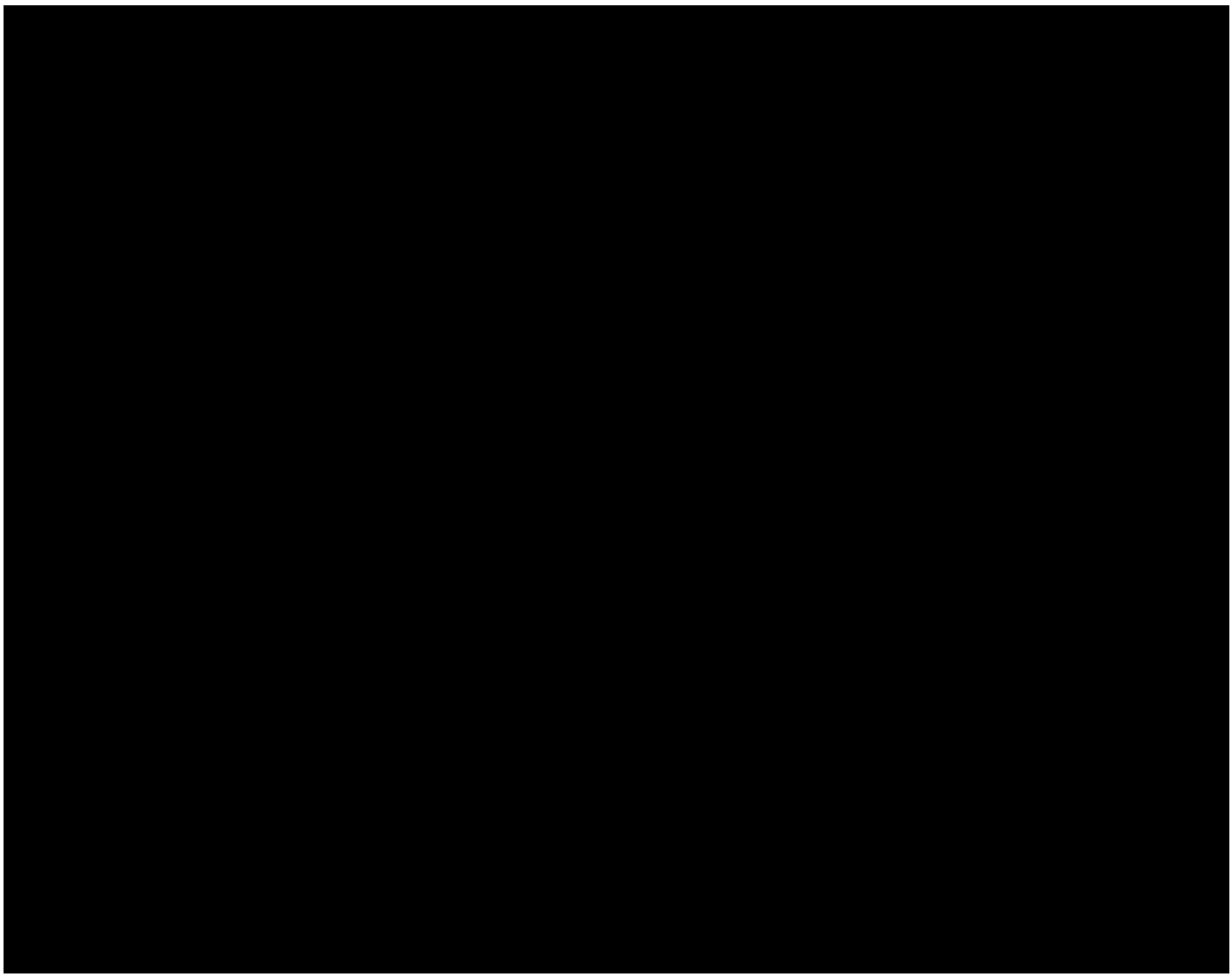
136. The limited distribution "is likely to have a significant impact on potential generic competition," in that "[d]iscontinuing Namenda [IR] in late 2014 and shifting the market to Namenda XR ensures that by the time generic entry occurs in July 2015, there will be few to no prescriptions of Namenda left in the market." Tr. 326:3–16 (Harper); Tr. 124:21–125:9 (Stitt) (because Namenda is the only drug in the "particular cascade" of drugs used to treat Alzheimer's, "prescribers will be forced essentially to switch to the XR product."). This decreases the sales opportunities available to generic manufacturers because few patients are left on Namenda IR who can switch to generics under state substitution laws. Tr. 380:15–381:10; 409:12–23 (Berndt).

137. Forest internally predicted that, absent the forced switch, it would only be able to switch [redacted] of Namenda IR prescriptions to Namenda XR prior to generic entry. Tr. 217:25–218:5 (Saunders). If [redacted] of patients switched to Namenda XR, then generic substitution laws would cause about 90% of the remaining [redacted] of patients still taking Namenda IR to be switched

to generics within a few months of generic entry. Tr. 217:25–218:16 (Saunders).

138. Meury stated to investors that perhaps 5–30% or more of patients taking Namenda XR might switch back from Namenda XR to generic memantine at some point after generic entry, a process occasionally referred to as "erosion" or a "reverse commute." April 29, 2014 transcript of earnings call (PX366) at 12–13; Tr. 88:2-8 (Lah), 223:13-22 (Saunders), 390:9–392:17 (Berndt), discussing PX366 ("Q. Okay. Now what did you take way from this exchange? A. I take it that by April of this year, Forest had conducted a fair bit of research, its marketing folks had done that; that they came up with a wide range of estimates, and that Meury and Saunders believed the range of 5–30 percent is a reasonable range. But notably it's much, much less than 100 percent or the 90 percent you would get from a conventional launch."). Meury represented to investors in the April call that generic erosion would not be on the high side of that estimate. April 29, 2014 transcript of earnings call (PX366) at 13. That is, 63% of the market would typically be generic.

139. As a result of the limited distribution, Defendants will be able to maintain their monopoly share of the market for memantine for longer than they would have otherwise. Defendants predicted that they would have had a [redacted] share of the market and generics would have had a [redacted] share but for the hard switch. Instead, under the hard switch scenario, the results are essentially inverted. In 2016, Defendants are likely to achieve an [redacted] share of the market and generics are likely to achieve a [redacted] share. The following graphic, PX580, prepared by the State, is based on data from Defendants' files and reflects this market effect:



140. Dr. Hausman, Defendants' economic expert, corroborated [redacted] that as a result of the hard switch, market shares would dramatically change. Tr. 688:7–11 (Hausman). He did not dispute that with the hard switch, a large number of the patients that would have gone on to generics would instead end up on Namenda XR. Tr. 692:12–16 (Hausman).

141. Mylan predicted, in early January 2014, that prescriptions being written for XR would reduce the market for IR by [redacted]. Tr. 300:6–303:17 (Harper); Mylan Namenda sales forecast, January 2014 (PX142). Following Forest's announcement that it would discontinue IR in August, the generic manufacturer revised its estimate of IR market share loss to [redacted]. Tr. 303:18–304:23, 305:7–11 (Harper); Mylan Namenda sales forecast, (PX145) (April 2014). After doing a "deeper dive" in the summer of 2014, the generic manufacturer further revised its estimate, estimating that the forced switch would reduce the Namenda IR market by [redacted]. Tr. 310:14–25 (Harper); Mylan Namenda sales forecast (PX148) (July 2014). Mylan's January forecasts predict that Mylan's revenue from generic Namenda IR will stabilize around [redacted] per quarter. Mylan Namenda sales forecast, (PX142) (Jan. 2014). By contrast, Mylan's July forecasts predict that Mylan's revenue from generic Namenda IR will stabilize at [redacted] per quarter. Mylan Namenda sales forecast, July 2014 (PX148). Defendants' CEO made a similar projection as to the effectiveness of the forced switch. Saunders Dep. 117:16–118:2; Tr. 117:5-25 (Saunders).

142. To date, about 50% of existing patients have converted from Namenda IR to Namenda XR in anticipation of the

lack of availability of Namenda IR. 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" (PX41) (June 10, 2014).

143. As found above, several factors are likely to inhibit switching from Namenda XR to generic memantine once it becomes available in the market. Physicians and caregivers are reluctant to disrupt patients' medical routines without a medical reason to do so. Tr. 131:8–133:22 (Stitt), 508:1-3, 541:21-542:4 (Kane).

144. In addition, health plans are reluctant to pressure patients to switch from a drug that they are already taking, a rule that applies especially powerfully in the case of vulnerable patients such as those with Alzheimer's. Stitt Decl. (PX122) ¶¶ 45, 47; April 28, 2014 earnings call (PX82) at 13.

145. MVP, the New York health plan, for example, is unlikely to try to move patients taking Namenda XR to Namenda IR because of the challenges of moving a patient off a drug when he is doing well on the drug he is taking. Tr. 134:12–139:16 (Stitt); Stitt Decl. (PX122) ¶ 45.

146. This reduction in the market opportunity for generics, from an estimated [redacted] prescriptions down to [redacted] within a few months, and further to [redacted] in six to eight months, is a substantial harm to competition. Tr. 380:15–381:15 (Berndt).

147. The Defendants' expert and fact witness predict that third party payors and the other intermediaries discussed at length above will intervene to thwart Defendants' attempts to limit generic memantine's drive into the market. See generally Kolassa Decl. (DX821) and this Opinion's Findings of Fact ("FOF") § II, E. [redacted] First, as sophisticated market participants with extensive experience as both branded and generic manufacturers of drugs, Defendants are unlikely to have adopted the limited distribution strategy, [redacted] and incurring the legal expense and reputational costs associated with this action, [redacted] Second, Dr. Kolassa's exhaustive analysis of the cost pressures faced by manufacturers generalized across

different drug markets. Neither he nor the Defendants analogized between the memantine market and the drug markets in which the eight other examples of "hard switches" occurred. As found above, this market features a unique unsubstitutable product and patients that are extremely sensitive to changes in routine. It is these specific characteristics that make limited distribution so harmful to patients and to competition, and therefore so enticing a strategy upon which Defendants hope to profit.

B. Damage to Consumers

148. Consumers benefit from the lower prices of generic drugs. Tr. 803:6–8 (Kolassa).

149. Once patients have switched to Namenda XR, it is very unlikely that most of them will switch to generic Namenda IR. In April 2014, Forest's head of sales told investors that perhaps 5–30% of patients taking Namenda XR might switch from Namenda XR to generic Namenda at some point after generic entry. Yoon Decl. Ex. 5 at 13.

150. This reduction in the market opportunity for generics, [redacted] of the market going to

generics without the forced switch, to only about 5–30% with the forced switch, not only substantially harms competition but affects the cost of memantine to consumers. Tr. 336:9–337:8 (Berndt). Based on Defendants' own data, Dr. Berndt testified that health plans will pay at least [redacted] more and patients will pay [redacted] more for memantine because of the actions challenged in this litigation. Berndt Decl. ¶¶ 61–64. Dr. Berndt's testimony was credible and substantially not impeached.

151. Physicians are reluctant to disrupt patients' medical routines without a medical reason to do so. Lah Decl. (PX85) ¶ 25 (won't switch a patient who is stable and doing well). One of Defendants' medical experts testified that he continues his patients' current prescription even when he would not prescribe the drug himself to patients not already taking it. Jacobs Dep. 81:14–82:11 ("[I]f they are on a drug and it is working for them and there was no reason to change it, I wouldn't change it."). After patients have been forced to bear a change in routine by switching to Namenda XR, physicians are reluctant to have their patients switch again. Lah Decl. (PX85) ¶ 11; Stitt Decl. (PX122) ¶ 47 ("[P]hysicians are also reluctant

to switch patients to a different drug when the patient is already doing well on the current drug they are taking.").

152. According to Saunders, this "behavioral change" inhibits switching from Namenda XR back to generic memantine. Declaration of Saami Zain, dated September 24, 2014 Ex. 1; Saunders Dep. at 204–05, annexed to Yoon Decl. as Ex. 12.

153. Defendants' forced switch will also result in dramatically higher drug costs for insurers and patients, who might otherwise have chosen the less expensive generic. Stitt Decl. (PX122) ¶ 36 (Defendants' forced switch will lead MVP to "incur substantially higher costs for its member[s]" and hurt patients, who would have higher co-pays for the brand); Tr. 411:24–412:20 (Berndt); William Meury email and attachment re: Namenda Transition Plan 1.ppt (PX339) (showing increased profits); Tr. 405:16–406:1 (Berndt); Berndt Decl. Figure 4 and accompanying text (showing harm to patients and plans). As Stitt, an executive at MVP, explained:

> 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.

PX122 (Stitt Decl.) ¶ 56.

154. Alzheimer's patients who are Namenda's users (those with moderate to late stages of the disease) are an especially vulnerable group of patients. Lah Decl. (PX85) ¶ 24; Stitt Decl. (PX122) ¶ 45; Tr. 379:8–14; 383:12–14 (Berndt); Forest Laboratories F4Q 2014 Earnings Call Transcript (PX82). Given Alzheimer's patients' vulnerability, "[a]ny small change in medication raises the risk of an adverse event" and "[e]ven a small change in a patient's condition can require him or her to be moved to a care facility." Lah Decl. (PX85) ¶ 24; Tr. 58:5–15 (Lah).

155. Physicians can also be reluctant to switch medications because the patients and others, such as their caretakers, must be educated on how the new medication is taken. Stitt Decl. ¶ 47; Polivka-West Dep. 72:23–73:4.

156. Further, the forced switch could actually result in a portion of these vulnerable Alzheimer's patients having to switch medications (and face the risks of adverse events) twice: once because Namenda XR will be the only product available to

patients; and again because some small number of patients may switch back to the generic Namenda IR once it is available.

157. Defendants' surveys show that many physicians, caregivers, and pharmacists are concerned about potential harm to patients from the forced switch. When presented with the possibility that Defendants would restrict the availability of Namenda IR, physician responses to the survey included statements like "terrible," "how awful," "horrible," "what kind of game is the drug company playing?," "It puts an undue burden on us and would anger me," and "Is this legal?" Physician survey responses concerning limited distribution plan (PX311) at 1; Physician survey responses concerning limited distribution plan (PX298) at 5, 14. Other physicians specifically complained of the reduction in choice, stating that they "would be frustrated that a good therapy is no longer available" (Physician survey responses concerning limited distribution plan (PX311) at 3; Physician survey responses concerning discontinuation plan (PX299) at 4; Physician survey responses concerning limited distribution plan (PX298) at 22, that they "would like the choice to be decided between myself and my patients," (Physician survey responses concerning limited distribution plan (PX311) at 3) and that they suspect Forest "is

manipulating the market to shift to XR product in anticipation of generic availability." Physician survey responses concerning limited distribution plan (PX298) at 22.

158. Defendants' economic expert testified that, based on actual decisions made in the market, approximately [redacted] of physicians prefer Namenda IR and approximately [redacted] prefer Namenda XR. Tr. 716: 19–25 (Hausman).

159. Defendants' surveys also asked doctors and caregivers whether the discontinuation of Namenda IR would be "acceptable," as opposed to a word with a more positive connotation, such as "desirable." Tr. 503:10–16 ("To be acceptable, they would accept it. They wouldn't challenge it."). Even using Defendants own surveys and methodology, 21% of the caregivers surveyed by the Defendants did not find discontinuation of Namenda IR to be acceptable. The reasons provided by such caregivers include "patient used to it," "keep things the same for now," "he likes having his schedule stay the same," "doing well [with] it, no reason [to] change," and "I prefer not to change up her medication at this point." Caregiver survey responses concerning preference for IR versus XR (PX304) at 2, 3, 9, 10, 15.

160. Defendants' documents reflect their expectation that "[p]rescribers, patients, caregivers may be confused or dissatisfied with either withdrawal or limited distribution scenario and may choose to discontinue Namenda treatment." Zain Decl. Ex. 31 at 4. Consequently, Forest projected that somewhere between [redacted] of all Namenda patients would not switch to Namenda XR and instead cease memantine treatment entirely. Zain Decl. Ex. 30 at 31; Zain Decl. Ex. 44 at 1; Zain Decl. Ex. 45 at FRX-NY-01565787.

161. If Defendants are allowed to implement their hard switch strategy, harm to consumers, and the corresponding gain to Forest, would be approximately [redacted] based on Defendants' expert's data. Tr. 405:5-406:6 (Berndt). Consumers would bear approximately [redacted] in additional co-payment costs and [redacted] in third party payor costs. Tr. 405:5-406:6 (Berndt).

162. Based upon the facts found above, the public interest would be served by an injunction. Defendants are entitled to a just return on their investment in Namenda IR, but having enjoyed that return for over a decade, the law now requires them to allow generic competitors a fair opportunity to

compete using state substitution laws. Tr. 417:17–418:14 (Berndt) (rejecting Defendant's "free-riding" argument, and explaining quid-pro-quo of patent exclusivity followed by generic entry).

163. The facts with respect to the harm to competition, to the consumers and consequently the state, the ultimate payor of certain costs, have been found above.

164. Aside from the effect resulting from federal and state legislation, the Hatch-Waxman Act and the state substitution laws, the Defendants have not established any harm resulting from the continued sale of Namenda IR.

165. [redacted]

166. The continuation of sales of Namenda IR adds choice to physicians, patients' health plans and insurers and

constitutes a soft switch which has been the industry practice when introducing a new drug.

167. The Defendants have not presented any evidence to establish material economic harm resulting from the continued sale of Namenda IR after the introduction of Namenda XR, other than that which is anticipated upon the entry of generic competition resulting from the relevant legislation.

Conclusions of Law

VII. The Preliminary Injunction Standard

The general purpose of a preliminary injunction is to avoid irreparable injury to the movant and to preserve the court's power to render a meaningful decision after a trial on the merits. See WarnerVision Entm't Inc. v. Empire of Carolina, Inc., 101 F.3d 259, 261 (2d Cir. 1996); see also 11A Charles A. Wright & Arthur R. Miller, Fed. Prac. & Proc. Civ., § 2947 (3d ed.).

A party seeking a preliminary injunction must establish: (1) either (a) a likelihood of success on the merits, or (b) sufficiently serious questions going to the merits of its claims to make them fair ground for litigation, plus a balance of the hardships tipping decidedly in favor of the moving party; (2) irreparable harm; and (3) that issuance of the injunction would be in the public interest. See Oneida Nation of N.Y. v. Cuomo, 645 F.3d 154, 164 (2d Cir. 2011) (internal quotations and citations omitted); Red Earth LLC v. United States, 657 F.3d 138, 143 (2d Cir. 2011).

With respect to the likelihood of success element, a movant must satisfy a higher standard where: "(i) an injunction will alter, rather than maintain, the status quo, or (ii) an 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." Id. at 33–34. Under this higher standard, a movant must show a "clear" or "substantial" likelihood of success on the merits or make a "clear or substantial showing of sufficiently serious questions of merits in their favor." See Wright v. New York State Dep't of Corr. & Cmty. Supervision, 568 F. App'x 53, 55 (2d Cir. 2014) quoting Tom Doherty, 60 F.3d at 33-34 (discussing the heighted standard with respect to likelihood of success on the merits); Jolly v. Coughlin, 76 F.3d 468, 473 (2d Cir. 1996) (same); Suthers v. Amgen, Inc., 372 F. Supp. 2d 416, 425 (S.D.N.Y. 2005) (discussing the heighted standard with respect to substantial question analysis); Shred-It Am., Inc. v. Haley Sales Inc., 01-cv-0041E, 2001 WL 209906, at *1 (W.D.N.Y. Feb. 26, 2001) (same). The movant must also make a "strong" showing of irreparable harm. Doe v. New York University, 666 F.2d 761, 773 (2d Cir. 1981). Defendants urge that the heightened standard as described in Tom Doherty be applied in this case. Defs.' Mem. in Opp'n 13-15.

The instant motion does not require the heightened standard set out in Tom Doherty. While, "[t]he distinction between mandatory and prohibitory injunctions is not without ambiguities or critics . . . [a] preliminary injunction is usually prohibitory, [i.e., forbids or restrains an act,] and seeks generally only to maintain the status quo pending a trial on the merits." Louis Vuitton Malletier v. Dooney & Bourke, Inc., 454 F.3d 108, 114 (2d Cir. 2006) (internal quotations omitted) citing Tom Doherty, 60 F.3d at 34 and Black's Law Dictionary 788 (7th ed.1999). The State is seeking an injunction barring Defendants from altering their current Namenda IR sales and distribution strategy pending a final resolution of this case. AC ¶ d. The requested interim relief would maintain the status quo, i.e., continue Defendants' current Namenda IR sales and distribution activities in order to preserve the Court's power to make a final determination regarding the legality of Defendants' proposed new course of action. The authorities Defendants cite in support of the higher standard are inapposite, as those pertain to injunctions that would alter rather than perpetuate the status quo. See e.g., Lincoln Cercpac v. Health and Hospitals Corp., 920 F.Supp. 488, 494 (S.D.N.Y. 1996) (holding that an injunction to re-open

an already-closed hospital would be mandatory rather than prohibitive, since it would upset the status quo); Cacchillo v. Insmed, Inc., 638 F.3d 401, 405 (2d Cir. 2011) (holding that an injunction requiring a company to provide a document that it had, up to that point, refused to provide is mandatory rather than prohibitive); SEC v. Unifund SAL, 910 F.2d 1028, 1039 (2d Cir. 1990) (holding that a prohibition against violating securities laws in the future is mandatory rather than prohibitive); Union Cosmetic Castle, Inc. v. Amorepacific Cosmetics USA, Inc., 454 F. Supp. 2d 62, 68 (E.D.N.Y. 2006) (holding that an injunction requiring a company to re-establish a severed business relationship is mandatory rather than prohibitive); Vantico Holdings v. Apollo Mgmt., LP, 247 F. Supp. 2d 437, 451 (S.D.N.Y. 2003) (holding that an injunction requiring a party to alter the way it votes is mandatory rather than prohibitive).

The second aspect of the Tom Doherty heightened standard is also inapplicable. A preliminary injunction would not provide the State with substantially all of the final relief it seeks in this case. The State seeks a permanent injunction and civil penalties for current violations of New York law and seeks to recover damages caused by Defendants' "misleading

announcements of the timing and scope of their discontinuation of Namenda IR." Pl.'s Mem. in Supp't 20; AC ¶ c. Moreover, the preliminary injunction would only bar Defendants from altering current Namenda IR distribution until a final adjudication of this case is completed.

Since a heightened mandatory injunction standard does not apply in this case, the State may show the following to succeed on its motion for a preliminary injunction: (1) a sufficiently serious question going to the merits of its claims to make them fair ground for litigation; (2) irreparable harm in the absence of the preliminary injunction; (3) a balance of the hardships tipping decidedly in its favor; and (4) that issuance of the injunction would be in the public interest. See Oneida, 645 F.3d at 164.

VIII. Substantial Questions of Antitrust Violations Exist

The State has presented facts as set forth above to support its claims of violations of Sections 1 and 2 of the Sherman Act, and of New York State's Donnelly Act.

A. The Appropriate Market is the U.S. Memantine Drug Market

An initial step in antitrust claim analysis requires identification of the market, which consists of a relevant product and geographic market. PepsiCo, Inc. v. Coca-Cola Co., 315 F.3d 101, 105 (2d Cir. 2002) (components of market definition); Geneva Pharm. Tech. Corp. v. Barr Labs. Inc., 386 F.3d 485, 496 (2d Cir. 2004) (market definition is the initial step to both Section 1 and Section 2 claims). A relevant geographic market is the area "in which the seller operates and where consumers can turn, as a practical matter, for supply of the relevant product." United States v. Eastman Kodak Co., 63 F.3d 95, 104 (2d Cir. 1995). A relevant product 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). As the geographic market is not in dispute here, definition of the product market is the relevant inquiry. FOF ¶ 70.

In defining the market, courts consider the choices available to consumers in the market. See Eastman Kodak Co. v. Image Tech. Servs., 504 U.S. 451, 482 (1992) citing United States v. Grinnell Corp., 384 U.S., at 572. Courts consider

"practical indicia [such as] industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price change, and specialized vendors." See Brown Shoe Co. v. United States, 370 U.S. 294, 325 (1962). Cross-elasticity of demand is a common empirical methodology used to determine whether two or more products comprise the same market. See e.g. Bogan v. Hodgkins, 166 F.3d 509, 516 (2d Cir. 1999) citing Brown Shoe, 370 U.S. at 325; Chapman v. New York State Div. for Youth, 546 F.3d 230, 238 (2d Cir. 2008); Hayden Pub. Co. v. Cox Broad. Corp., 730 F.2d 64, 71 (2d Cir. 1984). The cross-elasticity of demand calculation measures change in sales of a product to price changes of a potential substitute. E. I. du Pont, 351 U.S. at 400. A high cross-elasticity of demand suggests substitutability, while a low one does not; consumers will respond to an increase in the price of one product by purchasing the relatively inexpensive second product only if the two products are substitutes. See id. As a result, two products with high cross-elasticity of demand are properly grouped into the same market since they are substitutes. Id.

A single product may constitute a relevant market where there are no reasonably interchangeable substitutes. See Image Tech., 504 U.S. at 481–82. To be a substitute product for purposes of product market definition, customers must be willing to switch to a competitive product as a result of a price change. United States v. H&R Block, Inc., 833 F. Supp. 2d 36 (D.D.C. 2011).

As in this instance, courts have found a single brand-name drug and its generic equivalents 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."); In re Terazosin Hydrochloride Antitrust Litig., 352 F. Supp. 2d 1279, 1319 n.40 (S.D. Fl. 2005).

The facts found above establish the State's contention that the appropriate product market in this case is the nationwide memantine market. See generally FOF § IV. CIs and memantine are not considered substitutes nor are they prescribed

as such by physicians. FOF ¶¶ 58, 62. CIs are used to treat patients with mild-stage Alzheimer's while memantine is not indicated for such patients, and the two types of drugs are predominantly complements rather than supplements. FOF ¶ 57.

Defendants' contention that the appropriate product market should include CIs is not well supported by the evidence. As found above, Defendants' cross elasticity of demand analysis was less convincing than the State's. FOF ¶ 67. Industry categorizations of memantine and CIs as part of the "Alzheimers' Drug Market" or an "anti-dementia" category do not alter the observable behavior of patients and physicians, as reflected in the cross elasticity of demand analyses summarized above. See FOF § IV.B. Categorizations in this instance may not be based on substitutability, but rather serve as umbrella terms encompassing distinct product markets: akin to, perhaps, categorizing two distinct non-substitutable products such as a sponge and soap under the umbrella of cleaning supplies. Similarly, the fact that both CIs and memantine tablets can be produced using the same machinery and sold along the same distribution channels does not establish substitutability. Adopting Defendants' contention, tablet forms of dissimilar medicines, for example heart medication and statins, may be

considered substitutes because they can be made on the same machines and distributed along the same sales channels.

The appropriate geographic and product market for antitrust purposes in this case has been established as the memantine market in the United States.

B. The Defendant's Monopoly Power

To establish a claim of unlawful monopolization under Section 2 of the Sherman Act, the State must show that Defendants: (a) have monopoly power in a relevant market and; (b) acquired or maintained such monopoly power through anticompetitive exclusionary conduct. See Grinnell, 384 U.S. at 570-71. To establish a claim of unlawful attempted monopolization under Section 2 of the Sherman Act, the State must show that Defendants: (1) engaged in anticompetitive behavior; (2) with specific intent to monopolize; and (3) with a dangerous probability of achieving monopoly power. Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 456 (1993); PepsiCo, 315 F.3d at 105 (2d Cir. 2002). The two claims are substantially identical, with the exception that attempted monopolization requires a showing of specific intent to

monopolize. The remaining elements can be addressed jointly. Exclusionary behavior under the monopolization claim and anticompetitive conduct under the attempted monopolization claim overlap. The first monopolization and the third attempted monopolization elements vary only by degree. See Tops Markets, Inc. v. Quality Markets, Inc., 142 F.3d 90, 100 (2d Cir. 1998) ("the same concept of market power as that used in a completed monopolization claim [applies] . . . [though] a lesser degree of market power may establish an attempted monopolization claim than that necessary to establish a completed monopolization claim").

Having established that the relevant market is the nationwide memantine market, the issue is whether Defendants have monopoly power in the relevant market, i.e., "the ability to control prices or exclude competition." United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377, 391 (1956); PepsiCo, 315 F.3d at 107. While a "patent does not of itself establish a presumption of market power in the antitrust sense," In re Indep. Serv. Organizations Antitrust Litig., 203 F.3d 1322, 1325 (Fed. Cir. 2000), a high market share is an indication of monopoly power. Tops Markets, 142 F.3d at 98 (quoting Broadway Delivery Corp. v. United Parcel Serv. of

America, Inc., 651 F.2d 122, 129 (2d Cir.1981) ("the higher a market share, the stronger is the inference of monopoly power"). A complete market power analysis considers market share in light of the relevant market's particular characteristics, including "strength of the competition, the probable development of the industry, the barriers to entry, the nature of the anticompetitive conduct and the elasticity of consumer demand." Id. citing Int'l Distribution Centers, Inc. v. Walsh Trucking Co., 812 F.2d 786, 792 (2d Cir. 1987); see also Hayden, 730 F.2d at 69 citing United States v. Columbia Steel Co., 334 U.S. 495, 527 (1948). Market power may also be established by considering evidence of anticompetitive effects of the challenged conduct. FTC v. Ind. Fed'n of Dentists, 476 U.S. 447, 460-61 (1986) ("proof of actual detrimental effects . . . can obviate the need for an inquiry into market power, which is but a surrogate for detrimental effects."); Geneva Pharms, 386 F.3d at 509; Tops Markets, 142 F.3d at 98 (market power may be proven by direct evidence of anticompetitive effects); Todd v. Exxon Corp., 275 F.3d 191, 206 (2d Cir. 2001) ("If a plaintiff can show that a defendant's conduct exerted an actual adverse effect on competition, this is a strong indicator of market power.").

As established by the facts found above, prior to generic entry into the market, Defendants are the exclusive producers of all forms of memantine. FOF ¶ 41. Until that time, Defendants control price and distribution for memantine, and have a patent-protected right to exclude all competition. FOF ¶ 126. As CIs are not indicated for moderate to severe Alzheimer's patients, most patients in that group have no alternative to memantine. FOF ¶ 57. Prior to July 2015, Defendants have 100% of the market, there is no competition, development is controlled by Defendants, Defendants' patent are absolute barriers to entry, and demand is inelastic: Defendants have monopoly power. See generally FOF § IV.

Starting in July 2015, however, several generic manufacturers enter the memantine market and Defendants' memantine market share is projected to drop below 100%. See FOF ¶¶ 126-27, 136. Determining whether Defendants will continue to enjoy monopoly power following generic entry requires projections of future conditions in the memantine market.

[redacted] FOF ¶ 147. At minimum, this conflict establishes that a serious question exists as to whether

Defendants will control sufficient market share to qualify as strong evidence of monopoly power. As found above, Defendants projected control of [redacted] of the memantine market ([redacted] with XR and [redacted] with the upcoming fixed dose combination) in 2016. FOF ¶ 139. This is a considerable market share, indeed "a share above 70% is usually strong evidence of monopoly power." Broadway Delivery Corp. v. United Parcel Serv. of Am., Inc., 651 F.2d 122, 129 (2d Cir. 1981).

Moreover, depending on other market factors, courts in the Second Circuit have permitted findings of market power with shares less than 50%. See United States v. Visa USA, Inc., 344 F.3d 229, 240 (2d Cir. 2003) (MasterCard found to have market power with 26% market share); Broadway Delivery, 651 F.2d at 129 ("the jury should not be told that it must find monopoly power lacking below a specified share or existing above a specified share"); In re Payment Card Interchange Fee & Merchant Discount Antitrust Litig., 562 F. Supp. 2d 392, 400 (E.D.N.Y. 2008) (a finding of market share less than 30% would not foreclose the possibility of proving monopoly power).

In the hard switch scenario, Defendants' generic competitors will be limited to the [redacted] of the memantine market

not controlled by XR and the anticipated FDC Namenda product. FOF ¶ 139. The switch-resistant Namenda users already taking XR, i.e., the majority of all memantine users at the time of generic entry, will likely exhibit the same resistance to adopting generic IR as exhibited by current IR patients resisting XR. FOF ¶¶ 85, 154. Physician and health plan hesitations to change their patients' medications will exacerbate this inertia. FOF ¶¶ 143-45, 155.

Defendants' dominance in the memantine market creates an adverse effect on memantine pricing and competition. FOF ¶ 117. Non-AB-rated generic drugs are not able to compete effectively for sales of a branded drug in the same class, even if the price of the generics is much lower than the brand. FOF ¶ 133. The Lipitor example, where the absence of AB-substitution limited a generic to only 30% of the market, is illustrative. FOF ¶ 133. Furthermore, generic drugs are typically not marketed to physicians or patients. FOF ¶ 128. Defendants' conduct, by emphasizing the more expensive patent-protected formulations of memantine and eliminating distribution of the Namenda IR formulation subject to generic substitution laws, may therefore significantly alter the average price of memantine in the market. FOF ¶ 117.

The evidence found above, while not definitive, adequately establishes a substantial question as to whether Defendants have monopoly power over the relevant market.

C. Anticompetitive Conduct by Defendants

While the mere possession of monopoly power is not unlawful, monopolists cannot run their businesses in an anticompetitive manner. See e.g., Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 407 (2004); United States v. Microsoft, 253 F.3d 34, 64 (D.C. Cir. 2001); C.R. Bard, Inc. v. M3 Sys., 157 F.3d 1340 (Fed. Cir. 1998); United States v. Dentsply Int'l, 399 F.3d 181 (3d Cir. 2005).

The central inquiry is whether "a monopoly [is] engaging in exclusionary conduct as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." Microsoft Corp., 253 F.3d at 58 quoting Grinnell, 384 U.S. at 571; see also Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 274 (2d Cir. 1979); Port Dock & Stone Corp. v. Oldcastle Ne., Inc., 507 F.3d 117, 124 (2d Cir. 2007); In re Adderall XR Antitrust Litig., 754 F.3d 128,

133 (2d Cir. 2014), as corrected (June 19, 2014); cf. United States v. Colgate & Co., 250 U.S. 300, 307 (1919) ("In the absence of any purpose to create or maintain a monopoly, the [Sherman] act does not restrict the long recognized right of trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal) (emphasis added).

A monopolist's decision to withdraw a product from customers may violate antitrust laws if done for the sole purpose of harming competition, i.e., if it constitutes exclusionary conduct. See e.g., Abbott Labs. v. Teva Pharm. USA, Inc., 432 F. Supp. 2d 408, 424 (D. Del. 2006) (defendant's decision to withdraw a prior drug formulation of TriCor in an effort to shift patients to a new one and exclude generic competition may be exclusionary); Xerox Corp. v. Media Scis. Int'l., 511 F. Supp. 2d 372, 388 (S.D.N.Y. 2007) (discontinued and redesigned printer models to "foreclose all other competition, and not to improve the product" may be exclusionary); 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") (internal 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"); see also 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").

The D.C. Circuit case United States v. Microsoft lays out a useful framework for determining whether Defendants have engaged in anticompetitive conduct. 253 F.3d at 58. The plaintiff must demonstrate that the defendant's conduct had an anticompetitive effect. Id. If the plaintiff establishes an anticompetitive effect, then the monopolist may proffer a procompetitive justification for its conduct – "a nonpretextual claim that its conduct is indeed a form of competition on the merits because it involves, for example, greater efficiency or enhanced consumer appeal." Id. at 58-59. If the monopolist succeeds, then the plaintiff must rebut that justification or

demonstrate that the anticompetitive harm of the conduct outweighs its procompetitive effect. Id. at 59.

The Microsoft case has been widely cited by courts in this circuit, and its framework is frequently employed. See e.g., Meredith Corp. v. Sesac, LLC, 1 F. Supp. 3d 180, 222 (S.D.N.Y. 2014) (citing Microsoft, 253 F.3d at 59, for the proposition that "the determination of § 2 liability calls for a weighing of the exclusionary conduct against any 'valid business reasons' for it."); IHS Dialysis v. Davita, Inc., 2013 U.S. Dist. LEXIS 47532, *24 (S.D.N.Y. Mar. 31, 2013) (citing Microsoft, 253 F.3d at 58 for the proposition "[w]hether any particular act of a monopolist is exclusionary, rather than merely a form of vigorous competition, can be difficult to discern: the means of illicit exclusion, like the means of legitimate competition, are myriad."); In re Fresh Del Monte Pineapples Antitrust Litig., 2009 U.S. Dist. LEXIS 97289, *21, 55, 69 (S.D.N.Y. Sept. 30, 2009) (utilizing the Microsoft test to determine a § 2 violation). This framework has also more recently been applied in another forced switch antitrust decision, In Re Suboxone Antitrust Litigation, MDL No. 2445 (E.D. Pa. Dec. 3, 2014).

As explained below, anticompetitive effect is adequately demonstrated under the Microsoft framework and Defendants' procompetitive justifications are either not plausible or outweighed by the anticipated anticompetitive effects of the limited distribution strategy.

1. The State Demonstrated Anticompetitive Effect

The State demonstrated a substantial risk that Defendants' limited distribution strategy would harm competition in the memantine market, as found above. See generally FOF § VI. Both regulators and commentators recognize the substantial anticompetitive effect that circumvention of state substation laws can have. See Brief for Federal Trade Commission as Amicus Curiae at 9, Mylan Pharms., Inc., v. Warner Chilcott Pub. Ltd. Co., No. 2:12-CV-03824-PD (E.D. Pa. Dec. 13, 2012) (PX4) ("As a practical matter, if a generic cannot be substituted at the pharmacy counter, the economically meaningful market for the generic product disappears."); Brief for Intellectual Prop. & Antitrust Law Professors as Amici Curiae at 14, Mylan (PX5) ("Under Hatch-Waxman and state substitution laws, generics can only compete cost-effectively through substitution on the new or old branded drug version."); cf. FTC v. Actavis, 133 S.Ct. 2223, 2228 (2013) ("The Hatch-Waxman process, by allowing the generic to piggy-back on the pioneer's approval efforts, speed[s] the

introduction of low-cost generic drugs to market . . . thereby furthering drug competition.") (internal quotations and citations omitted).

Defendants undertook to achieve significantly higher levels of conversion from IR to XR precisely by reducing generic competition, putting in place a limited distribution strategy to serve as an "obstacle" to generic switching, thwarting state substitution laws. The result of the forced switch, as found above, is inflation of XR's share of the memantine market. FOF ¶¶ 134, 137. Most patients are effectively denied access to IR for the six months prior to generic entry.

That the limited distribution does not ban all competition does not demonstrate absence of exclusionary behavior. Exclusionary behavior need not result in "total foreclosure" of competition, but rather is found where "the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." Dentsply, 399 F.3d at 191; LePage's Inc. v. 3M, 324 F.3d 141, 159 (3d Cir. 2003); Microsoft, 253 F.3d at 69; In re Fresh Del Monte Pineapples Antitrust Litig., 04-MD-1628, 2009 WL 3241401, at *16 (S.D.N.Y. Sept. 30, 2009) aff'd sub nom. Am. Banana Co. v. J. Bonafede

Co., 407 F. App'x 520 (2d Cir. 2010). "Where a course of action is ambiguous, 'consideration of intent may play an important role in divining the actual nature and effect of the alleged anticompetitive conduct.'" Berkey Photo, 603 F.2d at 288 quoting United States v. United States Gypsum Co., 438 U.S. 422, 436 n.13 (1978).

The State has met its burden under the first prong of Microsoft.

2. Defendants' Procompetitive Justifications Are Pretextual

In evaluating a monopolization claim, the trier of fact must distinguish "between conduct that defeats a competitor because of efficiency and consumer satisfaction, and conduct that not only (1) tends to impair the opportunities of rivals, but also (2) either does not further competition on the merits or does so in an unnecessarily restrictive way." Trans Sport, Inc. v. Starter Sportswear, Inc., 964 F.2d 186, 188-89 (2d Cir. 1992) (internal quotations and citations omitted); see also Microsoft, 253 F.3d at 59, 65.

The Supreme Court has held that where consumer choices are made as a result of "forcing" customers to purchase a product, then that is not competition on the merits. Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 27 (1984) (condemning tying as anticompetitive where it "restrain[s] competition on the merits by forcing purchases that would not otherwise be made"). Where "the conduct has no rational business purpose other than its adverse effects on competitors, an inference that it is exclusionary is supported." Stearns Airport Equip. Co. v. FMC Corp., 170 F.3d 518, 522 (5th Cir. 1999).

Saunders stated, contemporaneously with the adoption of the hard switch by Forest, that the purpose of the switch was anticompetitive: to put barriers obstacles in the path of producers of generic memantine and thereby protect Namenda's revenues from a precipitous decline following generic entry. FOF ¶ 116. He further stated: "if we do the hard switch and we've converted 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 [prescriptions]. 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. It is an obstacle that will allow us to, I think, again go into to a slow decline versus a complete cliff."). FOF ¶ 116.

Saunders's motivation for the hard switch, expressed at the hearing, that his team could better "focus" on XR and FDC if IR was no longer sold by Defendants, was not as specific, or as persuasive, as his earlier representations to shareholders, quoted above. Compare FOF ¶ 78 with ¶ 116; see also FOF ¶ 122.

As found above, Defendants' and Defendants' experts' rationalizations for the hard switch strategy are not only later-in-time but also not as persuasive. The only quantified savings from the limited distribution are roughly [redacted] of the loss of IR revenue within the first six months. FOF ¶ 119. Defendants did not quantify the remaining pro-competitive justifications identified in conjunction with this case. FOF ¶¶ 116, 120. Nor did Saunders elaborate on how the hard switch strategy would allow for greater focus. FOF ¶¶ 116, 120. There is no indication that these ancillary benefits were the basis for Defendants' hard switch strategy. FOF ¶ 121.

Finally, by contending at the hearing that a preliminary injunction against the forced switch would require significant changes to Defendants' operations as a result of the potential loss of [redacted] in sales, Defendants have essentially conceded that it is this expectation of [redacted] increased sales of Namenda XR that is driving their business decision to engage in the forced switch. No other non-pretexual pro-competitive purpose has been established, either at the hearing or by any contemporary Forest analysis.

3. Any Procompetitive Justifications Are Outweighed by the Anticompetitive Impact of the Conduct

To avoid liability, Defendant may offer legitimate business justifications for their exclusionary conduct that outweigh the anticompetitive effects. Microsoft, 253 F.3d at 59; Xerox, 511 F. Supp. 2d at 389. Since these legitimate business justifications must outweigh the anticompetitive effect of the conduct 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. Microsoft, 253 F.3d at 58–59, 64–66; Xerox, 511 F. Supp. 2d at 388–89; Abbott Labs., 432 F. Supp. 2d at 422. Rather, in such cases, the procompetitive benefits

of the business justification must outweigh the anticompetitive effects.

As discussed above, Defendants have not identified how the limited distribution efficiencies would outweigh [redacted]. The savings from the limited distribution are dwarfed by the loss of IR revenue within the first six months. FOF ¶ 119. The remaining justifications were not quantified. FOF ¶¶ 119-120. More to the point, these cost savings are dwarfed by the considerable anticompetitive harm: both to patients, who will pay [redacted] in higher co-payments or have to switch medications twice, and to third party payors, who will pay more than [redacted]. FOF ¶ 161.

On the basis of these factual findings, Defendants' justifications are outweighed by the anticompetitive effects of the limited distribution. Therefore, there is a serious question as to whether Defendants' limited distribution strategy constitutes competitive conduct.

D. Sherman Act Section 1 Claim

To establish a claim under Section 1 of the Sherman Act, the State must demonstrate: (a) concerted action between Defendants and Foundation Care; (b) resulting in an unreasonable restraint of trade affecting the United States. See Tops Markets, 142 F.3d at 95-96; 15 U.S.C. § 1 ("Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal"); see also Leegin Creative Leather Products, Inc. v. PSKS, Inc., 551 U.S. 877, 885 (2007) (noting that Section 1 is properly construed to bar only unreasonable restraints, not all restraints).

Concerted action within the meaning of Section 1 exists when an agreement between "separate economic actors pursuing separate economic interests . . . deprives the marketplace of independent centers of decisionmaking." Am. Needle, Inc. v. Nat'l Football League, 560 U.S. 183, 195 (2010) (internal quotations and citations omitted). Foundation Care and Defendants are separate economic actors, occupying differing roles in the memantine supply chain: under the hard switch strategy, Defendants remain the sole supplier, or "vendor," and Foundation Care becomes the sole distributor, termed the "independent contractor." FOF ¶ 104. This is sufficient to

establish concerted action. See Anderson News, LLC v. Am. Media, Inc., 680 F.3d 162, 182 (2d Cir. 2012).

Allegations of restraints that are not per se unlawful are analyzed under the rule of reason test, where "the factfinder weighs all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition." Leegin, 551 U.S. at 885 (2007) (internal citations and quotations omitted). "When applying the rule of reason, courts weigh all of the circumstances surrounding the challenged acts to determine whether the alleged restraint is unreasonable, taking into account factors such as specific information about the relevant business, the restraint's history, nature, and effect, and whether the businesses involved have market power." Gatt Commc'ns, Inc. v. PMC Associates, L.L.C., 711 F.3d 68, 75 (2d Cir. 2013) (internal quotations omitted) citing Leegin, 551 U.S. at 885).

The Section 2 analysis above satisfies the unreasonable restraint prong. Defendants have monopoly power in the memantine market. See generally FOF § IV. The hard switch strategy will likely have an anticompetitive effect on that

market, denying current memantine patients access to IR tablets and driving up the average price of memantine following generic entry. See generally FOF § VI. In sum, the hard switch strategy constitutes an unreasonable restrain on trade without a pro-competitive justification, as discussed above.

The cases Defendants cite in opposition to this claim do not alter this conclusion. While it is true that manufacturers generally have control over distribution, E & L Consulting, Ltd. v. Doman Indus. Ltd., 472 F.3d 23, 30 (2d Cir. 2006), they are not permitted to exert that control in a manner that violates the antitrust laws. See Leegin, 551 U.S. at 892 (discussing the illegality of vertical restraints).

In E & L Consulting, the Second Circuit affirmed dismissal of a Section 1 claim for failure to plead that the concerted action would yield an adverse effect on the market. 472 F.3d at 31. The facts in that case established that the defendant-monopolist would continue to enjoy monopoly power with or without the agreement in question. Id. at 29 (the monopolist held 95% of the market). Since the defendant in E & L Consulting did not need the agreement to further its monopoly, the Second Circuit concluded that the agreement was not a proper

basis for Section 1 liability. Id. at 30. By contrast, Defendants in this case face potential competition from numerous generic manufacturers in summer of 2015, and are relying on the MSA to maintain their market power. This is also not a case where the vertical agreement is made for a pro-competitive reason. Compare the anticompetitive effect in this case with that in Cont'l T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36 (1977) ("[v]ertical restrictions promote interbrand competition by allowing the manufacturer to achieve certain efficiencies in the distribution of his products").

As with the Section 2 claims, the State has demonstrated a substantial question exists as to the legality of the MSA as governed by Section 1 of the Sherman Act.

E. State Law Violations by Defendants

The Donnelly Act makes illegal and void any contract, arrangement, or agreement that restrains competition in any business, or unlawfully interferes with the free exercise of any activity in the conduct of any business, and is generally construed in accordance with the Sherman Act. See N.Y. Gen.

Bus. Law § 340; Anheuser-Busch, Inc. v. Abrams, 71 N.Y.2d 327, 334 (N.Y. 1988).

"A plaintiff alleging a claim under the Donnelly Act must identify the relevant product market, allege a conspiracy between two or more entities, and allege that the economic impact of that conspiracy was to restrain trade in the relevant market." Thome v. Alexander & Louisa Calder Found., 890 N.Y.S.2d 16, 32 (App. Div. 2009); see also, Benjamin of Forest Hills Realty, Inc. v. Austin Sheppard Realty, Inc., 823 N.Y.S.2d 79 (App. Div. 2006); Yankees Entm't & Sports Network, LLC v. Cablevision Sys. Corp., 224 F. Supp. 2d 657, 678 (S.D.N.Y. 2002).

The Donnelly Act analysis tracks the Section 1 of the Sherman Act claim, as analyzed above. As with the Section 1 claim, the State has met its burden of demonstrating a substantial question going to the merits of this claim.

Under Section 63(12), the New York State Attorney General may sue defendants for violations of state or federal law, including Sherman Act or Donnelly Act violations, affecting more than one person within New York State. N.Y. Exec. L. §

63(12); State v. Feldman, 210 F. Supp. 2d 294, 300 (S.D.N.Y. 2002) (antitrust violations are predicate offenses); State v. Stevens, 497 N.Y.S.2d 812, 813 (N.Y. Sup. Ct. 1985); People v. Wilco Energy Corp., 728 N.Y.S.2d 471, 471 (2d Dep't 2001) (the Attorney General can show repetition of any separate and distinct fraudulent or illegal act, or conduct which affects more than one person to satisfy the "repetition" requirement under the law).

As discussed above, the State has established a substantial question on the merits of its Sherman and Donnelly Act antitrust claims, and therefore adequately established these claims as well.

IX. A Preliminary Injunction Is Appropriate

Upon the establishment of serious questions of antitrust violations as concluded above, the standard questions for preliminary injunction relief remain and are concluded in favor of the State. The irreparable injury has been established, the balance of hardships tips markedly in the favor of the State, and the public interest is best served by preliminary relief maintaining the status quo.

Since the introduction of Namenda XR in 2013, Forest has successfully marketed and sold both XR and IR products. FOF ¶ 53. Namenda IR has been in the market since 2004 and its yearly sales have exceeded $1.5 billion, as found above. FOF ¶ 44. The present Forest sales program is consistent with an accepted industry practice of a soft switch when a new product is introduced, a practice that maintains consumer choice before and after generic entry into the market. FOF ¶ 36. To maintain the status quo is appropriate relief under the circumstances here presented.

A. Irreparable Harm Has Been Established

Although the State has maintained otherwise, see Pl.'s Mem. in Supp't 40, it is not entitled to a presumption of irreparable harm. See 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"); Salinger v. Colting, 607 F.3d 68, 78 n.7 (2d Cir. 2010) (noting that eBay Inc. v. MercExchange, LLC, 547 U.S. 388, (2006), eliminated all

presumptions of irreparable harm absent contrary explicit congressional intent); see also Weinberger v. Romero-Barcelo, 456 U.S. 305, 313 (1982) (statute should not be read lightly to replace traditional equity test). Therefore, the State "must demonstrate that absent a preliminary injunction [it] will suffer an injury that is neither remote nor speculative, but actual and imminent, and one that cannot be remedied if a court waits until the end of trial to resolve the harm." Grand River Enter. Six Nations, Ltd. v. Pryor, 481 F.3d 60, 66 (2d Cir. 2007) (internal quotations and citations omitted). Consequently, the State must show that 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 Chemicals, Inc. v. Bank of India, 175 F.3d 245, 249 (2d Cir. 1999).

The facts found above established that that patients, caregivers, and physicians will be constrained in obtaining Namenda IR in the absence of a preliminary injunction. FOF ¶ 112. Permanent damage to competition in the memantine market can also result from Defendants' planned hard switch strategy. See generally FOF § VI.A.

In addition, in the absence of a preliminary injunction and in the accomplishment of the Defendants' hard switch, consumers will pay almost $300 million more for a memantine drug than if the present sales patter is maintained. Although this is a projected financial loss to Alzheimer's patients, it can be avoided by maintaining the status quo. See Bon-Ton Stores v. May Dep't Stores Co., 881 F. Supp. 860, 866 (W.D.N.Y. 1994) ("With respect to irreparable harm, doubts as to whether an injunction sought is necessary . . . should be resolved in favor of granting the injunction.") (internal quotations and citations omitted).

B. The Balance of Hardships Tips in Favor of the State

In determining whether to grant a preliminary injunction, courts consider the balance of harms between the movant and the party subject to the injunction. See Amoco Prod. Co. v. Vill. of Gambell, 480 U.S. 531, 542 (1987); Random House, Inc. v. Rosetta Books LLC, 283 F.3d 490, 492 (2d Cir. 2002).

The facts found above demonstrate that the hard switch will injure competition and consumers. See generally FOF § VI. Conversely, the Defendants have not demonstrated any harm

resulting from their continuing the same IR distribution strategy they have been using since 2004. FOF ¶ 38. And Defendants have failed to quantify any material costs that would result from an injunction. FOF ¶¶ 116, 120. No evidence has been submitted that continuing to supply the market with Namenda IR, an activity they have been doing by choice for over a decade, constitutes a hardship. To the contrary, the evidence suggests that continuing to sell IR will be a net benefit to Defendants [redacted]. FOF ¶ 118.

Having to compete with other firms in the market is what the antitrust laws require, not a cognizable harm. Harm is not established by refraining conduct that "seems clearly to be an effort to game the rather intricate FDA rules to anticompetitive effect." Abbott Labs., 432 F. Supp. 2d at 422. As found above, Defendants actually risk losing [redacted] in revenues gained through anticompetitive, i.e., illegally, conduct. This is not a cognizable harm.

C. The Public Interest Favors Granting the Injunction

Finally, "[c]ourts 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.") (internal quotations and citations omitted." United States v. First Nat'l City Bank, 379 U.S. 378, 383 (1965); accord Register.com, Inc. v. Verio, Inc., 356 F.3d 393, 424 (2d Cir. 2004) quoting Standard & Poor's Corp. v. Commodity Exch., Inc., 683 F.2d 704, 711 (2d Cir. 1982).

Here, the State seeks to enforce laws on behalf of the public. FOF ¶ 1. Courts 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 marketplace, here the memantine market. See United States v. Siemens Corp., 621 F.2d 499, 506 (2d Cir. 1980).

Additionally, a preliminary injunction will protect the public interest by safeguarding the fundamental compromise envisioned by the Hatch–Waxman Act, which sought to reconcile the sometimes conflicting public policy goals of making affordable generic drugs available to consumers and protecting

pharmaceutical companies' incentives to innovate. FOF § II.E. Defendants have 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. FOF ¶ 38. The hard switch violates the spirit of the Hatch-Waxman Act and the public policy underlying it.

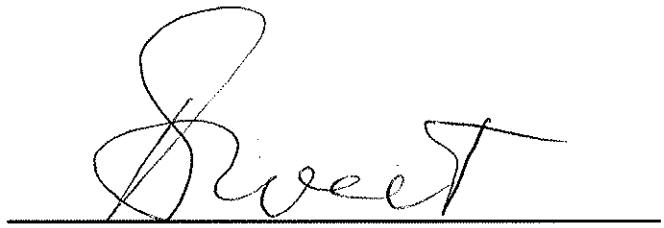
Defendants have contended that allowing them to engage in the hard switch will allow increased innovation in the long term, as greater financial resources are made available to Defendants. Defs.' Mem. in Opp'n 23. However, optimizing the incentives for innovation requires that the legal system reward pharmaceutical companies for truly innovative conduct that benefits consumers, by means of better drugs that physicians and patients are willing to switch to voluntarily. Providing financial rewards for anticompetitive conduct is not in the public interest.

Conclusion

Based upon the finding of fact conclusions of law set forth above, a preliminary injunction will issue. The State will submit a proposed preliminary injunction by 5:00 PM on December 12, 2014, and a hearing will be held in Courtroom 23B on December 15, 2014 at noon.

It is so ordered.

New York, NY
December 11, 2014



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