

JUDGE SWEET  
UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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THE PEOPLE OF THE STATE OF NEW YORK :

by and through ERIC T. SCHNEIDERMAN, :  
Attorney General of the State of New York, :

Plaintiff, :

v. :

ACTAVIS, PLC, and :

FOREST LABORATORIES, LLC, :

Defendants. :

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Case No.:

COMPLAINT



1. The People of the State of New York, by their attorney, Eric T. Schneiderman, Attorney General of the State of New York, bring this civil action against Defendants Actavis, plc (“Actavis”) and its wholly owned subsidiary Forest Laboratories, LLC (“Forest”) (collectively “Defendants”) to prevent Defendants from violating federal and state antitrust laws by improperly maintaining and extending their monopoly in the market for certain drugs that treat Alzheimer’s disease.

PRELIMINARY STATEMENT

2. This case is brought to prevent Defendants from illegally maintaining their monopoly position and inflating their profits at the expense of patients suffering from Alzheimer’s disease. The manipulative tactic that the Defendants seek to employ here is what some in the industry, including Defendants’ own CEO, have called a “forced switch.” In a forced switch, a pharmaceutical company that sells a drug facing imminent generic competition

withdraws its drug from the market, forcing patients to switch to a different form of the drug with patents that expire later. The switch has the effect of impeding the entry of lower-cost generic drugs. A physician recently complained to Defendants, aptly describing their contemplated action as “immoral and unethical.” It is also illegal.

3. Defendants sell a blockbuster drug to treat Alzheimer’s disease, called Namenda. Namenda is Forest’s top selling drug, and is protected by patent and regulatory exclusivities that prevent generic versions from entering the market until July 2015. But rather than allowing patients with Alzheimer’s to continue to take Namenda and switch to the less expensive generic version when it becomes available, as contemplated by federal and state drug laws, Forest instead hatched a scheme that interferes with patients’ ability to make this switch.

4. Defendants’ strategy is to discontinue or severely restrict patient access to its original, immediate-release version of Namenda, known as Namenda IR, prior to generic entry in order to force patients to switch to Forest’s newer, virtually identical, extended-release version of Namenda, called Namenda XR. Because Namenda XR is protected by patents for many years longer than the original Namenda IR, Defendants’ goal is to use the “forced switch” to reap several more years of monopoly profits than they would have earned otherwise. Under generic substitution laws, a pharmacist will not be able to substitute lower-priced generic Namenda IR (known as memantine) for Namenda XR. As a result, once patients have switched to Namenda XR, it will destroy the market for the generic form of Namenda IR because of the dramatically increased burden, cost, and time needed to arrange for patients who have been switched to Namenda XR to switch back to the original version.

5. Rather than compete on the merits, and allow Alzheimer’s patients and their physicians to choose which drug – Namenda IR or Namenda XR – to use based on each patient’s

individual medical and financial circumstances, Defendants have taken it upon themselves to make that decision for them. Purely to squeeze every last dollar out of their Namenda franchise, and with no concern about the effects that its “forced switch” could have on the highly vulnerable Alzheimer’s patient population, Defendants are substituting their own, profit-driven motives for the judgment of physicians and patients. And, Defendants are abusing their exclusivity rights by continuing to prohibit generic manufacturers from providing generic Namenda to this needy patient population while at the same time refusing to make their own Namenda product available to these patients.

6. If Defendants are permitted to implement this illegal scheme to exclude generic competition, they predict that they will earn hundreds of millions of dollars more in profits from their Namenda monopoly than they would have otherwise. And by doing so, they will defeat the intent of the legislative compromises underlying federal and state laws governing generic competition – which grant brand name drug companies more than a decade of protection from generic competition in return for quick and effective entry by generic drugs at the conclusion of the exclusivity period. The immediate casualties of Defendants’ manipulative conduct will be the financially strapped health care system, as well as patients with Alzheimer’s who must bear not only unwarranted costs, but also completely unnecessary changes in their medical routine.

7. In this action, the Attorney General seeks, among other things, an injunction that would restrain Defendants from continuing their unlawful scheme, require them to take appropriate steps to keep Namenda IR available in the market without disruption, and let patients – and their doctors – decide which drug is right for them.

## JURISDICTION & VENUE

8. This Complaint alleges violations of Section 2 of the Sherman Act, 15 U.S.C. § 2. The Complaint also alleges violations of the Donnelly Act, New York State General Business Law §§ 340-47 and the New York State Executive Law § 63(12). It is filed in this Court pursuant to, *inter alia*, Section 16 of the Clayton Act, 15 U.S.C. § 26.

9. The Attorney General seeks an injunction under federal and state antitrust laws to prevent Defendants from implementing their anticompetitive scheme to harm patients and exclude generic competition. The Attorney General has authority to pursue injunctive relief under federal law in its *parens patriae* capacity to prevent harm to the State's general economy, and on behalf of the State as an indirect purchaser of Namenda IR and Namenda XR that is likely to be harmed by the unlawful conduct described here. The Attorney General also seeks disgorgement of Defendants' ill-gotten gains, civil penalties pursuant to state law, and/or damages and restitution. The Attorney General also seeks additional remedies for Defendants' deceptive conduct in implementing its unlawful scheme to harm competition.

10. This Court has jurisdiction of the action under the provisions of 28 U.S.C. §§ 1331 and 1337, as well as under the principles of supplemental jurisdiction codified in 28 U.S.C. § 1367(a). This Court's exercise of supplemental jurisdiction over Plaintiff's state law claims would avoid unnecessary duplication and multiplicity of actions, and should be exercised in the interests of judicial economy, convenience, and fairness.

11. Venue is proper in this district under Section 12 of the Clayton Act, 15 U.S.C. §§ 22 and 28 U.S.C. § 1391(b) and (c) because at all times relevant to the bringing of this action, Defendants transacted business, did business, were found or resided in the Southern District of New York and because the claims alleged arose, in part, in this judicial district.

## PARTIES

12. Plaintiff Eric T. Schneiderman is the Attorney General of the State of New York and brings this action on behalf of the People of the State of New York in connection with the Attorney General's role to protect the State of New York and its residents from exploitative, anticompetitive business practices.

13. Defendant Actavis is a public limited company registered in Ireland and headquartered at 1 Grand Canal Square, Docklands, Dublin 2, Ireland. On July 1, 2014, Actavis completed the acquisition of Defendant Forest Laboratories, LLC. Prior to that time, Forest was a separate corporation headquartered in New York. Forest is still located at 909 Third Avenue, New York, NY 10022 and Forest maintains a number of other New York state locations. Forest is the entity that hatched the unlawful scheme described in this Complaint, and since the acquisition, Actavis has continued and expanded the unlawful conduct.

14. Through Forest, Actavis markets the branded form of the drug memantine, known as Namenda in the United States. Namenda has been sold in interstate commerce throughout the United States, including New York, and in New York intrastate commerce. Defendants' unlawful conduct, as alleged in this Complaint, has occurred in and has had a substantial effect on interstate commerce, as well as intrastate commerce in New York.

15. Defendants' United States revenues for Namenda exceeded \$1 billion in Forest's 2014 fiscal year.

## REGULATORY BACKGROUND

### I. STATUTORY FRAMEWORK

#### A. The Federal Food, Drug, and Cosmetic Act

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

17. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly referred to as the Hatch-Waxman Act (“Hatch-Waxman” or “Act”), which was intended to encourage and facilitate competition from lower-priced generic drugs, while also providing further incentives for pharmaceutical companies to invest in new drug development. By creating benefits and incentives for both generic and branded pharmaceutical manufacturers, the Act attempts to reconcile the competing policy goals of encouraging innovation and expediting access to less expensive generic versions of important but costly branded drugs.

18. Generic alternatives to branded pharmaceutical drugs are critical to controlling health care costs for consumers in New York and elsewhere in the United States. As noted in the United States Senate on the 25<sup>th</sup> anniversary of the Hatch-Waxman Act, the use of FDA-

approved generic medicines saved the health care system approximately \$734 billion between 1999 and 2009 alone.<sup>1</sup>

19. One means by which Hatch-Waxman encourages generic competition is by creating a simplified, quicker, and less costly process for obtaining FDA approval for generic pharmaceuticals. Under the Act, a company seeking to market a generic version of a drug that already has been approved pursuant to 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 previously approved under the NDA.<sup>2</sup> By permitting the generic to rely on studies submitted by the NDA applicant (*i.e.*, the branded drug manufacturer), the Act significantly reduces generic drug development costs and speeds up the FDA approval process for generic drugs.

20. As part of the legislative compromise underlying the Act, the Act also includes several provisions that grant branded drug manufacturers opportunities to lengthen the exclusivity period during which they are protected from competition from generic drugs beyond the 20-year patent term. For example, the Act allows a branded drug manufacturer to seek up to a five-year patent extension to compensate for lost time caused by the FDA regulatory approval process. *See* 35 U.S.C § 156. In addition, the Act, as amended by the Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296, allows a branded manufacturer to 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.

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<sup>1</sup> S. Res. 287, 111<sup>th</sup> Cong. (1<sup>st</sup> Sess. 2009).

<sup>2</sup> A generic is “bioequivalent” to a branded drug when the rate and extent of absorption of the generic drug is not significantly different from the rate and extent of absorption of the branded drug, when administered at the same dosage. *See* 21 C.F.R. §320.1(a).

## **B. State Generic Substitution Laws**

21. Another fundamental aspect of the legislative framework governing market entry by generic drugs is a comprehensive set of state generic substitution laws. All states have some form of generic drug substitution law that allows a pharmacist filling a prescription for a branded drug to instead substitute and dispense a less expensive bioequivalent generic drug for that prescription. This practice facilitates price competition at the pharmacy and results in dramatically reduced drug costs for patients and the health care system after generic entry – while still ensuring that patients receive the same therapeutic benefits.

22. New York law, for example, requires a pharmacist to dispense “a less expensive drug product containing the same active ingredients, dosage form and strength as the drug product prescribed, ordered or demanded” as long as the substituted drug is on an approved list of substitutes issued by the Department of Health and unless the prescriber indicates otherwise. N.Y. Educ. Law. § 6816-a. Further, every prescription issued in New York has an explicit instruction to dispense a less expensive generic equivalent in lieu of the branded counterpart unless the prescriber writes “dispense as written” or “d a w” in a box on the script. N.Y. Educ. Law § 6810(6).

23. State substitution laws are a critical element in facilitating lower-cost generic competition. These laws permit effective price competition between branded and generic drugs at the pharmacy. If pharmacists needed to contact the physician to ask permission to substitute a generic drug for the chemically-identical brand name drug each time the pharmacist filled a prescription, that would significantly and unnecessarily increase the costs and time required for dispensing generic drugs and impede the use of less expensive generics.



24. The price competition at the pharmacy that state generic substitution laws facilitate is the primary mechanism by which generic drugs are able to compete and reach the market. Competition at the pharmacy is especially important due to the unique characteristics of the pharmaceutical markets. Generic manufacturers take market share away from branded pharmaceuticals by making their generic drugs available at a discount. They do not engage in expensive marketing to physicians and patients, as branded firms do. Significant marketing expenditures by a generic manufacturer would likely increase the price of that generic. Moreover it would not necessarily lead to greater sales by the marketer because, typically, there is more than one generic drug available per branded drug. Thus, a manufacturer marketing a generic drug to physicians or patients has no way to make sure that, once the physician is convinced to write the prescription for the generic drug in question, the pharmacist will dispense a generic product manufactured by the marketer as opposed to one manufactured by another generic manufacturer.<sup>3</sup>

25. Because it typically would not make economic sense for a generic manufacturer to market its drug to patients and doctors, the primary means by which generic manufacturers obtain sales is through price competition at the pharmacy, made possible through application of generic substitution laws. Indeed, this is fundamental to the existing regulatory framework. For these reasons, among others, the Federal Trade Commission explained in a recent amicus brief

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<sup>3</sup> A generic manufacturer might spend marketing funds to convince a physician to prescribe its drug (*e.g.*, memantine), but when the patient submits the prescription to the pharmacist, the pharmacist may instead dispense memantine manufactured by a different generic manufacturer. And, if the marketer's product is even slightly more expensive as a result of the need to recover its marketing costs, that makes it even more likely that the marketer's efforts will be in vain because the pharmacist will prefer to dispense a less expensive generic product.

that, “[a]s a practical matter, if a generic cannot be substituted at the pharmacy counter, the economically meaningful market for the generic product disappears.”<sup>4</sup>

26. An important element of state generic substitution laws is the concept of an “AB-rated” generic drug. State substitution laws require a pharmacist to dispense a less expensive generic drug in place of the branded drug only if the generic drug is “AB-rated” to the branded drug. A generic drug is considered “AB-rated” only if it is therapeutically equivalent (in addition to being bioequivalent) to its branded counterpart. This requires that the generic not only have the same active ingredient, clinical effect and safety profile as the branded drug, but also the same dosage form, strength, and route of administration.

27. The AB-rated requirement provides an opportunity for branded manufacturers to game the system by seeking to interfere with price competition by generics. If a brand manufacturer tweaks its drug in a minor way (such as changing from a capsule to tablet, or making a minor change in dosage) it will prevent the generic drug from being AB-rated to the “revised” branded drug, and thereby prevent the generic from being considered a permissible substitute at the pharmacy. As explained in more detail below, this tactic creates barriers to effective price competition, and as a result, can effectively defeat the intent of the legislative scheme and significantly impede the use of lower cost generic drugs.

### **C. The Effects of Generic Competition and Brand Name Manufacturers’ Tactics to Evade Them**

28. Generic drugs are usually priced substantially below their brand-name drug equivalents. Typically, the first generic drug to enter the market is priced at a percentage discount off the branded drug. As more generic competitors enter the market, price competition

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<sup>4</sup> Brief for Federal Trade Commission as Amicus Curiae at 9, *Mylan Pharms., Inc., v. Warner Chilcott Pub. Co.*, No. 12-3824 (E.D. Pa. Nov. 21, 2012) [hereinafter FTC Mylan Amicus Brief], available at [http://www.ftc.gov/sites/default/files/documents/amicus\\_briefs/mylan-pharmaceuticals-inc.et-al.v.warner-chilcott-public-limited-company-et-al./121127doryxamicusbrief.pdf](http://www.ftc.gov/sites/default/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.et-al.v.warner-chilcott-public-limited-company-et-al./121127doryxamicusbrief.pdf).

accelerates and the prices of the generic products continue to fall steeply. According to a study commissioned by the Generic Pharmaceutical Association, in 2012, generic drugs saved the U.S. health system \$217 billion, which equates to an average savings of \$4 billion every week of the year.<sup>5</sup> According to an FDA study using average retail drug prices between 1999 and 2004, entry of a second generic reduces the average generic price to nearly half of the branded price, and entry of additional generics reduced prices to 20% of the branded price – in other words, an 80% discount.<sup>6</sup>

29. Most consumers switch from a branded drug to the AB-rated generic drug upon its introduction as a result of price competition at the pharmacy, facilitated by state generic substitution laws. Typically, when the branded manufacturer's exclusivity ends and multiple generics enter the market (as would be the case here), within one year a branded drug loses approximately 90% of its market share.

30. Once exclusivity is lost and generic entry occurs – an event sometimes referred to as the “patent cliff” – the brand name manufacturer can expect a significant drop in profits, as it is forced to either compete by dramatically lowering prices, or accept dramatically lower sales (almost all companies choose the latter option). The tradeoff of longer exclusivity rights in return for quick and effective generic entry after loss of exclusivity was fundamental to the policies and procedures that Congress established in the Hatch-Waxman Act, and embraced by the states in their generic substitution laws.

31. Nevertheless, confronted with an imminent loss of profits at the patent cliff, pharmaceutical companies often seek to stall the impact of generic competition. One method

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<sup>5</sup> Generic Pharmaceutical Association, *Generic Drug Savings in the U.S.* (2013), [http://www.gphaonline.org/media/cms/2013\\_Savings\\_Study\\_12.19.2013\\_FINAL.pdf](http://www.gphaonline.org/media/cms/2013_Savings_Study_12.19.2013_FINAL.pdf)

<sup>6</sup> FDA, *Generic Competition and Drug Prices* (Mar. 1, 2010), <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm>.

employed has been to enter into anticompetitive patent settlements with generic manufacturers that include payments to the generic firm in return for an agreement to delay entry of the generics. These types of agreements are generally unlawful under the recent Supreme Court decision in *FTC v. Actavis*, 133 S. Ct. 2223 (2013).

32. A second strategy is a “product extension” strategy: the firm develops a follow-on drug with a later patent expiration, and encourages patients and their physicians to switch from the drug going off patent (and about to go off the “patent cliff”) to the new version of the drug. Because generic versions of the original drug will not be AB-rated to the “revised” branded drug, if physicians write prescriptions for the new version instead of the original version, then generic entry will be thwarted – even if, in practice, the cost savings offered by the generic drug far outweigh any advantages offered by the new version of the branded drug.

33. Sometimes, these follow-on drugs may be truly better than the original drug. In other instances, the new versions of the drugs offer little to no therapeutic advantage over the prior versions, and the reformulation of the drug is merely an attempt to game the regulatory system and interfere with effective price competition between branded and generic drugs. Efforts to switch patients to a follow-on drug with little to no clinical benefit – solely for the purpose of interfering with generic competition and extending the monopoly life of a drug franchise – is sometimes referred to as “product hopping.”

34. Product hopping usually involves a minor, non-therapeutic reformulation to a branded drug such as a change in form or dosage. Rather than allowing patients to stay on the old version, which would permit effective price competition between the branded product and lower priced generics after the exclusivity period expires, the brand manufacturer takes steps prior to generic entry to move patients from the original product to the reformulated one. If

successful, the rewards for this strategy can be massive. As noted, because the generic version of the original drug will not be AB-rated to the new, reformulated version of the drug, state substitution laws will not allow the pharmacist to substitute the generic for the reformulated product. Due to the barriers that prevent effective competition between generics and branded drugs at the pharmacy when state generic substitution laws do not act to facilitate substitution, the branded manufacturer will thus avoid – or significantly reduce – the “patent cliff.”

35. Successful implementation of a product extension strategy typically requires that patients be switched prior to generic entry. Accomplishing the switch at this time ensures that the generics have no chance to compete for those patients via the more efficient mechanisms that the state substitution laws provide. As the FTC explained recently: “[i]f the brand manufacturer reformulates its product before a generic receives FDA approval,” then the generic manufacturer is unlikely to be able to make significant sales with a generic version of the original branded drug.<sup>7</sup> Instead, “the generic’s only practical option is to go back to the drawing board and reformulate its own product to be bioequivalent to the brand reformulation and thus substitutable at the pharmacy.”<sup>8</sup> Of course, even that strategy will not work if the branded manufacturer’s patents for the new version of the drug have not yet expired (as is true here).

36. Importantly, once a brand manufacturer has successfully achieved a switch to a follow-on product, it can expect that most “switched” patients will not make a second switch back to the generic version of the original product (when the generic is released). There are several reasons why this is the case, all generally relating to the ineffectiveness and inefficiency of price competition by generics in the absence of the application of generic substitution laws. First, as explained above, it would not make business sense for generic manufacturers to engage

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<sup>7</sup> FTC Mylan Amicus Brief at 10.

<sup>8</sup> *Id.*

in marketing efforts to encourage physicians and patients to switch patients' prescriptions back to a generic version of the original drug – and doing so would undermine the feasibility of selling low cost generic drugs.

37. Second, absent a specific request from a patient, physicians are unlikely to act on their own to switch the patient back. As explained by the FTC: “The physician – who selects the drug product but does not pay for it – has little incentive to consider price when deciding which drug to prescribe.”<sup>9</sup>

38. Third, while patients are concerned about price, they are frequently unaware that comparable, lower-cost generic drugs are on the market (and as noted, it is infeasible for generic manufacturers to market to them).

39. Finally, while insurers may be aware of competing generics and motivated to encourage switching, they face substantial challenges in doing so. Even when they engage in substantial efforts to encourage patients to switch, these efforts are frequently very costly, and may have limited success.

40. There are various tactics that a branded manufacturer may use to try to encourage physicians and patients to switch to its new follow-on drug prior to generic entry. Commonly, the company will aggressively promote the follow-on drug and stop marketing the original drug. The company will typically advocate to physicians that the new product is superior and should be prescribed instead of the original. At the extreme end of the spectrum, a pharmaceutical company may seek to *force* physicians and patients to make the switch to the new drug. This might be accomplished by restricting the distribution and availability of the original drug, or completely removing the original product from the market and leaving patients with no other option but to switch.

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<sup>9</sup> *Id.* at 6.

41. For a drug manufacturer seeking to implement a product extension strategy by *compelling* patients to switch drugs, it is especially important that the branded drug manufacturer take action before a generic enters the market. Prior to generic entry, the branded manufacturer controls all drug sales for the original drug and can use the tactics described above effectively to move patients from one of its own drugs to another. But after generic entry, there will be effective price competition between the original branded drug and generic substitutes as a result of the application of generic substitution laws, and most of the patients taking the original drug will likely switch to the generic version. Once that happens, the brand manufacturer still has the opportunity to compete on the merits, that is, to market to patients and physicians to convince them that the new, reformulated drug is worth the extra cost as compared to the generic. But the opportunities available to the brand manufacturer to manipulate prescribing practices become much more limited.

42. As described below, in the case of Namenda, Forest took the product hopping strategy to an egregious, virtually unprecedented extreme. In most cases, drug companies try to engineer a “soft switch” to the new version of the drug by heavily marketing it and arguing their best case as to its clinical superiority – without creating artificial barriers to the use of the original drug. In this case, however, Forest was not satisfied with that strategy because it was dissatisfied with the number of patients who were willing to switch voluntarily. So, instead, in order to perpetuate its monopoly profits for several more years, Forest has chosen to implement a “forced” or “hard switch:” it will *force* patients to switch to Namenda XR, whether they want to or not. Defendants intend to accomplish this by eliminating – or severely limiting – patient access to the original version of Namenda starting several months before generic Namenda IR

becomes available, thus leaving patients and their physicians with no choice but to use Namenda XR instead.

43. Forest's forced switch is an effort to game the regulatory system and manipulate patients and physicians through business practices that have no real business purpose other than to impede competition from less expensive generic drugs and perpetuate Defendants' monopoly profits. A physician recently aptly described Forest's conduct in a complaint to the company as immoral and unethical.<sup>10</sup> It also constitutes unlawful monopolization in violation of state and federal antitrust laws.

### **THE RELEVANT PRODUCTS AND MARKET**

#### **I. ALZHEIMER'S AND DEFENDANTS' DRUG NAMENDA (MEMANTINE)**

##### **A. Alzheimer's Disease**

44. Alzheimer's disease is a devastating neurodegenerative disorder affecting over five million Americans. Patients with Alzheimer's progressively deteriorate, with worsening symptoms, until death. While the symptoms of Alzheimer's vary from patient to patient, common early symptoms include short-term memory loss, difficulty performing familiar tasks, disorientation, trouble with language, and mood swings. Patients with more severe Alzheimer's may be unable to walk or be unable to recognize and communicate with family members and friends. As the disease progresses, patients are unable to function independently, and become more and more dependent on caregivers.

45. Currently, there is no cure for Alzheimer's. Patients and their loved ones depend on a handful of medications approved to treat the disease, hoping that the medications may be

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<sup>10</sup> In addition, the media recently quoted an Alzheimer's patient describing Defendants' tactic in this way: "They are yanking the rug right out from under me... And that is not fair play." See Jonathan Lapook, *Forced Switch? Drug cos. develop maneuvers to hinder generic competition*, CBS News, Aug, 28, 2014, <http://www.cbsnews.com/news/drug-companies-develop-maneuvers-to-hinder-generic-competition/>.



able to temporarily alleviate some systems or slow down the progression of others. Currently, five drugs are FDA approved for the treatment of Alzheimer's: Aricept, Cognex, Exelon, Razadyne, and Namenda.

**B. The Relevant Market**

46. Aricept, Cognex, Exelon, and Razadyne are drugs known as an acetylcholinesterase inhibitor ("AChEI") and they all work in the same basic manner. AChEIs reduce the breakdown in the brain of a chemical called acetylcholine, a chemical messenger that transmits information between nerve cells. However, Alzheimer's destroys the cells that make acetylcholine, in turn making AChEIs less effective as the disease progresses.

47. Memantine, branded and marketed by Forest as Namenda in the United States, is an N-Methyl-D-Aspartate ("NMDA") receptor antagonist and functions differently than AChEIs. Essentially, Namenda works to prevent the overstimulation of glutamate, an amino acid that excites nerves, and in excess, is a powerful nerve-cell killer. Namenda is the only NMDA antagonist approved by the FDA for treatment of Alzheimer's in the United States, and has been approved for use in patients with moderate and severe Alzheimer's.

48. Namenda is not generally prescribed as a substitute for AChEIs. Instead, the drugs are usually prescribed together, or at different stages. About 70% of Alzheimer's patients taking Namenda are taking an AChEI as well. Doctors commonly prescribe an AChEI first, and then Namenda is either added or patients are moved to Namenda when the disease has progressed to a moderate stage and AChEIs become ineffective. Although there is little clinical support for the use of Namenda for Alzheimer's patients in the early stages of the disease, some physicians will prescribe it in conjunction with an AChEI when the diagnosis is first made, relying on the fact that there are few significant adverse side effects associated with Namenda.

49. The relevant product market at issue in this case is NMDA antagonists—which, as noted, currently include only those drugs with memantine as their active ingredient. As described above, memantine has a unique mechanism of action and typically is used at different stages of the disease than AChEIs, the only other authorized treatment for Alzheimer's. The fact that these two classes of drugs are frequently prescribed together indicates that they are complements, not substitutes, and do not compete head to head. In fact, Forest intends to introduce a new drug that is a "fixed dose combination" of Namenda and an AChEI.

50. The relevant geographic market is the United States. While memantine is produced and sold elsewhere, only Defendants have FDA approval to market the drug in the United States.

51. Currently, Defendants hold a monopoly in the relevant market because they are the exclusive sellers of Namenda IR and Namenda XR.

### **C. Namenda Sales in the United States**

52. Memantine has been marketed in Germany since the 1990s for the treatment of dementia, among other things.

53. On or about June 2000, Merz Pharm GmbH & Co. KGaA ("Merz"), a German company, and Forest entered into a license and cooperation agreement for the development of memantine to be used for Alzheimer's. As part of the agreement, Forest obtained exclusive rights to market a memantine product in the United States under Merz's patent no. 5,061,703 (the '703 patent).

54. In December 2002, Forest submitted a New Drug Application ("NDA") to FDA, seeking approval to market memantine tablets (5mg, 10mg, 15mg, and 20mg) – branded as Namenda – for the treatment of Alzheimer's.

55. As part of its FDA submission for Namenda tablets, Forest identified the '703 patent as covering its proposed memantine tablets and FDA listed the '703 patent in FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly referred to as the "Orange Book"), which identifies and provides certain information on FDA-approved drug products. The '703 patent, obtained in 1991, currently expires in April 2015.

56. In October 2003, FDA approved Forest's NDA for Namenda immediate release (IR) tablets.

57. In January 2004, Forest commercially launched Namenda tablets.

58. Namenda has become a very successful drug for Forest, with revenues of over \$1.5 billion in the past fiscal year (March 2013-April 2014). Forest also sells an oral solution version of Namenda, which has less than 5% of Namenda's sales, and is not material here.

**D. Forest Obtains a Five-Year Patent Extension, and Enters into Settlements Providing for Generic Entry in January 2015**

59. As a means of extending its profits on Namenda tablets, Forest sought to extend the life of the '703 patent, further delaying entry of generic competition. To do so, Forest submitted an application to the Patent and Trademark Office ("PTO") seeking a five-year patent extension due to the time spent obtaining FDA approval for Namenda IR tablets (during which time the patent "clock" was ticking but Forest could not market the drug). In March 2009, the PTO granted Forest the entire five-year extension. As a result, the '703 patent is set to expire on April 11, 2015, rather than the original date of April 11, 2010.

60. Beginning in early 2008, numerous generic manufacturers filed ANDAs with FDA seeking to market generic formulations of Namenda IR, contending that the '703 patent was either invalid or not infringed by their products. Pursuant to certain provisions of the Hatch-



Waxman Act, Forest filed patent lawsuits against each company that filed an ANDA for Namenda.

61. Ultimately, Forest settled with all of the generic manufacturers involved. The Defendants agreed to allow generic entry for Namenda IR tablets in January 2015, a few months before the April 2015 patent expiration date, subject to certain provisions that might delay a generic launch in certain circumstances.

**E. Forest Obtains Six Additional Months of Exclusivity for Namenda IR Tablets, Pushing Generic Entry to July 2015**

62. In January 2014, Forest submitted an application to FDA seeking an additional six months of exclusivity for Namenda IR tablets, based on studies regarding the use of memantine in pediatric patients with autism.<sup>11</sup>

63. On June 18, 2014, Forest announced that FDA had granted its request for six months of pediatric exclusivity for memantine. As a result, under their settlement agreements with Forest, the date that generics are now permitted to enter the market with generic versions of Namenda IR has been delayed from January 2015 to July 2015.

**II. FOREST'S EFFORTS TO STALL THE EFFECTS OF GENERIC ENTRY**

64. At some point after Forest launched Namenda IR tablets, it began to prepare for the inevitable patent cliff – *i.e.*, the date that sales of Namenda IR would steeply decline as a result of the launch of less expensive generic versions. This was of great import to Forest because, by 2012, Namenda was its most profitable drug.

65. To reduce the effects of the upcoming patent cliff for Namenda IR, Forest decided to pursue a “product extension” strategy. To successfully retain substantial sales for its

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<sup>11</sup> As noted, the FDCA offers six months of additional non-patent exclusivity to facilitate studies in pediatric populations (21 U.S.C. § 355a).

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

66. Forest developed two new follow-on drugs with patent expiration dates significantly later than that of Namenda IR. First, it reformulated Namenda as a once-a-day extended release capsule to be taken once a day instead of twice daily (Namenda XR). Second, it worked to develop a fixed-dose-combination product that would include both memantine and donepezil (the most commonly used AChEI). The patents that cover Namenda XR expire several years after the patents the cover Namenda IR. And the patents that cover the new fixed dose combination expire even later than the Namenda XR patents.

**A. Forest Launches Namenda XR in June 2013 and Seeks to Convert Patients from Namenda IR to Namenda XR**

67. On August 21, 2009, Forest submitted an NDA seeking to market Namenda XR. In support of its NDA, Forest submitted various studies supporting its claims of safety and efficacy for Namenda XR. In its NDA submission for Namenda XR, Forest did not submit any head-to-head studies comparing the efficacy of Namenda XR to Namenda IR, nor did it otherwise demonstrate that Namenda XR was more efficacious than Namenda IR.

68. Forest launched Namenda XR in June 2013, three years after obtaining FDA approval for the drug. The apparent reason for the delay was to reap as much profit as possible from Namenda IR, prior to launching XR. At the time Namenda XR was launched, Forest anticipated that generics would enter in January 2015. The June 2013 launch would give Forest sufficient time—18 months—before generic entry to persuade health plans to put Namenda XR

on a preferred tier and start moving patients to Namenda XR. If health plan coverage for XR and IR was equivalent, patients would be more likely to switch from Namenda IR to Namenda XR prior to generic entry.

69. Forest has forecasted the effects on current and future profits for its Namenda franchise based on whether it succeeds in switching patients to Namenda XR. Consistent with its product extension strategy – *i.e.*, its effort to extend the life of its Namenda franchise beyond the Namenda IR “patent cliff,” its forecasts indicated dramatically increased profits if it were able to switch large numbers of patients to Namenda XR. Accordingly, switching patients to Namenda XR became the key to Forest’s profit strategy for Namenda.

70. Crucially, Forest realized that, to be successful, its product switch had to be accomplished before less expensive generic versions of Namenda IR (“generic Namenda” or “generic memantine”) tablets became available in the market. This is because when generic memantine becomes available, there will be effective price competition between generic memantine and Namenda IR at the pharmacy, and as a result, many patients that remain on Namenda IR tablets after generic entry will likely switch to generic memantine. Forest knew that convincing these patients (or their physicians or health insurers) to switch to Namenda XR based solely on the merits of the different drugs would be very difficult. Forest would need to convince them to leave an inexpensive generic drug and pay significantly more (possibly five times more) for a different version of the very same drug (with no greater evidence of efficacy) – solely because it could be taken once a day instead of twice daily.

71. However, if Forest could manage to get patients, physicians and insurers to switch to Namenda XR prior to generic entry, then Forest would be able to prevent manufacturers of generic memantine from engaging in effective price competition for these patients. This is

because generic memantine tablets will not be AB-rated to Namenda XR, and therefore a pharmacist will not be able to substitute lower-priced generic memantine for Namenda XR under state substitution laws. Rather, the pharmacist would have to obtain physician consent for the substitution, which is time consuming and costly. Similar limitations would also be faced by a health insurer or generic competitor that sought to convince a patient to switch back to Namenda IR. By ensuring that generic manufacturers could not engage in meaningful competition for the sales to the switched patients, Forest's strategy makes it much more likely that Forest will be able to retain these sales once generic memantine becomes available.

72. Consequently, Forest knew that switching a large portion of the Namenda patient base to Namenda XR prior to entry of generic memantine tablets would – by preventing the application of generic substitution laws and thus inhibiting effective price competition– create significant practical barriers to generic competition that would allow Forest to retain a significantly higher portion of its Namenda sales in the face of generic substitution than it would have otherwise.

73. In June 2013, Forest held a Namenda XR launch event in Dallas for its employees. Forest invited its sales representatives to the event, at which several Forest executives gave speeches. During these speeches, the executives consistently emphasized the urgency of switching patients from Namenda IR to Namenda XR. The following are examples of statements made by Forest executives during the Namenda XR launch:

- “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.”
- “The 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.”

74. Forest’s internal documents also emphasize the importance of accomplishing its product switch in advance of the entry of generic memantine. For example, a document titled “Namenda Franchise Business Plan”, dated September 2013, set specific goals for conversion levels to be achieved “prior to the Namenda LOE [loss of exclusivity] in 2015.” A separate presentation lists “Maximize XR Conversion leading up to IR LOE [loss of exclusivity]” as part of Forest’s managed care strategy.

75. Since 2013, Defendant has undertaken an aggressive marketing campaign aimed at converting as many IR patients to XR as possible prior to Namenda IR losing exclusivity. The promotional budget for the Namenda franchise in fiscal year 2014 was designed with “[a]ll funds . . . allocated to drive conversion from Namenda to Namenda XR.”

**B. Dissatisfied With the Results of its Efforts to Switch Patients and Physicians Voluntarily to Namenda XR, Forest Hatches a Scheme to *Force* Them to Switch**

76. As Forest sought to accomplish the switch from IR to XR, Forest executives had concerns that conventional strategies designed to influence patients’ drug choices would be insufficient to convert a satisfactory number of patients from Namenda IR to Namenda XR prior to entry of generic Namenda.

77. There are several reasons why many patients and their physicians are reluctant to switch from Namenda IR to Namenda XR. First, the benefits of a switch from Namenda IR to Namenda XR are marginal. Some patients and their caregivers may benefit from the ability of patients to take Namenda once a day, instead of twice a day, but this is a trivial benefit for most patients, especially those who are already taking multiple medications.

78. Second, for many, if not most, patients (and their physicians), the benefits of the change of administration are outweighed by the risks of changing the medical routine of a highly vulnerable patient. Without studies that show that a new medication has meaningful benefits over a patient's current medication, physicians are reluctant to switch an Alzheimer's patient from a medicine on which he or she is doing well to a new drug.

79. Despite aggressive marketing and pricing, Forest's forecasts showed that it was realistic to expect that only about 30% of patients using Namenda IR tablets could be converted to Namenda XR prior to availability of generic memantine. Plainly, if the choice were left to physicians and patients, a large number of them would stay on the original formulation. As one Forest executive lamented, "I could see doctors just being apathetic about it and if patient is fine and not complaining of any issues, why switch?" Forest ultimately became dissatisfied with the number of patients it would be able to switch through conventional strategies that relied on advocating for Namenda XR on its own merits.

80. Accordingly, Forest began to consider whether it should *force* physicians and patients to switch to Namenda XR, whether they liked it or not. By at least as early as Fall 2012, Forest began to consider a plan to discontinue (or dramatically restrict distribution of) Namenda IR tablets several months prior to the availability of generic memantine, in order to accomplish through a "forced switch" what it had been unable to accomplish based on promoting Namenda XR on its own merits.

81. After a year evaluating whether to discontinue Namenda IR tablets prior to generic entry, by October 2013, Forest executives made the decision to discontinue Namenda IR.

82. An October 2013 power point presentation titled "Namenda IR & XR Conversion Plan" lays out the case for discontinuing Namenda IR tablets. The document summarizes

Forest's predictions that the "forced switch" would result in dramatically increased profits for the company – in the hundreds of millions of dollars --even though it would result in short-term profit reductions as some frustrated patients would stop taking Namenda altogether. The document also addressed concerns about negative public reactions that could result from the forced switch.

83. Defendants' internal analyses assessed the profitability of two potential scenarios, both of which in practice would result in a "forced switch." First, Forest analyzed the financial implications of a decision to discontinue Namenda IR completely. Second, Forest analyzed the financial implications of a decision to restrict patient access to Namenda IR by supplying it only under "limited distribution." The financial effects of each strategy were found to be almost identical; even in the limited distribution scenario, Forest concluded that the reduced access to Namenda IR tablets would have the practical effect of forcing virtually all patients to switch to Namenda XR. In other words, in their planning in late 2013, Defendants knew that the "limited distribution" option had the same practical effect of forcing a switch as did the discontinuance option.

84. In a Power Point presentation contained in an email between two executives dated June 26, 2013 and titled "Namenda IR to XR Conversion Project," the author of the presentation notes that, with respect to Forest's conversion strategy, "Either [a withdrawal or limited distribution] approach would be unprecedented – would be operating in uncharted territory." The presentation also recognizes that "Prescribers, patients, caregivers may be confused or dissatisfied with either withdrawal or limited distribution scenario and may choose to discontinue Namenda treatment."

85. On October 18, 2013, a Forest executive distributed an email to numerous colleagues, disclosing the decision to discontinue Namenda tablets.

“Dear All: Forest has made the decision to discontinue sales of Namenda IR and transition all patients to Namenda XR.”

86. According to its own predictions, the profits that Forest will make from the “forced switch” will come largely from impeding generic competition. As noted above, the typical effect of AB-rated generic entry is a 90% shift of brand market share to generics within one year. Forest, however, has predicted that as few as 20% of patients whom Forest forces to Namenda XR may end up switching back to generic memantine tablets after generic entry.

87. During Defendant’s January 21, 2014 earnings call, Forest’s CEO, Brenton Saunders, unabashedly explained the motivation behind the forced switch strategy: “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 Rx’s. 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.”<sup>12</sup>

88. Similarly, another high level Forest executive, considering the likelihood that patients converted to Namenda XR would switch back to Namenda IR, observed that “anyone converted [to Namenda XR] is likely to stay converted.”

89. Forest knows that discontinuing or severely restricting the availability of Namenda IR will have serious consequences for patients. First, physicians’ freedom to choose the medications they prefer for their patients will be eliminated, or dramatically curtailed. It will

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<sup>12</sup> Forest CEO Brenton Saunders himself used the term “forced switch” in Forest’s Q3 2013 Earnings Call (Jan. 21, 2014) (“We believe that by potentially doing a forced switch, we will hold on to a large share of our base users...”).

be Forest—rather than the patient or the physician—that selects the patients’ therapy. Upon discontinuing or limiting distribution of Namenda IR tablets, Namenda XR will be the only readily available FDA-approved NMDA antagonist (aside from the rarely prescribed Namenda oral solution).

90. Second, patients will be forced to undergo an unnecessary change in medication and dosage that could be disruptive to their routine. It is very difficult to predict how this change in routine could impact a patient. In addition, the recommended dosage for Namenda XR (28 mg) is significantly greater than the typical dosage for Namenda IR (two 10 mg tablets, for a total of 20 mg). These reasons are why many physicians have been reluctant to move their patients to Namenda XR, and probably never will if not forced by Forest to do so.

**C. Forest Begins to Implement and then Modifies its “Forced Switch” Scheme**

91. On February 14, 2014, Forest issued a press release titled “Forest Laboratories to Discontinue Namenda tablets. Focus on once daily Namenda XR,” and announced that it planned to discontinue the sale of Namenda IR tablets effective August 15, 2014. The press release further indicated that the Namenda XR formulation (and the rarely-prescribed oral solution) would still be available to consumers. On the same day, Forest notified the FDA that it would “be discontinuing the sale of Namenda [IR] Tablets effective August 15, 2014.” Defendant also published open letters to physicians and caregivers on its website announcing its plans to discontinue Namenda IR tablets as of August 15, 2014, and urging caregivers to speak with their loved ones’ “healthcare provider[s] as soon as possible to discuss switching to NAMENDA XR.” Forest hoped and expected that the February 14, 2014 public announcement and letters to physicians and caregivers would spur the “forced switch,” but it also took other actions to ensure the success of its anticompetitive scheme.

92. For example, Forest also took steps to make it more difficult for Namenda IR tablets, or generic memantine, to be sold to Medicare patients – the largest customer base for the drug. A large portion of Namenda patients have their prescriptions paid for by Medicare, the government sponsored health insurance program that provides health insurance to most Americans over 65 years of age.

93. On February 5, 2014 – a few days prior to the public announcement of the “forced switch” – a Forest employee wrote an email to the Executive Vice President for Sales at the time, proposing that Forest contact the Center for Medicare and Medicaid Services (“CMS”), the federal agency responsible for the Medicare program, to request that Namenda IR tablets be removed from the 2015 Formulary Reference File (“FRF”) to discourage health plans from including it in their own formularies:

“I proposed 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 formularies. We also want to tell them not to remove the suspension.”

94. Following along with the approved plan, in a letter dated February 18, 2014, Forest informed CMS that Forest was planning to discontinue Namenda IR on August 15, 2014 and that CMS should remove Namenda IR tablets from the FRF.

95. Forest knew that if Namenda IR tablets were not listed on the 2015 FRF, most health plans would not cover Namenda IR beginning in January 2015, making it difficult for physicians to prescribe Namenda IR.

96. On February 28, 2014, the Attorney General of the State of New York served Forest with a subpoena in connection with an investigation of Forest’s plans to discontinue Namenda IR and thus foreclose generic competition.

97. As at the time of the filing of this Complaint, the Namenda website maintained by Forest still prominently states that Defendants intend to proceed with the forced switch in the Fall of 2014.<sup>13</sup>

### **III. THE ANTICOMPETITIVE PURPOSE AND EFFECTS OF DEFENDANTS' CONDUCT**

98. Namenda has been the most valuable drug in Forest's portfolio since generic Lexapro launched in March 2012. Namenda is Forest's largest selling drug, earning over \$1.5 billion in Forest's most recent fiscal year (fiscal year ended March 31, 2014). Rather than lose much of this revenue stream, Forest embarked on a strategy to inhibit generic competition and unlawfully maintain its monopoly in the market for NMDA antagonists. By discontinuing or restricting access to Namenda IR prior to generic entry, Defendants specifically intend to force the entire Namenda population to switch Namenda XR, thereby interfering with the ability of manufacturers of generic memantine to obtain sales through price competition, through the application of generic substitution laws. As a result, Defendants will increase their own profits at the expense of vulnerable Alzheimer's patients in New York and throughout the United States, as well as others, by interfering with patients' and doctors' abilities to choose the course of treatment that they feel is most appropriate and cost-effective.

99. By implementing a strategy to discontinue or limit the availability of Namenda IR, Forest projects that it will make hundreds of millions of dollars more in profits over the long term than if it were to keep Namenda IR on the market and allow generic competition to operate in the manner contemplated by the Hatch-Waxman Act and generic substitution laws. These projected profits reflect gains Defendants would not obtain absent this anticompetitive, anti-generic strategy. These increased profits also reflect higher drug costs paid by health plans and

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<sup>13</sup> See [www.namenda.com](http://www.namenda.com) (last visited Sept. 15, 2014).

patients who would otherwise have chosen the less expensive generic memantine tablets, but instead must pay for the more expensive branded Namenda XR. Forest's gains thus come at the direct expense of patients and the health care system generally, which must bear the costs of more expensive drugs.

100. Defendants' purpose in discontinuing or otherwise limiting the availability of Namenda IR is to restrain competition. There is no legitimate business justification or procompetitive rationale for their scheme. In fact, there is no rational economic reason for Defendants' decision to discontinue or restrict access to Namenda IR – Forest's highest grossing product – other than to exclude generic competition. Indeed, it is virtually unprecedented for a pharmaceutical company to discontinue a billion dollar drug without a medical reason for doing so.

101. Forest's internal documents indicate that Forest's strategy is economically irrational in the short term – Forest expects its strategy to result in a significant *reduction in profits* from Namenda in the period prior to the entry of generic memantine, as compared to the profits it would have realized had it kept IR on the market. This short-term loss is largely the result of patients who, in response to the lack of availability of Namenda IR, decide not to switch to Namenda XR. These patients are likely to be lost to the Namenda franchise forever. Internal documents refer to this patient loss as “disruption.” In some projections, Defendant estimates as much as “20% franchise disruption” if it withdraws Namenda IR from the market prior to generic entry. One Forest Power Point presentation dated October 10, 2013 contains sales projections comparing Forest's projected income for Namenda based on whether and when Namenda IR tablets are withdrawn. Under all of the scenarios, Forest projects that it will lose



tens if not hundreds of millions of dollars in the short term if it withdraws Namenda IR from the market.

102. The same projections indicate that, despite the short-term losses, withdrawing Namenda IR is significantly *more profitable in the long run* because Forest expects that its short-term loss will be outweighed by the benefits that will come from preventing generics from engaging in effective price competition through the operation of generic substitution laws. By robbing patients and payers of the benefits of effective price competition, Defendants' strategy dramatically increases the costs associated with generic entry and hobbles the overall competitive significance of generic memantine, resulting in dramatically increased profits for Defendants over the long term.

103. The forced switch is not motivated by any desire to obtain efficiencies, such as lower manufacturing costs. Namenda IR is a highly profitable drug—over \$1 billion per year, and well worth the manufacturing costs. For example, a Forest executive who was in charge of manufacturing acknowledged under oath that there was no reason why Forest could not produce both Namenda XR and Namenda IR, and that “freeing up any of the manufacturing equipment for the Namenda [IR] tablets” would not “assist in . . . increasing . . . manufacturing production of XR” because the two formulations are manufactured with different equipment and processes. Further, if Defendants desired to streamline their operations by focusing only on Namenda XR, they could have identified less harmful and less restrictive ways of accomplishing that goal, such as outsourcing the manufacturing and/or distribution of Namenda IR or delaying the discontinuance of Namenda IR until generics are on the market. Rather, the only explanation for Defendants' withdrawal of Namenda IR from the market – and doing so prior to generic entry – is a goal to prevent AB-rated automatic generic substitution, and thus impede generic entry.

104. Defendants must be stopped from implementing these anticompetitive and wrongful strategies. This is necessary not only because of the significant harm threatened in this case, but because failure to deter this wrongful and illegal behavior may encourage other pharmaceutical companies to do the same.

**IV. FOREST REPEATEDLY EXAGGERATES THE IMMINENCE OF ITS PLANS TO DISCONTINUE NAMENDA IR TO PRESSURE PATIENTS AND THEIR PHYSICIANS TO SWITCH TO NAMENDA XR**

105. Between February and June 2014, Forest regularly emphasized publicly its intent to discontinue Namenda IR on August 15, 2014.

106. In its Form 10-K filing with the Securities and Exchange Commission for fiscal year 2013 (ending March 31, 2014), Forest made multiple representations that it would discontinue Namenda IR on August 15, 2014. For example, 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.”

107. In fact, however, high level executives at Forest were aware at that time that pervasive problems in the manufacturing and supply of Namenda XR presented a substantial risk that Forest would be unable to discontinue Namenda IR and effectively implement its proposed forced switch by August 15, 2014 because it would be unable to supply the market with sufficient Namenda XR.

108. Further, Forest executives have provided testimony, under oath, suggesting that their plans to discontinue Namenda IR were not as imminent or certain as is suggested by Forest’s communications to the public.

109. Defendants issued a statement on June 10, 2014 announcing that Forest would no longer be discontinuing Namenda IR on August 15, but would instead continue to market Namenda “into the Fall of 2014.”

110. Between February and June 2014, as it became increasingly evident that Forest could not implement the hard switch on August 15, 2014, Forest was under an obligation to bring that information to the public, but failed to do so in a timely manner.

111. Defendants’ eventual notice that it would continue to market Namenda IR “into the Fall” is so ambiguous that it still does not provide meaningful notice of when Forest plans to discontinue Namenda IR.<sup>14</sup> As a result of Forest’s misrepresentations regarding its true timetable, physicians, patients, and insurers are still being led to believe that Forest may discontinue Namenda IR as early as September 2014, even though the actual timing is much less certain.

112. Forest’s clear intent in obfuscating the timing of the discontinuance of Namenda IR is to pressure physicians, patients, and insurers to hasten the switch of patients to Namenda XR and to refrain from making the more economical and convenient decision to continue use of Namenda IR so that patients may seamlessly switch to generic memantine when it becomes available.

113. To date, more than 40% of existing patients have converted from Namenda IR to Namenda XR in anticipation of Namenda IR’s discontinuance. In the face of the impending discontinuance of Namenda IR, the number of converted patients continues to increase.

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<sup>14</sup> As of the date of filing, [www.namenda.com](http://www.namenda.com) states the following: “Important message regarding NAMENDA (memantine HCl). Forest plans to discontinue the sale of NAMENDA 5 mg and 10 mg tablets in the Fall of 2014. This is not due to any safety or efficacy issue related to NAMENDA tablets. The oral solution of NAMENDA will continue to be available, along with NAMENDA XR (memantine HCl) extended release capsules.” (last visited Sept. 15, 2014)

114. Forest previously considered accomplishing its forced switch by means of a “limited distribution” strategy, rather than a complete discontinuation of Namenda IR. Although Forest has never publicly announced that it is considering a “limited distribution” strategy in lieu of discontinuation, it is possible that Defendants will decide to accomplish the same goal of interfering with generic competition by significantly restricting patient access to Namenda IR rather than technically “discontinuing” it.

115. In the event that Forest chooses to restrict patient access to Namenda IR through a limited distribution strategy (instead of discontinuing it completely), the effects on patients and generic competition will essentially be the same – as Forest itself has predicted. Patients will still have very limited access to Namenda IR, and the result, in practice, will still be a “forced switch.”

116. Depending on the method of limited distribution that Forest chooses, limited distribution could be an administrative nightmare for physicians, who would have to fill out yet more paperwork to obtain the drug for their patients, with no financial incentive to do so. Restricting Namenda IR would also burden patients and caregivers, who may not be able to go through their preferred pharmacy to acquire the drug, or at least not in their usual manner. And if “medical necessity” must be demonstrated in order to obtain the drug, that will further decrease the likelihood that patients will be able to obtain it. Since Namenda IR and Namenda XR are practically the same drug – and there are no published clinical trials comparing their safety and efficacy – some physicians may be uncomfortable stating that there is a “medical necessity” for Namenda IR tablets, even if they believe that prescribing that drug would be in the best interests of a particular patient.

117. Accordingly, Defendants' "forced switch" is unlawful, whether implemented as a discontinuation, or restricted distribution, of Namenda IR.

### **FIRST CAUSE OF ACTION**

(Monopolization – Section 2 of the Sherman Act, 15 U.S.C. § 2.)

118. The Attorney General repeats and re-alleges the paragraphs above as if fully stated herein.

119. Defendants have violated and continue to violate the Sherman Act, 15 U.S.C. § 2, in that, as a result of Defendants' past acts and future planned acts, Defendants have monopoly power in the market for NMDA antagonists and are maintaining and enhancing their monopoly as a result of their exclusionary, anticompetitive conduct.

### **SECOND CAUSE OF ACTION**

(Attempted Monopolization – Section 2 of the Sherman Act, 15 U.S.C. § 2.)

120. The Attorney General repeats and re-alleges the paragraphs above as if fully stated herein.

121. Defendants have violated and are continuing to violate the Sherman Act, 15 U.S.C. § 2 in that Defendants have: (1) engaged in anticompetitive conduct; (2) with a specific intent to maintain a monopoly in the market for NMDA antagonists; and (3) have a dangerous probability of maintaining monopoly power.

### **THIRD CAUSE OF ACTION**

(Violation of the Donnelly Act – N.Y. General Business Law §§ 340 *et seq.*)

122. The Attorney General repeats and re-alleges the paragraphs above as if fully stated herein.

123. Defendants have violated and continue to violate General Business Law §§ 340 *et seq.*, in that they are restraining competition in New York for the purpose of establishing or maintaining a monopoly in the market for NMDA antagonists.

#### **FOURTH CAUSE OF ACTION**

(Repeated or persistent illegality – Section 63(12) of NY Exec. Law)

124. The Attorney General repeats and re-alleges the paragraphs above as if fully stated herein.

125. The acts and practices of Defendants alleged above constitute conduct proscribed by § 63(12) of the Executive Law, in that Defendants engaged in repeated illegal acts – violations of Section 2 of the Sherman Act as well as the Donnelly Act – in the carrying on, conducting or transaction of business within the meaning and intent of Executive Law § 63(12).

#### **FIFTH CAUSE OF ACTION**

(Repeated or persistent fraud – Section 63(12) of NY Exec. Law)

126. The Attorney General repeats and re-alleges the paragraphs above as if fully stated herein.

127. The acts and practices of Defendants alleged above constitute conduct proscribed by § 63(12) of the Executive Law, in that Defendants have engaged in repeated fraudulent acts or otherwise demonstrated persistent fraud by deceptively exaggerating the timing and scope of their plan to discontinue Namenda IR, as part of an effort to increase the pressure on patients, physicians, and insurers to switch to Namenda XR. On information and belief, patients, physicians, and insurers are relying on the statements by Defendants with respect to the timing of

the discontinuance of Namenda IR when making decisions of whether and/or when to switch to Namenda XR.

**WHEREFORE**, Plaintiff demands judgment against Defendants as follows:

- a. Adjudging and decreeing that Defendants have violated Section 2 of the Sherman Act, 15 U.S.C. § 2 and the Donnelly Act, NY GBL § 340;
- b. Adjudging and decreeing that Defendants have violated NY Exec. Law § 63(12);
- c. Directing Defendants to disgorge all amounts obtained and to be obtained in connection with or as a result of the violations of the law alleged herein, and all amounts by which Defendants have been or will be unjustly enriched in connection with or as a result of the acts and practices alleged herein; and to pay restitution and damages to injured parties;
- d. Enjoining Defendants preliminarily and permanently from discontinuing Namenda IR until generic memantine is available in the market and for a reasonable period thereafter, enjoining Defendants from engaging in any ongoing and future violations of law and directing such other equitable relief as may be necessary to redress Defendants' violations of law;
- e. Awarding New York civil penalties, and/or damages and restitution for Defendants' violations of the Donnelly Act and other applicable New York laws;
- f. Awarding New York the costs of this action, including reasonable attorneys' fees and expert's fees;
- g. Granting such other and further relief as may be just and proper.

Dated: September 15, 2014

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