No. 15-___

IN THE

Supreme Court of the United States

ALLERGAN PLC AND FOREST LABORATORIES, LLC,
Petitioners,

v.

STATE OF NEW YORK, BY AND THROUGH
ERIC T. SCHNEIDERMAN, ATTORNEY GENERAL,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Brand drug manufacturers seeking to market a new prescription drug must undergo a long and expensive process to obtain FDA approval. Under the 1984 Drug Price Competition and Patent Term Restoration Act, better known as Hatch-Waxman, generic drug manufacturers can obtain FDA approval for a "bioequivalent" generic drug more easily, by piggy-backing on the brand's approval efforts. Once the brand drug's patent and other exclusivities expire and generic versions enter the market, state drug substitution laws permit or require pharmacists to dispense lower-priced, therapeutically equivalent generic drugs in place of brand drugs, unless the prescriber directs otherwise. Under most (but not all) states' definitions of therapeutic equivalence, however, pharmacists may not substitute a generic drug that has a different dose than the prescribed brand without the physician's approval.

The Second Circuit held below that brand drug manufacturers have a federal antitrust duty to facilitate the operation of state drug substitution laws so as to maximize the future sales of their generic competitors. Petitioners are a brand drug manufacturer and its subsidiary, who sought to exercise their rights under the Patent Act to limit distribution of an outdated version of their patented Alzheimer's drug in favor of an innovative new formulation with different dosing and longer patent protection. The Second Circuit held that so doing would violate section 2 of the Sherman Antitrust Act because it would reduce the number of prescriptions most state substitution laws would automatically hand over to Petitioners' generic rivals once the old drug's exclusivities ended. The questions presented are:

1. Whether exercising rights granted by the Patent Act—in particular, not selling one patented product and selling a different patented product instead—can violate the Sherman Antitrust Act?

2. Whether drug manufacturers have a federal antitrust duty to facilitate the operation of state drug substitution laws to maximize competitors' sales?

CORPORATE DISCLOSURE STATEMENT

In accordance with Supreme Court Rule 29.6, Petitioners make the following disclosures:

Forest Laboratories, LLC is an indirect wholly owned subsidiary of Allergan plc, a public limited company incorporated in Ireland and traded on the New York Stock Exchange under the ticker symbol AGN. No publicly held company owns ten percent or more of the stock of Allergan plc.

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OPINIONS BELOW

The Second Circuit's opinion is reported at 787 F.3d 638 and reproduced at App. 1a-44a. The district court's opinion is unreported and reproduced at App. 45a-143a.

JURISDICTION

The Second Circuit issued its decision on May 22, 2015, App. 1a, and denied rehearing en banc on August 7, 2015, App. 146a. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2, provides:

> Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

Section 154(a)(1) of the Patent Act, 35 U.S.C. § 154(a)(1), provides:

> Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, of the right to exclude others

> from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process, referring to the specification for the particulars thereof.

Section 271(d) of the Patent Act, 35 U.S.C. § 271(d), provides in relevant part:

> No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: … (4) refused to license or use any rights to the patent ….

INTRODUCTION

The Second Circuit affirmed an unprecedented antitrust injunction forcing a brand drug manufacturer to continue making and selling an outdated patented drug it wanted to replace with a new and improved version. The court held that withdrawing twice-daily Namenda IR in favor of innovative once-daily Namenda XR violated section 2 of the Sherman Act because certain state pharmacy laws treat the two drugs differently. In particular, most states allow or require pharmacists to dispense a generic version of IR in place of brand IR, but not in place of brand XR. The Second Circuit held that instead of maximizing their own sales and profits, Petitioners had to keep selling IR to maximize the sales state drug laws would automatically hand over to Petitioners' generic rivals.

That ruling rests on two deeply flawed holdings that contradict decades of decisions by this Court and other courts of appeals. First, the Second Circuit held that section 2 of the Sherman Act prohibits the same conduct Congress authorized through the Patent Act—namely, unilaterally refusing to sell a patented product, and selling a different patented product instead. That counterintuitive notion directly conflicts with numerous decisions of this Court holding that patentees have the absolute right to choose whether or not to use or sell their inventions, and that the mere exercise of patent rights cannot give rise to antitrust liability. The Second Circuit also widened a recognized circuit split over the nature and scope of a patentee's immunity from antitrust scrutiny.

Second, the Second Circuit held that brand drug manufacturers have a federal antitrust duty to facilitate the operation of certain states' drug laws to maximize competitors' sales. That holding conflicts with decisions of this Court holding that there is no general antitrust duty to aid competitors, that antitrust law is not a vehicle for enforcing other regulatory regimes, and that the application of a uniform federal statute like the Sherman Act cannot turn on the vagaries of state law. The court also precipitated a split with three other circuits that hold that preventing free-riding by competitors is a legitimate business justification that precludes antitrust liability.

This Court's review is needed immediately. The Second Circuit's decision affects how drug manufacturers invest today to invent and improve treatments that won't become available for years or even decades. By penalizing drug manufacturers who seek to maximize returns on their innovations, the decision below is already chilling critical efforts to develop life-saving

medications. Respondent the State of New York has promised to use the decision below to obtain future nationwide injunctions preventing drug manufacturers from replacing out-of-date products. This Court should grant certiorari now to restore innovators' patent rights and clarify their antitrust duties.

STATEMENT

A. Regulatory Background

1. To obtain FDA approval to market a "new drug," the Federal Food, Drug, and Cosmetic Act ("FDCA") requires the drug's manufacturer to submit a new drug application ("NDA") showing that the drug is "safe" and "effective" for its intended use. 21 U.S.C. § 355(b)(1). Making that showing entails "a long, comprehensive, and costly testing process." *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013).

Under the Hatch-Waxman amendments to the FDCA, once the FDA approves a brand drug for marketing, generic manufacturers can obtain similar marketing approval far more easily. In particular, "a generic competitor [may] file an abbreviated new drug application (ANDA) piggy-backing on the brand's NDA." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012). "Rather than providing independent evidence of safety and efficacy, the typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug." *Id*. (citing 21 U.S.C. § 355(j)(2)(A)(ii), (iv)).

2. Once drugs have FDA approval and enter the market, state law regulates which drugs pharmacists can dispense to fill prescriptions from physicians. Since the 1970s, states have passed laws to encourage pharmacists to fill prescriptions for brand drugs by

dispensing lower-priced generic drugs instead. "Today, all 50 states and the District of Columbia have [such] laws." App. 7a. "[D]rug substitution laws either permit or require pharmacists to dispense a therapeutically equivalent, lower-cost generic drug in place of a brand drug absent express direction from the prescribing physician that the prescription must be dispensed as written." App. 7a-8a.

State drug substitution laws vary widely. Most importantly, different states define therapeutic equivalence differently. The FDA's "Orange Book" considers a generic to be "AB" rated, and therefore substitutable, if it has the same active ingredient, strength, route of administration, and dosage form as the brand drug, among other criteria. FDA, Approved Drug Products with Therapeutic Equivalence Evaluations vii–x, xiii-xiv (35th ed. 2015). Twenty-nine states and the District of Columbia have expressly adopted the FDA's AB standard. App. 32a-33a & n.33. Another sixteen states do not reference the FDA standard, but according to the Second Circuit, prohibit pharmacists from substituting a generic of a different dose than the brand without physician approval. App. 33a n.33. The five remaining states—Minnesota, North Dakota, Oklahoma, Vermont, and Washington—facially permit or require pharmacists to substitute differently-dosed generics without physician approval. App. 33a n.33.[1]

[1] The Second Circuit stated that it "cannot determine" whether Oklahoma permits pharmacists to substitute differently-dosed generics. App. 33a n.33. But Oklahoma law plainly permits substitution of a generic selected by the pharmacist if the purchaser consents. Okla. Stat. tit. 59, § 353.13(D) (prohibiting substitution "without authority of the prescriber or purchaser"); Okla. Admin. Code § 535:15-5-7.5(4) (providing that the "[d]etermination of

B. Factual Background

Petitioner Allergan plc is one of the world's largest brand drug manufacturers, and Petitioner Forest Laboratories, LLC is its subsidiary.[2] Petitioners manufacture two pertinent drugs approved to treat moderate-to-severe Alzheimer's disease. The first is Namenda IR, a twice-daily tablet released in 2004. The second is Namenda XR, an innovative capsule released in mid-2013 with the same active ingredient as IR, but once-daily dosing. App. 11a-13a. XR's once-daily dosing can reduce errors in pill administration, ease burdens on caregivers, and improve the compliance of patients, who are by definition forgetful, often resist pills as a dignitary affront, and whose conditions often worsen as the day progresses. App. 72a, 75a. Once-daily dosing also aligns XR with other Alzheimer's treatments, all of which are administered once daily. App. 12a. Based on agreements granting early entry to certain generic manufacturers, IR's patent and other regulatory exclusivities ended on July 11, 2015. App. 12a-13a & n.16. Based on a similar agreement, XR's exclusivities currently run until January 2020.

XR supplants any market need for IR, and the FDA has approved instructions for switching from IR to XR. App. 74a. Under most states' drug substitution laws, however, once IR's exclusivities ended and generic IR entered the market, pharmacists could substitute generic IR for brand IR, but not for brand XR, due to its different dosing. Accordingly, Petitioners recognized that once

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product selection if substitution is requested or approved" must be made "by a pharmacist" and not "by supportive personnel").

[2] Below, Petitioner Allergan plc was known as Actavis plc. On March 17, 2015, Actavis plc purchased Allergan, Inc., and on June 15, 2015, it renamed itself Allergan plc.

they began selling XR, continuing to sell IR served no purpose except to provide prescriptions that state drug laws would hand over to Petitioners' generic rivals.

So in February 2014, Petitioners announced plans to cease distributing IR, and encouraged patients to switch to XR. To smooth the transition, Forest announced in November 2014 that it would continue to make IR available through a mail-order pharmacy to any patient whose doctor deemed it medically necessary. App. 14a-15a, 94a. These announcements helped ensure that patients would experience XR's once-a-day benefits, and avoided helping generics free-ride on state substitution laws. But Petitioners did nothing to prevent generics from entering the market, or from competing on the merits by pitting cheaper twice-daily generic IR against innovative, more convenient once-daily brand XR.

C. Proceedings Below

1. On September 15, 2014, Respondent the State of New York sued Petitioners, seeking declaratory relief, an injunction, disgorgement, restitution, and damages on the theory that Petitioners' announced intention to replace IR with XR violated New York's antitrust statute and sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1-2. App. 50a-52a. Respondent wanted to fill a perceived gap in its own drug substitution law, which, like most states' laws, prohibits pharmacists from filling prescriptions for XR by dispensing generic IR. App. 32a-33a. But instead of amending its law, or simply allowing the market to decide whether generic IR's lower price is worth the inconvenience and other costs that come with twice-daily dosing, Respondent asked a federal court to compel Petitioners to continue selling brand IR. App. 16a.

2. On December 11, 2014, the district court granted Respondent's motion for a preliminary injunction. The court held that replacing IR with XR would violate New York and federal antitrust law by depriving generic manufacturers of the benefit of most state substitution laws, to the detriment of their future market share. App. 46a, 127a-134a. On December 15, 2014, the court enjoined Petitioners to "continue to make Namenda IR … available on the same terms and conditions applicable since … Namenda XR entered the market." App. 144a. The injunction ran through August 10, 2015, "thirty days after … generic [IR] … [became] available." App. 145a.

3. On May 22, 2015, based on a concededly "novel" theory of antitrust liability, the Second Circuit affirmed. App. 4a. While nominally addressing the propriety of the district court's preliminary injunction, the court left no doubt about the merits under section 2 of the Sherman Act. The court acknowledged that "[a]s a general rule, courts are properly very skeptical about claims that competition has been harmed by a dominant firm's product design changes." App. 23a (quoting *United States v. Microsoft Corp.*, 253 F.3d 34, 65 (D.C. Cir. 2001) (en banc)). But the court nonetheless "conclude[d]" that

> the combination of withdrawing a successful drug from the market and introducing a reformulated version of that drug, which has the dual effect of forcing patients to switch to the new version and impeding generic competition, without a legitimate business justification, violates § 2 of the Sherman Act.

App. 37a.

The court rejected Petitioners' argument that the mere exercise of patent rights is categorically immune from antitrust scrutiny. The court recognized that a patent "grant[s] a legal monopoly," and "'is an exception to the general rule against monopolies.'" App. 22a & n.21 (quoting *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945)). But in the court's view, "the *combination* of [Petitioners]' withdrawal of IR and introduction of XR in the context of generic substitution laws … places their conduct beyond the scope of their patent rights for IR or XR individually." App. 39a.

On August 7, 2015, the Second Circuit denied rehearing en banc. App. 146a. While the injunction gave Respondent everything it sought under federal law, Respondent's state-law claim for "restitution and damages" for "persistent fraud or illegality in the carrying on, conducting or transaction of business," N.Y. Exec. Law § 63(12); *see* App. 51a, remains pending before the district court.

REASONS FOR GRANTING THE PETITION

I. This Court Should Grant Review to Resolve Whether the Exercise of Core Patent Rights Can Violate the Antitrust Laws

A. The Decision Below Conflicts with Decisions of this Court

1. In an unbroken line of cases stretching back more than a century, this Court has held that antitrust liability cannot arise from the mere exercise of rights granted by the Patent Act.

In *Virtue v. Creamery Package Manufacturing Co.*, 227 U.S. 8 (1913), this Court rejected claims that a patentee violated the antitrust laws by licensing another company to use its patent and bring infringement claims against competitors. *Id.* at 32-33. This Court explained that, "[o]f course, patents and patent rights cannot be made a cover for a violation of law …. But patents are not so used when the rights conferred upon them by law are only exercised." *Id.*

The same principle appears in *United States v. United Shoe Machinery Co.*, 247 U.S. 32 (1918), which rejected claims that a monopolist violated section 2 by leasing patented machinery on restrictive terms. *Id.* at 35. This Court recognized that "[o]f course, there is restraint in a patent," since it confers "the right to exclude others from the use of the invention, absolutely or on the terms the patentee chooses to impose." *Id.* at 57. But that right "is the compensation which the law grants for the exercise of invention." *Id.* Because the leases were "[no]thing more than the exercise of the patent monopoly," and did not "transcend the rights given to patentees," there was no antitrust violation. *Id.* at 57, 61.

This Court has reiterated the point in case after case. *United States v. Gen. Elec. Co.*, 272 U.S. 476, 485 (1926) ("It is only when [a monopolist] … steps out of the scope of his patent rights … that he comes within the operation of the Anti-Trust Act."); *Simpson v. Union Oil Co. of Cal.*, 377 U.S. 13, 24 (1964) ("The patent laws … are *in pari materia* with the antitrust laws and modify them *pro tanto*."); *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177 (1965) ("[A] patent is an exception to the general rule against monopolies …." (quoting *Precision Instrument*, 324 U.S. at 816)).

This Court confirmed the point most recently in *FTC v. Actavis*. There, the Court held that "reverse payment settlements"—in which patentees pay alleged infringers to give up invalidity claims and stay out of the market until the patent expires—are subject to antitrust scrutiny. 133 S. Ct. at 2227. The Court reasoned that such settlements prevent adjudication of the patent's "actual preclusive scope," and therefore fall outside the "scope of the patent monopoly." *Id*. at 2231. But the Court made clear that conduct *within* the "scope of the patent monopoly"—that is, the exercise of rights granted by "any patent statute …, whether expressly or by fair implication"—still enjoys "antitrust law immunity." *Id*. at 2231, 2233.

2. In an even longer line of cases, this Court has held that a patent owner's rights include the right to refuse to use, sell, or license the invention, while excluding competitors.

It "has been settled doctrine since at least 1896" that a patent owner "has no obligation either to use [the patented invention] or to grant its use to others." *Hartford-Empire Co. v. United States*, 323 U.S. 386, 423-33 (1945). This Court first recognized that principle in the antitrust context in *E. Bement & Sons v. National Harrow Co.*, 186 U.S. 70 (1902), which upheld a patent pooling arrangement against an antitrust challenge. *Id*. at 91. This Court explained that "[i]f [a patentee] will neither use his device nor permit others to use it, he has but suppressed his own." *Id*. at 90 (quoting *Heaton-Peninsular Button-Fastener Co. v. Eureka Specialty Co.*, 77 F. 288, 294 (6th Cir. 1896)). Similarly, in *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436 (1940), this Court affirmed an antitrust injunction because "[t]he picture [t]here revealed [wa]s *not* that of a patentee exercising its right to refuse to

sell … the patented product." *Id*. at 457 (emphasis added). And in *Hartford-Empire*, this Court reversed an antitrust injunction that prohibited the defendants from applying for patents they did not intend to use. 323 U.S. at 431-32. The Court explained that "[a] patent owner is not in the position of a quasi-trustee for the public or under any obligation to see that the public acquires the free right to use the invention." *Id*. at 432.

Cases outside the antitrust context are equally legion. *Cont'l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 424, 429 (1908) (patented invention is patentee's "absolute property," and "it is the privilege of any owner of property to use or not use it, without question of motive"); *Crown Die & Tool Co. v. Nye Tool & Mach. Works*, 261 U.S. 24, 34-35 (1923) ("[T]he benefit which the government intended to secure [by issuing a patent] was not the making or use of the patent for the benefit of the public during … the grant, … but only the benefit of its public use after the grant expired."); *Woodbridge v. United States*, 263 U.S. 50, 55-56 (1923) ("[A] patentee is not obliged either to make, use, or vend his invention during the period of his monopoly."); *Special Equip. Co. v. Coe*, 324 U.S. 370, 378-79 (1945) ("[F]ailure of the patentee to make use of a patented invention does not affect the validity of the patent.").

3. The decision below cannot be reconciled with these lines of cases. Petitioners had an unqualified right under the Patent Act to refuse to sell IR, and exercising that right cannot violate the antitrust laws. Yet the Second Circuit affirmed an antitrust injunction forcing Petitioners to continue selling patent-protected IR against their will.

i. The Second Circuit relied principally on this Court's statement in *Actavis* that "patent and antitrust policies are both relevant in determining the scope of the patent monopoly—and consequently antitrust law immunity—that is conferred by a patent." App. 38a (quoting *Actavis*, 133 S. Ct. at 2231). But this Court has *already* "determin[ed]" that "the scope of the patent monopoly" includes the right not to sell the patented product. Indeed, it "has been settled doctrine since at least 1896." *Hartford-Empire*, 323 U.S. at 432-33.

Actavis involved a question this Court had not previously addressed—whether the patent monopoly includes a right to enter into reverse payment settlements. 133 S. Ct. at 2231-32. This Court answered that question in the negative by weighing "considerations … related to patents" and "traditional antitrust factors." *Id*. But the factors that place reverse payment settlements beyond the patent monopoly do not give lower courts carte blanche to disregard this Court's decisions and reevaluate *other* conduct this Court has previously held falls *within* the patent monopoly.

In effect, the Second Circuit held that *Actavis* silently overruled this Court's considered decisions in *Bement*, *Continental Paper Bag*, *Crown Die & Tool*, *Woodbridge*, *Ethyl Gasoline*, *Hartford-Empire*, and *Special Equipment*. But "it is this Court's prerogative alone to overrule [even] one of its precedents," *State Oil Co. v. Khan*, 522 U.S. 3, 20 (1997), let alone seven at once.

ii. The Second Circuit also relied on *United States v. Line Material*, 333 U.S. 287 (1948), for the proposition that "patent law gives [Petitioners] a temporary monopoly on individual drugs—not a right to use their patents as part of a scheme to interfere with competition 'beyond the limits of the patent monopoly.'" App. 38a (quoting *Line Material*, 333 U.S. at 308). To the

court, "the *combination* of [Petitioners]' withdrawal of IR and introduction of XR … places their conduct beyond the scope of their patent rights for IR or XR individually." App. 39a.

That reasoning grossly distorts *Line Material* and ignores the basic distinction between concerted restraints of trade, prohibited by section 1 of the Sherman Act, and unilateral monopolization, prohibited by section 2. *Line Material* involved an *agreement* fixing the price of two firms' patented products, which this Court held unreasonably restrained trade in violation of section 1. 333 U.S. at 305, 314-15. "No issue of monopoly [under section 2] [wa]s involved." *Id*. at 304-05. Below, the Second Circuit expressly declined to address Respondents' section 1 claim, and held that Petitioners' *unilateral* conduct violated section 2. App. 39a. Nothing in *Line Material* remotely suggests that the unilateral exercise of multiple patent rights somehow provides an exception to the settled rule that patent rights don't give rise to antitrust wrongs.

Moreover, this Court's decision in *Pacific Bell Telephone Co. v. Linkline Communications, Inc.*, 555 U.S. 438 (2009), forecloses the Second Circuit's strange notion that exercising multiple patent rights separately is perfectly lawful, but doing so in combination subjects the patentee to treble damages and potential criminal liability. In *Linkline*, plaintiffs "tried to join [one] claim that cannot succeed with [another] claim that cannot succeed, and alchemize them into a new form of antitrust liability never before recognized by this Court." *Id*. at 457. This Court "decline[d] the invitation to recognize such claims," because "[t]wo wrong claims do not make one that is right." *Id*. Respondent's attempt to combine unmeritorious challenges to the

withdrawal of IR and the introduction of XR should have met the same fate.

B. The Decision Below Widens a Circuit Split

Certiorari is all the more warranted because the courts of appeal are hopelessly divided over the nature and scope of a patent owner's immunity from antitrust liability. The decision below widens that division, turning a two-way split into a three-way split.

1. Four courts of appeals have held that conduct within the scope of the patent monopoly—and in particular, the refusal to use, sell, or license the patented invention—is categorically immune from antitrust scrutiny.

The Federal Circuit so held in *In re Independent Service Organizations Antitrust Litigation* ("*ISO*"), 203 F.3d 1322 (Fed. Cir. 2000). There, a repair service brought antitrust claims against Xerox for refusing to sell the service patented replacement parts for Xerox copiers and printers. *Id*. at 1324. The court found no antitrust violation for a simple reason: "We answer the threshold question of whether Xerox's refusal to sell its patented parts exceeds the scope of the patent in the negative. Therefore, our inquiry is at an end." *Id*. at 1328 (footnote omitted).

The Third, Sixth, and D.C. Circuits agree. The Third Circuit has explained that "[t]he right to refuse to license is the essence of the patent holder's right under the patent law," and therefore rejected claims that a patentee committed an antitrust violation by charging licensing fees "so high as to preclude acceptance." *W.L. Gore & Assocs. v. Carlisle Corp.*, 529 F.2d 614, 623 (3d Cir. 1976). The Sixth Circuit similarly holds that "[a] patent holder who lawfully acquires a patent

cannot be held liable under Section 2 of the Sherman Act for maintaining the monopoly power he lawfully acquired by refusing to license the patent to others." *Miller Insituform, Inc. v. Insituform of N. Am., Inc.*, 830 F.2d 606, 609 (6th Cir. 1987). And the D.C. Circuit has rejected an antitrust challenge to a restrictive license on the simple ground that "[n]one of the[] restraints [went] beyond what the patent itself authorizes." *United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1128 (D.C. Cir. 1980).

2. The Ninth Circuit, by contrast, has held that the exercise of patent rights is only presumptively immune from antitrust scrutiny. In *Image Technical Services, Inc. v. Eastman Kodak Co.*, 125 F.3d 1195 (9th Cir. 1997), the Ninth Circuit addressed the same claim the Federal Circuit confronted in *ISO*—an independent repair service complained that a manufacturer refused to sell the service patented replacement parts. *Id*. at 1200. But rather than treat the patent monopoly as a threshold question, the Ninth Circuit adopted a "rebuttable presumption," whereby "a monopolist's desire to exclude others from its protected work is a presumptively valid business justification for any immediate harm to consumers." *Id*. at 1218 (quotation marks and brackets omitted). Plaintiffs can rebut this presumption by showing "that the monopolist acquired the [patent] in an unlawful manner" or by "show[ing] pretext," that is, "that the proffered business justification played no part in the decision to act." *Id*. at 1218-19.

Scholars have recognized that the Ninth Circuit's approach diverges from its sister circuits. *E.g.*, Patricia H. Moran, *The Federal and Ninth Circuits Square Off: Refusals to Deal and the Precarious Intersection Between Antitrust and Patent Law*, 87 Marq. L. Rev. 387, 387 (2003) (noting "the recent split in the circuit courts

concerning the rights of a patent holder to unilaterally refuse to deal"); Peter M. Boyle, Penelope M. Lister, & J. Clayton Everett, Jr., *Antitrust Law at the Federal Circuit: Red Light or Green Light at the IP-Antitrust Intersection?*, 69 Antitrust L.J. 739, 744, 746 (2002) ("[T]he Ninth Circuit and Federal Circuit came to diametrically different conclusions ….").

3. Below, the Second Circuit eschewed both of these approaches to a patentee's antitrust immunity, either of which would have required a ruling in Petitioners' favor. In the Federal, Third, Sixth, and D.C. Circuits, Petitioners' exercise of their patent rights would have been categorically immune from antitrust scrutiny. And in the Ninth Circuit, Petitioners' presumptively valid business justification would have remained unrebutted, as Respondent has never disputed that Petitioners' patents are valid or that patent rights played a role in Petitioners' decisions.

Before the decision below, the Second Circuit followed the majority rule, holding that "where a patent has been lawfully acquired, subsequent conduct permissible under the patent laws cannot trigger any liability under the antitrust laws." *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981). But the decision below fashioned a novel exception to that rule for "the *combination* of [the] withdrawal of [one patented product] and introduction of [another patented product] in the context of generic substitution laws." App. 39a. In effect, the Second Circuit held that, at least "in the context of generic substitution laws," multiple patent rights exercised in combination cancel each other out, rendering patent law irrelevant to the antitrust analysis. No other court has hinted at, much less adopted, that exception. This Court's intervention is needed

to resolve the lower courts' growing confusion over patent owners' immunity from antitrust scrutiny.

C. The Decision Below Is Wrong

Congress did not prohibit through the Sherman Act the same conduct it authorized through the Patent Act. The Patent Act grants every patent owner "the right to exclude others from making, using, offering for sale or selling the invention" for a 20-year period. 35 U.S.C. § 154(a)(1). That grant necessarily gives every patentee a limited monopoly, in derogation of the Sherman Act. In determining the scope of that monopoly, "Congress … could have provided that the grant should be conditioned upon the use of the patented invention." *Special Equip.*, 324 U.S. at 378. Indeed, Congress briefly did so in 1832, "authorizing the issue of patents to aliens conditioned upon the use of the invention." *Id*. (citing Act of 1832, 4 Stat. 577). But Congress "later repealed" that provision, *id*. (citing Act of 1836, § 21, 5 Stat. 117), and has never reinstated it. The implication is clear: A patentee who refuses to use the invention does not exceed the bounds of the patent monopoly, and therefore cannot commit an antitrust violation.

If section 154 were not enough, Congress amended another section of the Patent Act in 1988 to provide that "[n]o patent owner … shall be … deemed guilty of misuse or illegal extension of the patent right by reason of his having … (4) refused to license or use any rights to the patent." 35 U.S.C. § 271(d); Pub. L. No. 100-703, § 201, 102 Stat. 4676 (1988). That amendment cabined the doctrine of patent misuse by creating new safe harbors for conduct Congress determined did not "hav[e] anticompetitive effects." *Princo Corp. v. Int'l Trade Comm'n*, 616 F.3d 1318, 1329-30 (Fed. Cir.

2010) (en banc). New section 271(d)(4) in particular served to "[c]odif[y]" then-"current caselaw" holding that refusing to use or license a patent is perfectly lawful. 134 Cong. Rec. H10646 & n.4 (daily ed. Oct. 20, 1988) (statement of Rep. Kastenmeier) (citing *SCM*, 695 F.2d at 1195, and *Cont'l Paper Bag*, 210 U.S. at 426-30). This Court has recognized the incongruity that would arise if conduct falling within a safe harbor from misuse under section 271(d) still qualified as an antitrust violation. "It would be absurd to assume that Congress intended to provide that the use of a patent that merited punishment as a felony [under the Sherman Act] would not constitute 'misuse.'" *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 42 (2006).

Hatch-Waxman only confirms the point. The Second Circuit effectively curtailed the term of brand drug manufacturers' exclusive rights in order to ensure that the day after those rights end, generic competitors can not only enter the market, but achieve immediate, guaranteed commercial success. The Patent Act, however, confers exclusive rights for the *entire* 20-year term. That is part of why Congress passed Hatch-Waxman. Before Hatch-Waxman, generic manufacturers often could not even begin seeking FDA approval for a generic drug until the brand drug's patents expired, since the necessary testing would constitute infringement. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670 (1990). Hatch-Waxman responded by amending the Patent Act to provide that research "reasonably related to" FDA submissions "shall not be an act of infringement." 35 U.S.C. § 271(e)(1). The Second Circuit deemed that narrow statutory carve-out inadequate, and held that patentees also cannot exercise *other* patent rights that would reduce generic sales the day the patentee's exclusivities end. But amending the

Patent Act is the prerogative of Congress, not the Second Circuit.

II. This Court Should Grant Review to Resolve Whether Drug Manufacturers Have an Antitrust Duty to Facilitate State Drug Laws to Benefit their Competitors

A. The Decision Below Conflicts with Decisions of this Court

The Second Circuit also invented an expansive new antitrust duty. The court required a brand drug manufacturer to continue selling an obsolete product on past terms and conditions in order to maximize the sales certain state drug laws would hand over to its competitors. It is undisputed that, whether or not Petitioners continued to sell brand IR, once IR's exclusivities ended, generic manufacturers would be free to sell generic IR, and patients would be free to buy it. But the Second Circuit held that voluntary generic sales were not enough. Brand manufacturers must continue selling outdated drugs so that state drug laws can encourage or even force patients to buy generic substitutes.

1. That novel duty is flatly inconsistent with this Court's decisions in *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004), and *Linkline*, which make clear that monopolists have no general antitrust duty to aid their competitors.

Trinko involved antitrust claims alleging that Verizon refused to give competing telephone carriers sufficient access to Verizon's local network, as required by the Telecommunications Act of 1996. 540 U.S. at 402-05. This Court rejected that claim because with only narrow exceptions, "there is no duty to aid competitors." *Id.* at 411. The claim did not fit within the exception for

"[t]he unilateral termination of a voluntary … course of dealing" with a competitor, because Verizon's prior dealing was statutorily required, not voluntary. *Id*. at 409-10. Nor did the claim fit within the "essential facilities" doctrine recognized by some courts of appeals—the Telecommunications Act already required Verizon to open up its network, making judicially enforced sharing unnecessary. *Id*. at 410-11. Since no exception applied, the claim failed. *Id*. at 411.

In *Linkline*, independent Internet service providers asserted a so-called "price-squeeze" claim against AT&T, alleging that AT&T raised the price of wholesale inputs for Internet service while cutting the retail price, leaving an insufficient margin in between for competing Internet providers to survive. 555 U.S. at 442. This Court held that a plaintiff cannot state a price-squeeze claim "when the defendant has no obligation under the antitrust laws to deal with the plaintiff at wholesale." *Id*. at 445-46, 449. That result followed as "[a] straightforward application of … *Trinko*," which "ma[de] clear that if a firm has no antitrust duty to deal with its competitors …, it certainly has no duty to deal under terms and conditions that the rivals find commercially advantageous." *Id*. at 449-50.

The decision below conflicts with *Trinko* and *Linkline*. The Second Circuit did not even attempt to fit its new duty within a recognized exception to a monopolist's right to refuse to aid rivals. The court simply invented a new exception, under which replacing an obsolete product with a new one "is anticompetitive when it coerces consumers and impedes competition." App. 24a. But this Court has never suggested that monopolists must aid rivals to avoid "consumer coercion" (whatever that means). And while generic manufacturers undoubtedly prefer free-riding on state substitution laws to

competing on the merits, "the antitrust laws were passed for the protection of *competition*, not *competitors*." *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 224 (1993) (quotation marks omitted). As respected commentators have explained, the decision below "is contrary to the teaching of the United States Supreme Court, which has explicitly held that the antitrust laws do not impose a general duty to aid one's rivals." Joshua D. Wright & Douglas H. Ginsburg, Comment on the Canadian Competition Bureau's Draft Updated Intellectual Property Enforcement Guidelines 3 n.7 (2015) (citing *Trinko*).

2. The decision below conflicts with *Trinko* and *Linkline* in another way. While the Second Circuit purported to vindicate the goals of Hatch-Waxman and state substitution laws, *Trinko* and *Linkline* hold that the antitrust laws are not a vehicle for enforcing other regulatory regimes.

In *Trinko*, the plaintiff alleged that Verizon breached duties to aid competitors imposed by the Telecommunications Act. This Court explained that the fact "[t]hat Congress created these duties … does not automatically lead to the conclusion that they can be enforced by means of an antitrust claim." 540 U.S. at 406. And again in *Linkline*, this Court recognized that AT&T may have had a duty to deal with its competitors, but any such duty "arose only from FCC regulations," not from antitrust law. 555 U.S. at 448 n.2. The Court therefore held that a plaintiff cannot state a price-squeeze claim "when the defendant has no *antitrust duty* to deal with the plaintiff." *Id*. at 446 (emphasis added).

The distinction between antitrust law and other regulatory regimes should have applied with particular force here. Replacing IR with XR undisputedly would not violate Hatch-Waxman or any state substitution

law. If antitrust claims cannot enforce other laws that *prohibit* the conduct at issue, *a fortiori* they cannot enforce other laws that *permit* that conduct.

The Second Circuit rejected Petitioner's argument "that antitrust law is not a vehicle for enforcing the 'spirit' of drug laws" on the ground that "'antitrust law must always be attuned to the particular structure and circumstances of the industry at issue.'" App. 34a (quoting *Trinko*, 540 U.S. at 411). But *Trinko* relied on regulatory context to *reject* an antitrust claim. And this Court has rejected special antitrust rules for the "health care industry." *Arizona v. Maricopa Cnty. Med. Soc'y*, 457 U.S. 332, 349-50 (1982). Anyway, sensitivity to context is no excuse for transforming the Sherman Act into a roving commission to enforce the supposed "spirit" of federal and state drug regulations.

3. There is more. This Court has repeatedly held that "federal statutes are generally intended to have uniform nationwide application." *Miss. Band of Choctaw Indians v. Holyfield*, 490 U.S. 30, 43 (1989). Courts therefore "start … with the general assumption that in the absence of a plain indication to the contrary, … Congress when it enacts a statute is not making the application of the federal act dependent upon state law." *Id*. (quotation marks omitted). This Court has applied that rule in numerous contexts. *E.g.*, *id*. (Indian Child Welfare Act); *Dickerson v. New Banner Inst., Inc.*, 460 U.S. 103, 119 (1983) (Gun Control Act); *NLRB v. Natural Gas Util. Dist. of Hawkins Cnty.*, 402 U.S. 600, 603-04 (1971) (Wagner Act); *Jerome v. United States*, 318 U.S. 101, 104 (1943) (Bank Robbery Act); *United States v. Pelzer*, 312 U.S. 399, 402-03 (1941) (tax code).

The Sherman Act obviously is a uniform federal statute "intended to solve a national problem on a national scale." *Natural Gas Util. Dist.*, 402 U.S. at 603-04

(quotation marks omitted). Nothing in the statute suggests that Congress intended its application to differ from state to state based on "varying local conceptions, either statutory or judicial." *Id*. at 604 (quotation marks omitted). Conduct that violates the Sherman Act in New York must violate the Sherman Act in Minneapolis as well.

But the Second Circuit's new antitrust duty does not apply in Minneapolis. The court acknowledged that the laws of four states, including Minnesota, facially "allow substitution of generic IR for Namenda XR." App. 33a n.33.[3] Replacing IR with XR would not prevent generics from entering the market or competing on the merits anywhere, but in those states, it would not even alter the application of generic substitution laws. Those states may "account for less than 6% of the U.S. population," App. 33a n.33, but the Sherman Act contains no exception for small states. And even if all 50 states' laws happened to be the same, the decision below still "mak[es] the application of the federal act dependent upon state law." *Holyfield*, 490 U.S. at 43.

B. The Decision Below Precipitates a Circuit Split

The Second Circuit's new antitrust duty conflicts with the decisions of three other circuits, which all hold that preventing competitors from free-riding on a monopolist's advertising or other investments is a legitimate business purpose that enhances rather than impedes competition.

1. In *Olympia Equipment Leasing Co. v. Western Union Telegraph Co.*, 797 F.2d 370 (7th Cir. 1986), the Seventh Circuit confronted antitrust claims against a

[3] *Five* states clearly allow such substitution. *Supra* n.1.

monopolist that had previously provided free advertising for its competitors, but then stopped in order to boost its own sales. *Id*. at 372-73. The court overturned a jury verdict for the plaintiff, holding that "a firm with lawful monopoly power has no general duty to help its competitors, whether by holding a price umbrella over their heads or by otherwise pulling its competitive punches." *Id*. at 375. "You cannot conscript your competitor's salesmen to sell your product even if the competitor has monopoly power and you are a struggling new entrant." *Id*. at 378. The plaintiff therefore "had no right under antitrust law to take a free ride on its competitor's sales force." *Id*. at 377-78.

The Fourth Circuit held similarly in *Abcor Corp. v. AM International, Inc.*, 916 F.2d 924 (4th Cir. 1990). There, an independent repair service brought antitrust claims against a manufacturer that barred the service from buying replacement parts at the manufacturer's local repair center, "inhibit[ing] [the service]'s ability to handle emergencies." *Id*. at 929. The Fourth Circuit held that the manufacturer legitimately determined that the plaintiff "should bear its own inventory costs." *Id*. "If [the plaintiff] wants to ensure emergency access to a supply of parts, it may do so by maintaining its own stockpile rather than 'free riding' on the inventory costs incurred by [the manufacturer]." *Id*. Because the manufacturer "only eliminated [a] 'free ride' by shifting the inventory cost to the plaintiff," the "parts policy simply d[id] not rise to the … level of anticompetitive activity." *Id*. at 929-30.

The Eleventh Circuit too has held that "[t]he prevention of free-riding … provides a valid business justification" that precludes antitrust liability. *Morris Commc'ns Corp. v. PGA Tour, Inc.*, 364 F.3d 1288, 1298 (11th Cir. 2004). *Morris* concerned an antitrust

claim challenging restrictions the PGA Tour imposed on the media's right to sell real-time golf scores the PGA compiled through proprietary technology. *Id*. at 1290-92. The court rejected that claim because the PGA "met its business justification burden by showing that it seeks to prevent Morris from 'free-riding' on PGA's [scoring] technology." *Id*. at 1295.

2. Like the defendants in *Olympia Equipment*, *Abcor*, and *Morris*, Petitioners also sought to prevent competitors from free-riding on their considerable business investments. Petitioners spent hundreds of millions of dollars developing and promoting a blockbuster drug to treat a horrifying disease. But once IR's exclusivities ended, state substitution laws were poised to hand Petitioners' hard-won sales over to their generic competitors. Rather than recognizing that preventing such free-riding is a legitimate business purpose, the Second Circuit held that "what [Petitioners] call 'free riding' … is authorized by law; is the explicit goal of state substitution laws; and furthers the goals of the Hatch–Waxman Act by promoting drug competition." App. 33a-34a. The Fourth, Seventh, and Eleventh Circuits disagree: "Advertising a competitor's products free of charge … is the antithesis of competition." *Olympia Equip.*, 797 F.2d at 378; *see Abcor*, 916 F.2d at 929; *Morris*, 364 F.3d at 1298.

C. The Decision Below Is Wrong

"To safeguard the incentive to innovate, the possession of monopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive *conduct*." *Trinko*, 540 U.S. at 407. Petitioners allegedly showed insufficient solicitude for their competitors when choosing which products to sell on what terms. That is not anticompetitive.

Before IR's exclusivities ended, replacing IR with XR had no effect on competition whatsoever, because Petitioners possessed a lawful monopoly. Limiting competition within "the same company" raises no antitrust concerns, because it does not "deprive[] the marketplace of the independent centers of decisionmaking that competition assumes and demands." *Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 769 (1984). And after IR's exclusivities ended, generic competitors have been perfectly free to distribute, market, price, and sell their drugs as they please. True, generic manufacturers less able to rely on state substitution laws might have made fewer sales, but only if they failed to make offsetting efforts to make generic IR more attractive to doctors and patients. "[T]o the extent [Petitioners' conduct] obligated [generics] to increase [their] own advertising, competition was only enhanced." *Covad Commc'ns Co. v. Bell Atl. Corp.*, 398 F.3d 666, 674 (D.C. Cir. 2005) (citing Robert H. Bork, The Antitrust Paradox 314 (2d ed. 1993)).

The Second Circuit reasoned that judicial intervention was necessary because the patients and doctors who choose drugs do not pay their full costs. App. 10a, 34a & n.34. But numerous market forces push patients and doctors towards lower-priced drugs. Third-party payors encourage the use of generics through "[f]ormularies, tiered-drug structures, step programs, and prior-authorization requirements." App. 29a & n.29. "[P]harmacies typically realize higher profit margins on generic drugs due to health plan incentives." App. 10a n.11. Various stakeholders mount "counter-detailing" campaigns "to promote the use of generic pharmaceuticals." *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2661 (2011). And generic manufacturers themselves can and do advertise. *See Mylan Pharm., Inc. v.*

Warner Chilcott Pub. Ltd. Co., No. Civ. 12-3824, 2015 WL 1736957, at *14 (E.D. Pa. Apr. 16, 2015).

At bottom, the decision below posits that courts and antitrust enforcers know better than markets which new products are worth higher prices. The Second Circuit purported to balance the supposed "anticompetitive harms" from blunting the effect of state substitution laws against the "procompetitive benefits" of allowing brand drug manufacturers to maximize returns on their innovations. App. 36a-37a. But that kind of balancing inquiry "is not just unwise, it is unadministrable. There are no criteria that courts can use to calculate the 'right' amount of innovation, which would maximize social gains and minimize competitive injury." *Allied Orthopedic Appliances, Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 1000 (9th Cir. 2010). And if drug manufacturers guess wrong about that balancing inquiry, the consequences are dire—they can face crippling injunctions, treble damages, even criminal penalties.

III. The Questions Presented Are of Critical and Recurring Importance to Pharmaceutical Manufacturers and Patients

1. The scope of patent owners' immunity from antitrust liability and the existence of an antitrust duty to facilitate competitors' sales will profoundly affect the course of innovation in the pharmaceutical industry.

Pharmaceutical innovation is critical to the U.S. healthcare system. "There are roughly 7,000 known diseases; about 500 have a treatment." Amy Dockser Marcus, *Trials: A Desperate Fight to Save Kids & Change Science*, Wall Street Journal, Nov. 18, 2013, http://projects.wsj.com/trials/#chapter=1. New drug treatments not only improve patients' lives, but also reduce healthcare spending. According to one study,

using newer drugs "reduces non-drug expenditure 7.2 times as much as it increases drug expenditure." Frank Lichtenberg, *Benefits and Costs of Newer Drugs: An Update*, Nat'l Bureau of Econ. Research 9 (2002). In other words, "the replacement of older by newer drugs results in reductions in mortality, morbidity, *and* total medical spending." Frank R. Lichtenberg, *Are the Benefits of Newer Drugs Worth Their Cost? Evidence from the 1996 MEPS*, 20 Health Affairs 241, 250 (2001) (emphasis added).

Innovation often proceeds by small steps. "[R]epeated incremental improvement is the predominant mechanism of innovation and product development within most manufacturing and high-technology industries," and "[t]he pharmaceutical industry is no exception." Albert Wertheimer et al., *Too Many Drugs? The Clinical and Economic Value of Incremental Innovations*, 14 Investing in Health: The Social & Economic Benefits of Health Care Innovation 77, 78 (2001). HIV treatment, for example, once consisted of a complex "cocktail" of drugs that was difficult to administer and prone to error, but incremental innovation has now simplified it to a single pill. Joshua Cohen & Kenneth Kaitin, *Follow-On Drugs and Indications: The Importance of Incremental Innovation to Medical Practice*, 15 Am. J. Therapeutics 89, 90 (2008). Two-thirds of all new drugs approved by the FDA contain an active ingredient already on the market. Nat'l Inst. for Health Care Mgmt. Research & Educ. Found., Changing Patterns of Pharmaceutical Innovation 3 (2002). Almost two-third of the drugs on the World Health Organization's Essential Drug List—which compiles the drugs necessary for a basic national healthcare system—are incremental innovations. Joshua P. Cohen et al., *The Role of Follow-on Drugs and Indications on the WHO*

Essential Drug List, 31 J. Clinical Pharmacy & Therapeutics 6 (2006).

Incremental drug innovations have numerous benefits. More drugs enable physicians to tailor treatments to patient needs, provide backups if other drugs are unavailable, and facilitate competition on both price and quality. Wertheimer, *supra*, at 78-79. In addition, alternative dosing and delivery mechanisms can help patients take their medications more easily and consistently. *Id*. XR's once-daily dosing illustrates the point—studies confirm that patient compliance is "higher with once than multiple daily dosing regimens." Matthew Falagas et al., *Compliance with Once-Daily versus Twice or Thrice-Daily Administration of Antibiotic Regimens: A Meta-Analysis of Randomized Controlled Trials*, PLoS One (Jan. 5, 2015). And patients' failure to take their pills as prescribed "is a major barrier to realizing the benefits of medications." Robbie Nieuwlaat et al., *Interventions for Enhancing Medication Adherence*, Cochrane Database of Systematic Reviews 3 (Nov. 2014).

2. By penalizing brand drug manufacturers that seek to maximize returns on new drug formulations, the decision below decimates incentives to innovate. As the head of the Department of Justice's Antitrust Division recently explained, "[c]ompanies that know they may easily gain access to the patents or other intellectual property of their competitors have less incentive to undertake the risky and expensive research necessary to be innovators themselves. Likewise, innovative companies have less incentive to continue their efforts." Bill Baer, Assistant Att'y Gen., Remarks at 19th Annual Int'l Bar Ass'n Competition Conf. (Sept. 11, 2015), http://www.justice.gov/opa/speech/assistant-attorney-general-bill-baer-delivers-remarks-19th-annual-

international-bar. Moreover, "[n]o mature industry can sustain itself on income from breakthrough innovation alone. The pharmaceutical industry must generate revenue based predominantly on incremental innovations." Wertheimer, *supra*, at 108-09. Restricting revenue from incremental improvements thus will make R&D riskier and will reduce the resources for research into incremental and breakthrough innovations alike. *Id*. at 109-10.

The Second Circuit asserted that its new antitrust rule will discourage only "trivial or minor product reformulations" and not "riskier, but medically significant innovations." App. 37a. As explained, however, XR's once-daily dosing *is* a "medically significant innovation." And courts are ill-equipped to sort significant innovations from insignificant ones. *Trinko*, 540 U.S. at 407-08. Moreover, the limits of the Second Circuit's new rule are anyone's guess. When in the patent term does ceasing sales become unlawful? If distributing IR to patients whose doctors deemed it medically necessary was not enough, how much distribution would suffice? What if a patentee continued to sell an old product but raised its price, or stopped advertising? Deterring innovation is bad enough, but doing so under a nebulous rule is even worse.

Precisely because the decision below will dampen innovation, Federal Trade Commissioner Joshua Wright and the Hon. Douglas H. Ginsburg of the D.C. Circuit have urged foreign antitrust authorities not to follow it. "[E]ven small changes in product design[] can generate significant consumer benefits," and "[c]ompetition law is not a suitable instrument for micromanaging product design and innovation." Wright & Ginsburg, *supra*, at 2. Wright and Ginsburg therefore advised the Canadian Competition Bureau "against imposing

a competition law sanction on product switching absent clear and convincing objective evidence that [the new product] represents a sham innovation with zero or negative consumer welfare benefits." *Id*. at 1. Instead, they urged Canadian authorities to "treat product substitution as falling within the exemption for 'mere exercise' of a patent right." *Id*.; *see also* Baer, *supra* ("If there is no bad conduct by the patent holder …, but rather an assertion of lawful patent rights, competition enforcers need to stand down. Otherwise we are penalizing lawful innovation.").

These issues urgently require this Court's attention. Developing a new drug takes at least a decade. PhRMA, 2015 Biopharmaceutical Research Industry Profile 13 (2015). Investment decisions made today will determine whether innovative new treatments will become available 10 or 20 years from now. Patients counting on those treatments cannot wait for further percolation in the lower courts. This Court has not hesitated to grant certiorari in pharmaceutical and antitrust cases of similar national importance. *E.g.*, *Wyeth v. Levine*, 555 U.S. 555, 563 (2009); *Texaco Inc. v. Dagher*, 547 U.S. 1, 5 (2006); *PhRMA v. Walsh*, 538 U.S. 644, 650 (2003); *Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 456 (1992).

3. The nominally interlocutory posture of this case is no impediment to this Court's review. While the district court's preliminary injunction has now expired, the decision below is not moot, for two independent reasons.

i. First, the Second Circuit reached the merits of Respondent's section 2 claim, and Respondent seeks damages based on that claim.

The propriety of a preliminary injunction is usually distinct from the final merits, but here, the two issues

merged. Generally, "whether [a] preliminary injunction should have issued depend[s] on [a] balance of factors," including the "likelihood of success on the merits." *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 393-94 (1981). This Court has warned against "improperly equat[ing] 'likelihood of success' with 'success.'" *Id*. at 394. But the distinction between a preliminary injunction and the final merits "is a rule of orderly judicial administration, not a limit on judicial power," and thus "is not inflexible." *Thornburgh v. Am. Coll. of Obstetricians & Gynecologists*, 476 U.S. 747, 756-57 (1986), *overruled on other grounds by Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992). Accordingly, where "the facts are established or of no controlling relevance," an appellate court reviewing a preliminary injunction may "proceed[] to plenary review" and reach the ultimate merits. *Id*. at 757.

That is precisely what the Second Circuit did below. The opinion's language is unequivocal: "In sum, we conclude that the combination of withdrawing a successful drug from the market and introducing a reformulated version of that drug, … violates § 2 of the Sherman Act." App. 37a.

That ruling in turn affects a pending claim for relief. Respondent cannot seek any further relief under federal law, but Respondent continues to seek damages under a New York statute that authorizes "restitution and damages" for "persistent … illegality." N.Y. Exec. Law § 63(12). If this Court overturns the Second Circuit's holding that product replacement violates section 2, that pending damages claim must fail.

ii. Second, the district court's preliminary injunction is capable of repetition, yet evading review. That "established exception to mootness" applies where "(1) the challenged action is in its duration too short to

be fully litigated prior to cessation or expiration, and (2) there is a reasonable expectation that the same complaining party will be subject to the same action again." *Fed. Election Comm'n v. Wisc. Right to Life, Inc.*, 551 U.S. 449, 462 (2007).

Both requirements plainly are met here. Given how long it takes to develop new drug formulations and obtain FDA approval, brand drug manufacturers often replace old drugs with new versions only shortly before the old version's exclusivities expire. And Petitioners have numerous drugs they intend to replace with innovative new versions in coming years. But if Petitioners were to announce a replacement, Respondent could simply file suit within the Second Circuit and immediately obtain a nationwide injunction based on the decision below. Indeed, that is apparently Respondent's intention—Respondent's counsel describes the decision below as "a very useful framework … for future enforcement." Melissa Lipman, *Namenda Isn't End of NY AG's Pharma Work: Antitrust Chief*, Law360, May 29, 2015, http://www.law360.com/articles/661685/namenda-isn-t-end-of-ny-ag-s-pharma-work-antitrust-chief.

iii. In any event, even if the decision below were fully moot, the proper course would be for this Court to grant, vacate, and remand. Under *United States v. Munsingwear, Inc.*, 340 U.S. 36 (1950), "[w]hen a civil case becomes moot pending appellate adjudication, the established practice in the federal system is to reverse or vacate the judgment below and remand with a direction to dismiss." *Arizonans for Official English v. Arizona*, 520 U.S. 43, 71 (1997) (quotation marks and alterations omitted). This practice "prevent[s] an unreviewable decision from spawning any legal consequences" through its preclusive or precedential effect

on future cases. *Camreta v. Greene*, 131 S. Ct. 2020, 2035 (2011) (quotation marks omitted). Here, the decision below is a "legally consequential decision," *id.*, that Respondent and other enforcement agencies may use to challenge Petitioners' conduct in the future. If the "happenstance" of timing has rendered that decision moot, *id.*, vacatur is appropriate.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX

APPENDIX A

IN THE
UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

[Filed: 05/28/2015]

AUGUST TERM, 2014
No. 14-4624

PEOPLE OF THE STATE OF NEW YORK, by and through ERIC T. SCHNEIDERMAN, Attorney General of the State of New York,

Plaintiff-Appellee,

v.

ACTAVIS PLC, FOREST LABORATORIES, LLC,

Defendants-Appellants.

Appeal from the United States District Court
for the Southern District of New York.
No. 14 Civ. 7473 – Robert W. Sweet, *Judge*.

ARGUED: APRIL 13, 2015
DECIDED: MAY 22, 2015[1]

Before: WALKER, RAGGI, and DRONEY, *Circuit Judges*.

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[1] This opinion was filed under seal on May 22, 2015, and the parties were permitted to request redactions of confidential information. This published version of the opinion indicates the redactions allowed by the court.

The State of New York brought this antitrust action against Defendant-Appellant Actavis plc and its wholly-owned subsidiary Forest Laboratories, LLC (collectively, "Defendants"). New York alleges that as Namenda IR, Defendants' twice-daily drug designed to treat moderate-to-severe Alzheimer's disease, neared the end of its patent exclusivity period in July 2015, Defendants introduced a new once-daily version called Namenda XR. The patents on XR ensure exclusivity, and thus prohibit generic versions of XR from entering the market, until 2029. Faced with the prospect of competition from generic IR, Defendants decided to withdraw virtually all Namenda IR from the market in order to force Alzheimer's patients who depend on Namenda IR to switch to XR before generic IR becomes available. Because generic competition depends heavily on state drug substitution laws that allow pharmacists to substitute generic IR for Namenda IR—but not for XR, New York alleges that Defendants' forced-switch scheme would likely impede generic competition for IR. Moreover, the substantial transaction costs of switching from once-daily XR back to twice-daily IR therapy would likely further ensure that Defendants would maintain their effective monopoly in the relevant drug market beyond the time granted by their IR patents.

The United States District Court for the Southern District of New York (Robert W. Sweet, *Judge*) issued a preliminary injunction barring Defendants from restricting access to Namenda IR prior to generic IR entry. We conclude that the district court did not abuse its discretion by granting New York's motion for a preliminary injunction because New York has demonstrated a substantial likelihood of success on the merits of its claim under the Sherman Act, 15 U.S.C. § 2, and has made a strong showing of irreparable harm to competition and consumers in the absence

of a preliminary injunction. Accordingly, we affirm the district court's order issuing a preliminary injunction.

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JOHN M. WALKER, JR., *Circuit Judge*:

The State of New York brought this antitrust action against Defendant-Appellant Actavis plc and its wholly-owned subsidiary Forest Laboratories, LLC (collectively, "Defendants"). New York alleges that as Namenda IR, Defendants' twice-daily drug designed to treat moderate-to-severe Alzheimer's disease, neared the end of its patent exclusivity period in July 2015, Defendants introduced a new once-daily version called Namenda XR. The patents on XR ensure exclusivity, and thus prohibit generic versions of XR from entering the market, until 2029. Faced with the prospect of competition from generic IR, Defendants decided to withdraw virtually all Namenda IR from the market in order to force Alzheimer's patients who depend on Namenda IR to switch to XR before generic IR becomes available. Because generic competition depends heavily on state

drug substitution laws that allow pharmacists to substitute generic IR for Namenda IR—but not for XR, New York alleges that Defendants' forced-switch scheme would likely impede generic competition for IR. Moreover, the substantial transaction costs of switching from once-daily XR back to twice-daily IR therapy would likely further ensure that Defendants would maintain their effective monopoly in the relevant drug market beyond the time granted by their IR patents.

The United States District Court for the Southern District of New York (Robert W. Sweet, *Judge*) issued a preliminary injunction barring Defendants from restricting access to Namenda IR prior to generic IR entry. We conclude that the district court did not abuse its discretion by granting New York's motion for a preliminary injunction because New York has demonstrated a substantial likelihood of success on the merits of its claim under the Sherman Act, 15 U.S.C. § 2, and has made a strong showing of irreparable harm to competition and consumers in the absence of a preliminary injunction. Accordingly, we affirm the district court's order issuing a preliminary injunction.

BACKGROUND

This case raises a novel question of antitrust law: under what circumstances does conduct by a monopolist to perpetuate patent exclusivity through successive products, commonly known as "product hopping,"[2] violate the Sherman Act, 15 U.S.C. §§ 1 and 2. This question is an issue of first impression in the circuit courts.

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[2] The term "product hopping" was coined by Herbert Hovenkamp. *See* Alan Devlin, *Exclusionary Strategies in the Hatch-Waxman Context*, 2007 Mich. St. L. Rev. 631, 658 (2007) (citing Herbert Hovenkamp et al., *IP and Antitrust: An Analysis of Antitrust Principals Applied to Intellectual Property Law* (2002)).

Determining whether Defendants' actions are unlawfully anticompetitive requires some understanding of the idiosyncratic market characteristics of the complex and highly-regulated pharmaceutical industry, as well as some peculiar characteristics of treatment for Alzheimer's disease. We begin by describing several key features of the pharmaceutical industry.

I. FDA Requirements, the Hatch-Waxman Act, and State Drug Substitution Laws

In compliance with the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399f, when a pharmaceutical manufacturer seeks to bring a new drug to market, it must submit a New Drug Application ("NDA") for approval by the U.S. Food and Drug Administration ("FDA"). 21 U.S.C. § 355. An NDA must contain scientific evidence that demonstrates the drug is safe and effective, which inevitably requires "a long, comprehensive, and costly testing process." *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013). NDA-approved drugs are generally referred to as brand-name or brand drugs. An approved brand drug enjoys a period of patent exclusivity in the market at the end of which one or more generic drugs,[3] exhibiting the same characteristics as the brand drug, may enter the market at a lower price to compete with the brand drug.

In 1984, Congress amended the Federal Food, Drug, and Cosmetic Act by enacting the Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act" or "Hatch-Waxman"), Pub. L. No. 98-417, 98 Stat.

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[3] Generic drugs "are copies of brand-name drugs and are the same as those brand name drugs in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use." FDA, *Understanding Generic Drugs*, http://1.usa.gov/1SjEIso (last visited Apr. 14, 2015).

1585. Hatch-Waxman was designed to serve the dual purposes of both encouraging generic drug competition in order to lower drug prices and incentivizing brand drug manufacturers to innovate through patent extensions. To incentivize innovation, Hatch-Waxman grants brand manufacturers opportunities to extend their exclusivity period beyond the standard 20-year patent term: it allows a brand manufacturer to seek a patent extension of up to five years to compensate for time that lapsed during the FDA regulatory process, 35 U.S.C. § 156, and an additional six-month period of "pediatric exclusivity" if the manufacturer conducts certain pediatric studies, 21 U.S.C. § 355a. Defendants applied for, and received, both extensions for Namenda IR.

Hatch-Waxman also promotes competition from generic substitute drugs. It permits a manufacturer that seeks to market a generic version of an NDA-approved drug to file what is known as an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. § 355(j); *see also In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 130 (2d Cir. 2014). An ANDA allows a generic manufacturer to rely on the studies submitted in connection with the already-approved brand drug's NDA to show that the generic is safe and effective, provided that the ANDA certifies that the generic drug has the same active ingredients as and is "biologically equivalent" or "bioequivalent" to the already-approved drug.[4] 21 U.S.C. § 355(j)(2)(A)(iv); *see also Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012) (citing 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv)).

[4] An ANDA also requires a manufacturer to demonstrate other measures of equivalence between the brand and generic drugs, which are not relevant here. 21 U.S.C. § 355(j)(2)(A).

A generic drug is bioequivalent to a brand drug if "the rate and extent of absorption" of the active ingredient is the same as that of the brand drug. 21 U.S.C. § 355(j)(8)(B)(i). In other words, two drugs are bioequivalent if they deliver the same amount of the same active ingredient content into a patient's blood stream over the same amount of time. By enabling generic manufacturers to "piggy-back" on a brand drug's scientific studies, Hatch-Waxman "speeds the introduction of low-cost generic drugs to market, thereby furthering drug competition." *Actavis*, 133 S. Ct. at 2228 (internal quotation marks, alteration, and citation omitted); *see also* H.R. Rep. No. 98-857, pt. 2, at 9 (1984) (stating the Hatch-Waxman Act's "policy objective" was to "get[] safe and effective generic substitutes on the market as quickly as possible after the expiration of the patent").

By the time Congress enacted the Hatch-Waxman Act, many states had enacted drug substitution laws to further encourage generic competition.[5] Today, all 50 states and the District of Columbia have drug substitution laws.[6] Although the specific terms of these laws vary by state, drug substitution laws either permit or require pharmacists to dispense a therapeutically equivalent, lower-cost generic drug in place of a brand

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[5] *See* Alison Mason & Robert L. Steiner, Fed. Trade Comm'n, *Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws* 1 (1985), *available at* http://1.usa.gov/1IS44Ju ("FTC, *Generic Substitution*").

[6] Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 Fla. L. Rev. 1009, 1017 (2010) ("Carrier, *A Real-World Analysis*"); *see also* Jessie Cheng, Note, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 Colum. L. Rev. 1471, 1479-80 (2008) ("Cheng, *Product Hopping*").

drug absent express direction from the prescribing physician that the prescription must be dispensed as written.[7] For example, New York's drug substitution law requires a pharmacist to "substitute a less expensive drug product containing the same active ingredients, dosage form and strength as the drug product prescribed" provided certain conditions are met. N.Y. Educ. Law § 6816-a(1).

All state drug substitution laws prohibit pharmacists from substituting generic drugs that are not therapeutically equivalent to the brand drug, but state laws do not all define therapeutic equivalence in the same way.[8] Thirty states, including New York and the District of Columbia, adopt the FDA's definition of therapeutically equivalent and only allow generic substitution if the FDA designates the generic as "AB-rated" in a publication commonly referred to as the "Orange Book."[9] N.Y. Education Law § 6816-a(1); N.Y. Public Health Law § 206(1)(o). To receive an AB-rating, a generic must not only be bioequivalent but pharmaceutically equivalent to the brand drug, meaning it has the same

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[7] The FTC, like the district court, has found that only a "modest[]" difference in the frequency of substitution rates exists between states with mandatory substitution laws and states with permissive substitution laws. *See* FTC, *Generic Substitution*, at 99.

[8] *See* Jesse C. Vivian, *Generic-Substitution Laws*, U.S. Pharmacist (June 19, 2008), http://www.uspharmacist.com/content/s/44/c/9787; *see also* FTC, *Generic Substitution*, at 3 (Vivian, *Generic-Substitution Laws*).

[9] Some states explicitly require generic drugs to have an AB-rating, some states adopt the requirements of an AB-rating without using the term, some states develop formularies that list permissible or impermissible drug substitutes, and some states give discretion to individual pharmacists as long as the drugs are pharmaceutically equivalent. *See* Vivian, *Generic-Substitution Laws* tbl.2.

active ingredient, dosage form, strength, and route of administration as the brand drug. U.S. Dep't of Health & Human Servs., FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations* vii-x (35th ed. 2015), *available at* http://1.usa.gov/1PzbMxF (the "Orange Book"). The AB-rating requirement is designed to provide guidance regarding which drugs are therapeutically equivalent, but, as has been observed, it also provides an opportunity for brand manufacturers to "game" the system.[10] S.A. 28.

Hatch-Waxman and state substitution laws were enacted, in part, because the pharmaceutical market is not a well-functioning market. In a well-functioning market, a consumer selects and pays for a product after evaluating the price and quality of the product. In the prescription drug market, however, the party who selects the drug (the doctor) does not fully bear its costs, which creates a price disconnect. Moreover, a patient can only obtain a prescription drug if the doctor writes a prescription for that particular drug.

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[10] *See, e.g.*, Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 Tex. L. Rev. 685, 709 (2009) (explaining that the regulatory framework that governs the pharmaceutical industry "presents a perfect storm for regulatory gaming"); Cheng, *Product Hopping*, at 1494 ("Product hopping itself amounts to little more than a thinly disguised scheme to game the pharmaceutical industry's regulatory system."); Intellectual Property and Antitrust Professors *Amicus* Brief in Support of Appellee ("IP and Antitrust Prof. Br.") at 3 (explaining that product hopping "presents a paradigmatic case of a regulatory game. . . . [It] exploits the product-approval process precisely because of its exclusionary effects and converts it into a tool for suppressing competition" (alterations in original)); American Antitrust Institute *Amicus* Brief in Support of Appellee ("AAI Br.") at 6, 10-11 (explaining that branded manufacturers can game the system by changing the form of the brand product before generics enter the market).

The doctor selects the drug, but the patient, or in most cases a third-party payor such as a public or private health insurer, pays for the drug. As a result, the doctor may not know or even care about the price and generally has no incentive to take the price into account. *See* American Antitrust Institute *Amicus* Brief in Support of Appellee ("AAI Br.") at 6; *see also* Intellectual Property and Antitrust Professors *Amicus* Brief in Support of Appellee ("IP and Antitrust Prof. Br.") at 12. As the Federal Trade Commission has explained:

> The basic problem is that the forces of competition do not work well in a market where the consumer who pays does not choose, and the physician who chooses does not pay. Patients have little influence in determining which products they will buy and what prices they must pay for prescription.

Fed. Trade Comm'n Bureau of Consumer Prot., *Drug Product Selection* 2-3 (1979), *available at* http://bit.ly/1JqKd4G. ("FTC, Drug Product Selection"). State substitution laws are designed to correct for this price disconnect by shifting drug selection, between brand drugs and their corresponding generics from doctors, to pharmacists and patients, who have greater financial incentives to make price comparisons.[11] *See* AAI Br. at 8-9.

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[11] Perhaps counter-intuitively, pharmacists have an incentive to dispense lower-cost generic drugs because pharmacies typically realize higher profit margins on generic drugs due to health plan incentives. *See* Antitrust Economists *Amicus* Brief in Support of Appellants ("Antitrust Economists Br.") at 12; *see also* Carrier, *A Real-World Analysis*, at 1017 ("[State drug product selection] laws carve out a role for pharmacists, who are much more sensitive to prices than doctors.").

II. The Relevant Market

The relevant market, undisputed on appeal, is the memantine-drug market in the United States. Defendants manufacture Namenda, a memantine hydrochloride-based[12] ("memantine") drug designed to treat moderate-to-severe Alzheimer's disease. Namenda is currently available in two formulations: a twice-daily immediate-release drug, Namenda IR, and a once-daily extended-release drug, Namenda XR. When Forest introduced Namenda IR tablets in January 2004,

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[12] Memantine is an N-Methyl D-Aspartate ("NMDA") receptor antagonist that affects the glutamate pathway in the brain. As expert Dr. Alan Jacobs, a neurologist in private practice, explained at the preliminary injunction hearing:

> 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.

S.A. 16. Memantine-based drugs, like Namenda, partially block the brain's NMDA receptor in order to prevent "overexcitation" of that receptor, "which can cause toxicity to neurons in the brain." S.A. 17.

In contrast, the three other FDA-approved drugs on the market to treat Alzheimer's disease—Aricept, Exelon, and Razadyne—are all acetylcholinesterase inhibitors ("CIs"). CIs reduce the breakdown of acetylcholine, a chemical messenger that transmits information between nerve cells, in the brain. Rather than work on the glutamate pathway, like Namenda, CIs work on the acetylcholine pathway. CIs are generally prescribed to patients experiencing the early stage of Alzheimer's disease, and are prescribed in conjunction with—but not independently of—Namenda during the moderate-to-severe stages of Alzheimer's disease.

Namenda IR was the first medication approved for individuals suffering from moderate-to-severe Alzheimer's disease.[13] Namenda IR became one of Forest's best-selling drugs—generating approximately $1.5 billion in annual sales in 2012 and 2013. The FDA approved Namenda XR in June 2010, and Forest began marketing XR in 2013. The two drugs are the only memantine therapies in their class—N-Methyl D-Aspartate ("NMDA") receptor antagonists—currently on the market.[14]

Namenda IR and Namenda XR have the same active ingredient and the same therapeutic effect. The relevant medical difference between the two is that IR, which is released immediately into the bloodstream, is taken twice a day while XR, which is released gradually, is taken once a day.[15] All other Alzheimer's disease treatments are administered once a day.

The non-medical difference between IR and XR relates to their patent protection. Defendants' patents on Namenda IR prohibit any manufacturer from marketing a generic version of IR until July 11, 2015 (Namenda IR's "exclusivity period").[16] The exclusivity

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[13] Defendants also introduced a twice-daily liquid version of Namenda IR in 2005.

[14] Because CIs perform different functions, Aricept, Exelon, and Razadyne are not substitutes for Namenda.

[15] Additionally, Namenda IR and Namenda XR have different dosage forms. J.A. 673 n.57. Namenda IR is marketed in tablet form, whereas Namenda XR is marketed in capsule form. *Id.*; *see also Dosing for Patients Currently Taking NAMENDA*, http://www.namendaxrhcp.com/patients-currently-taking-namenda.aspx (last visited Apr. 16, 2014).

[16] Defendants' patents on Namenda IR prohibit generic entry until October 2015. But in 2009 and 2010, in order to resolve

period for Namenda XR does not expire until 2029. A brand drug's exclusivity period is significant because when that period ends and generic versions enter the market, the brand drug often loses more than 80 to 90% of the market within six months. This period following the end of patent exclusivity has been referred to in this litigation and throughout the industry as the "patent cliff."

III. Defendants' Introduction of Namenda XR and Withdrawal of Namenda IR

Namenda IR and Namenda XR currently occupy the entire memantine-drug market. However, five generic versions of IR have tentative FDA approval to enter the market on July 11, 2015, and seven others may enter the market as early as October 2015. Because Namenda XR has a different strength and daily dosage regimen—Namenda IR involves two immediate-release tablets of 10mg each and Namenda XR involves one 28mg extended-release capsule[17]—the generic IR versions that are poised to enter the market will be therapeutically equivalent under FDA regulations to Namenda IR, but not to Namenda XR. Therefore, pharmacists are prohibited from substituting generic IR for Namenda XR under most, if not all, state drug substitution laws.

When Defendants brought Namenda XR to market in July 2013 (approximately three years after it was approved), they adopted so-called "product extension"

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patent litigation, Forest entered into licensing agreements permitting ten generic competitors to enter the market three months before Namenda IR's official exclusivity period ends.

[17] *See Dosing for Patients Currently Taking NAMENDA*, Namenda XR, http://www.namendaxrhcp.com/patients-currently-taking-namenda.aspx (last visited Apr. 16, 2014).

strategies to convert patients from Namenda IR to Namenda XR and, thus, to avoid the patent cliff. Initially, Defendants sold both Namenda IR and XR but stopped actively marketing IR. During that time, they spent substantial sums of money[18] promoting XR to doctors, caregivers, patients, and pharmacists. They also sold XR at a discounted rate, making it considerably less expensive[19] than Namenda IR tablets, and issued rebates to health plans to ensure that patients did not have to pay higher co-payments for XR than for IR. The parties have referred to Defendants' efforts to transition patients to XR while IR was still on the market as the "soft switch," and we will adopt that term.

In early 2014, Defendants decided on a more direct approach. They were concerned that they would be unable to convert a significant percentage of Alzheimer's patients dependent upon memantine therapy from IR to XR prior to the entry of generic IR. Defendants' internal projections estimated that only 30% of Namenda IR users would voluntarily switch prior to July 2015. On February 14, 2014, Defendants publicly announced that they would discontinue Namenda IR on August 15, 2014, notified the FDA of their plans to discontinue Namenda IR, and published letters on their websites urging caregivers and healthcare providers to "discuss switching to Namenda XR" with their patients. S.A. 51-52. Defendants also sought to convert Namenda IR's largest customer base, Medicare patients, to XR by sending a letter to the Centers for Medicare & Medicaid Services requesting that the agency remove IR from the formulary list, so that Medicare health plans would not cover it. Their planned discontinuance

[18] The original numbers have been redacted.

[19] The original numbers have been redacted.

was delayed by a disruption in XR production, and in June 2014, Defendants announced that Namenda IR would be available until the fall of that year.

But before Defendants withdrew IR entirely, intervening events again prompted them to modify their plans. In September 2014, New York State filed a complaint alleging that Defendants' planned withdrawal of Namenda IR violated the antitrust laws. Defendants subsequently entered into an agreement with Foundation Care, a mail-order-only pharmacy, to provide for limited access to Namenda IR if medically required. Under the terms of the agreement, Foundation Care is authorized to dispense Namenda IR tablets only after receiving a form from a doctor stating that it is "medically necessary" for the patient to take Namenda IR. Defendants estimated internally that less than 3% of current Namenda IR users would be able to obtain IR through Foundation Care. S.A. 67. Although the agreement with Foundation Care makes IR available to a limited number of patients, Defendants' actions effectively withdrew Namenda IR from the market. The parties have referred to Defendants' efforts to withdraw Namenda IR from the market as the "hard switch" or "forced switch," terms we also adopt. The hard switch began on February 14, 2014 with the announcement of Defendants' intention to withdraw Namenda IR and was suspended in September 2014 when Defendants agreed to a "standstill" during the litigation proceedings described below. Because a manufacturer does not simply withdraw a drug at once, absent pressing safety concerns, announcing the imminent discontinuation of a drug is tantamount to withdrawal.

IV. Procedural History

In September 2014, New York State filed a complaint in the District Court for the Southern District of New York (Robert W. Sweet, *Judge*) alleging that Defendants were violating the Sherman Antitrust Act, 15 U.S.C. §§ 1 and 2, as well as New York's Donnelly Act, N.Y. Gen. Bus. Law § 340 *et seq.*, and seeking a permanent injunction and damages. New York also sought a preliminary injunction barring Defendants from restricting access to Namenda IR during the course of the litigation.

New York's theory of antitrust liability, in substance, is as follows. As Namenda IR neared the end of its exclusivity period, Defendants introduced Namenda XR and, before generic IR was available, withdrew Namenda IR in order to force patients to switch from IR to XR (for which generic IR will not be substitutable under most states' laws). In doing so, Defendants intended to thwart generic entry into and competition in the memantine-drug market in order to maintain their monopoly in that market.

The district court held a five-day hearing on the preliminary-injunction motion, during which it received testimony from 24 witnesses and reviewed over 1,400 exhibits. After considering that evidence, the district court made several key findings. (1) Withdrawing Namenda IR from the market prior to generic entry forces Alzheimer's patients dependent on memantine therapy to switch to Namenda XR because it is the only available alternative; (2) The generic versions of IR poised to enter the market in July and October of 2015 will not be AB-rated to XR because they have different strengths and dosages; (3) Pharmacists will not be permitted to substitute generic IR for Namenda XR under New York and many other states' substitution

laws because generic IR is not therapeutically equivalent to Namenda XR; (4) If Defendants forced Alzheimer's patients to switch to Namenda XR prior to generic entry, those patients would be very unlikely to switch back to twice-daily IR therapy even after less-expensive generic IR becomes available, due to the high transaction costs associated with Alzheimer's patients first switching from one formulation of a drug to a new formulation and then back to the original formulation ("reverse commuting"); (5) Preventing generic IR from competing under state drug substitution laws would likely thwart generic entry into and competition in the memantine-drug market; and (6) In withdrawing Namenda IR from the market, Defendants' explicit purpose was to impede generic competition and to avoid the patent cliff—which occurs at the end of a drug's exclusivity period when generics gain market share through state substitution laws.

Based on those findings, the district court granted New York's request for a preliminary injunction. The district court concluded that New York raised serious questions regarding the merits of its claims under Sections 1 and 2 of the Sherman Act and the Donnelly Act, demonstrated the potential for irreparable harm, and concluded that the balance of the equities favored an injunction. The injunction states:

> 1. During the Injunction Term . . . the Defendants shall continue to make Namenda IR (immediate-release) tablets available on the same terms and conditions applicable since July 21, 2013 . . .

2. Defendants shall inform healthcare providers, pharmacists, patients, caregivers, and health plans of this injunction . . . and the continued availability of Namenda IR . . .

3. The Defendants shall not impose a "medical necessity" requirement or form for the filling of prescriptions of Namenda IR during the Injunction Term.

S.A. 137-38. The injunction is effective from the date of issuance, December 15, 2014, until "thirty days after July 11, 2015 (the date when generic memantine will first be available) (the 'Injunction Term')." S.A. 138. Defendants timely appealed the grant of the preliminary injunction, and we granted expedited review.

DISCUSSION

We review a district court's grant of a preliminary injunction for abuse of discretion. *Faiveley Transp. Malmo AB v. Wabtec Corp.*, 559 F.3d 110, 116 (2d Cir. 2009). A district court has abused its discretion if it based its ruling on an error of law or a clearly erroneous assessment of the evidence, or if its "decision . . . cannot be located within the range of permissible decisions." *Id*. (internal quotation marks omitted). We review legal conclusions, such as the appropriate standard for relief, *de novo*. *See Somoza v. N.Y.C. Dep't of Educ.*, 538 F.3d 106, 112 (2d Cir. 2008).

On appeal, Defendants argue that (1) the district court applied the wrong legal standard for a preliminary injunction; (2) product hopping is not anticompetitive or exclusionary under § 2 of the Sherman Act; (3) Defendants' patent rights foreclose antitrust liability; (4) the agreement with Foundation Care does not violate § 1 of the Sherman Act; (5) New York failed to show

irreparable harm; and (6) the injunction is vague and overbroad.

I. The Applicable Preliminary Injunction Standard

Defendants argue that the district court erred by applying the ordinary standard for a preliminary injunction, rather than a heightened standard, because the injunction provides New York with "substantially all the relief sought." Defendants' Brief ("Defs. Br.") at 25. We agree that a heightened standard applies.

Section 16 of the Clayton Act entitles a party to obtain injunctive relief "against threatened loss or damage by a violation of the antitrust laws." *California v. Am. Stores Co.*, 495 U.S. 271, 280 (1990) (quoting 15 U.S.C. § 26). A party seeking a preliminary injunction must ordinarily establish (1) "irreparable harm"; (2) "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"; and (3) "that a preliminary injunction is in the public interest." *Oneida Nation of New York v. Cuomo*, 645 F.3d 154, 164 (2d Cir. 2011) (internal quotation marks omitted).

We have held the movant to a heightened standard where: (i) an injunction is "mandatory," or (ii) the injunction "will provide the movant with substantially all the relief sought and that relief cannot be undone even if the defendant prevails at a trial on the merits." *Tom Doherty Assocs., Inc. v. Saban Entm't, Inc.*, 60 F.3d 27, 33-34 (2d Cir. 1995). When either condition is met, the movant must show a "clear" or "substantial" likelihood of success on the merits, *Beal v. Stern*, 184 F.3d 117, 123 (2d Cir. 1999), and make a "strong showing" of irreparable harm, *Doe v. N.Y. Univ.*, 666 F.2d

761, 773 (2d Cir. 1981), in addition to showing that the preliminary injunction is in the public interest.

The injunction issued by the district court in this case remains in place until 30 days after generics enter the market, and therefore "grant[s] plaintiffs substantially all the relief they ultimately sought, in effect, as if the injunction had been permanent." *Eng v. Smith*, 849 F.2d 80, 82 (2d Cir. 1988). The district court found that Defendants' plan is contingent on switching patients to Namenda XR before generic IR enters the market. S.A. 20. The injunction, however, bars Defendants from withdrawing IR, and thus forcing a switch, "until thirty days after July 11, 2015 (the date when generic memantine will first be available)." S.A. 138. Because the injunction prevents Defendants' hard switch from succeeding, the injunction "render[s] a trial on the merits largely or partly meaningless." *Tom Doherty Assocs.*, 60 F.3d at 35.[20] Accordingly, the heightened standard applies.

That conclusion, however, is of little import in this case because New York has satisfied the heightened standard. The district court did not abuse its discretion in granting a preliminary injunction because New York has demonstrated a substantial likelihood of success on the merits of its monopolization and attempted monopolization claims under § 2 of the Sherman Act, *see Beal*, 184 F.3d at 123, and has made a strong showing that Defendants' conduct would cause irreparable harm to competition in the memantine-drug market and to consumers, *Doe*, 666 F.2d at 773. The district court's factual findings, which were based, for the most

[20] Although New York also seeks a permanent injunction, disgorgement, civil penalties, and damages, the preliminary injunction is the gravamen of the complaint.

part, on Defendants' own internal documents, cannot be said to be clearly erroneous, and its injunction prohibiting Defendants from withdrawing Namenda IR prior to generic entry was not an abuse of discretion as being outside the range of permissible decisions.

II. Monopolization and Attempted Monopolization Under § 2 of the Sherman Act

Section 2 of the Sherman Act makes it an offense to "monopolize, or attempt to monopolize . . . any part of the trade or commerce among the several States." 15 U.S.C. § 2; *see also Geneva Pharm. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 495 (2d Cir. 2004). To establish monopolization in violation of § 2, a plaintiff must prove not only that the defendant possessed monopoly power in the relevant market, but that it willfully acquired or maintained that power "as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004) (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966)). "To safeguard the incentive to innovate, the possession of monopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive conduct." *Id*. In order to show attempted monopolization, the plaintiff must prove: "(1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power." *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993). Attempted monopolization, unlike monopolization, requires a finding of specific intent. *See, e.g., Delaware & Hudson Ry. Co. v. Consol. Rail Corp.*, 902 F.2d 174, 180 (2d Cir. 1990).

Defendants' patents on Namenda IR indisputably grant them a legal monopoly in the U.S. memantine-drug market until July 11, 2015.[21] The parties do not dispute the district court's factual findings that the relevant market is the memantine-drug market in the United States and that Namenda IR and XR represent 100% of that market. S.A. 108-10. Consequently, the parties do not dispute that Defendants possess monopoly power. *See Geneva Pharm.*, 386 F.3d at 500 (monopoly power can be "proven directly through evidence of control over prices or the exclusion of competition," or "inferred from a firm's large percentage share of the relevant market").

Given that Defendants' monopoly power has been established, this case turns on whether Defendants willfully sought to maintain or attempted to maintain that monopoly in violation of § 2. In *United States v. Microsoft Corp.*, 253 F.3d 34, 58-60 (D.C. Cir. 2001) (en banc), the D.C. Circuit, sitting en banc, established a helpful framework for determining when a product change violates § 2 based on the rule-of-reason test articulated by the Supreme Court in *Standard Oil Co. v. United States*, 221 U.S. 1 (1911), and generally applied to antitrust claims. *See also Paycom Billing Servs., Inc. v. Mastercard Int'l, Inc.*, 467 F.3d 283, 289-90 (2d Cir. 2006) (explaining that courts analyze most antitrust claims under the rule of reason).[22]

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[21] *See Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945) ("[A] patent is an exception to the general rule against monopolies and to the right to access to a free and open market.").

[22] *See also Mid-Texas Commc'ns Sys., Inc. v. Am. Tel. & Tel. Co.*, 615 F.2d 1372, 1389 n.13 (5th Cir. 1980) ("It is clear, however, that the analysis under section 2 is similar to that under section 1 regardless whether the rule of reason label is applied per se."

Under the *Microsoft* framework, once a plaintiff establishes that a monopolist's conduct is anticompetitive or exclusionary, the monopolist may proffer "nonpretextual" procompetitive justifications for its conduct. 253 F.3d at 58-59. The plaintiff may then either rebut those justifications or demonstrate that the anticompetitive harm outweighs the procompetitive benefit. *Id*.

a. Anticompetitive and Exclusionary Conduct

"As a general rule, courts are properly very skeptical about claims that competition has been harmed by a dominant firm's product design changes." *Microsoft*, 253 F.3d at 65; *see also Foremost Pro Color, Inc. v. Eastman Kodak Co.*, 703 F.2d 534, 544-45 (9th Cir. 1983). Product innovation generally benefits consumers and inflicts harm on competitors, so courts look for evidence of "exclusionary or anticompetitive effects" in order to "distinguish 'between conduct that defeats a competitor because of efficiency and consumer satisfaction'" and conduct that impedes competition through means other than competition on the merits. *Trans Sport, Inc. v. Starter Sportswear, Inc.*, 964 F.2d 186, 188-89 (2d Cir. 1992) (quoting *U.S. Football League v. Nat'l Football League*, 842 F.2d 1335, 1359 (2d Cir. 1988)).

(citing *Byars v. Bluff City News Co.*, 609 F.2d 843, 860 (6th Cir. 1979))); *Cal. Computer Prods., Inc. v. Int'l Bus. Machs. Corp.*, 613 F.2d 727, 737 (9th Cir. 1979) ("[U]nder § 2 attempt as with § 1 monopolization individual conduct is measured against the same 'reasonableness' standard governing concerted and contractual activity under § 1.").

Well-established case law makes clear that product redesign is anticompetitive when it coerces consumers and impedes competition.[23] The leading case in our

[23] Our emphasis on consumer coercion in evaluating a monopolist's product redesign is in accord with several of our sister circuits. *See Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 994 (9th Cir. 2010) ("A monopolist's discontinuation of [an old product] may violate § 2 if it effectively forces customers to adopt its new [product]."); *Microsoft*, 253 F.3d at 65 (explaining that Microsoft's redesign of its operating system was anticompetitive because the redesign impeded competition "not by making Microsoft's own browser more attractive to consumers but, rather, by discouraging [manufacturers] from distributing rival products"); *cf. Multistate Legal Studies, Inc. v. Harcourt Brace Jovanovich Legal & Prof'l Publ'ns, Inc.*, 63 F.3d 1540, 1550 (10th Cir. 1995) (noting that illegal tie-ins under Section 1 may "qualify as anticompetitive conduct for Section 2 purposes"). Similarly, the other district courts that have considered product hopping cases also examined consumer coercion. And those district courts that have ruled in favor of plaintiffs alleging antitrust violations stemming from product hopping have found consumer coercion. *See In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, No. 13-MD-2445, 2014 WL 6792663, at *12 (E.D. Pa. Dec. 3, 2014) (plaintiffs alleged exclusionary conduct under § 2 where the brand manufacturer coerced patients into switching from the tablet form of a drug—for which their patent was set to expire—to a new film version of the drug by raising allegedly false safety concerns about the tablet and announcing that it would soon be withdrawn from the market); *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 430 (D. Del. 2006) (plaintiffs alleged antitrust violations where the defendants introduced new drug formulations and withdrew the prior versions whose exclusivity period would soon expire). In contrast, in cases in which there is no evidence of coercion, district courts have rejected such claims. *See Mylan Pharm. Inc. v. Warner Chilcott PLC et al.*, No. Civ. 12-3824, 2015 WL 1736957, at *13 (E.D. Pa. Apr. 16, 2015) (noting that because generics had already entered the market at the time of defendants' product reformulation, "doctors remained free to prescribe generic Doryx; pharmacists remained free to substitute generics

circuit for § 2 liability based on product redesign is *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263 (2d Cir. 1979). In that case, Kodak simultaneously introduced its new Kodacolor II film and new Kodak 110 camera, which was designed so that it could only be used with the Kodacolor II film (the "110 system"). *Id*. at 277-78. Kodak, which possessed a lawful monopoly in film but not in cameras, heavily advertised Kodacolor II film as "a remarkable new film," and for 18 months, Kodak made Kodacolor II film only for the 110 camera. *Id*. at 278. Berkey Photo, Inc. ("Berkey"), a smaller camera manufacturer, alleged that Kodak unlawfully used its monopoly in film to increase camera sales and monopolize the camera market. *Id*. We rejected that claim and held that the introduction of the 110 system and advertising of the Kodacolor II film did not violate the Sherman Act because "[Kodak's] success was not based on any form of coercion." *Id*. at 287. But, of significance to the case before us, we cautioned that "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." *Id*. at 287 n.39.[24]

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when medically appropriate; and patients remained free to ask their doctors and pharmacists for generic versions of the drug"); *Walgreen Co. v. AstraZeneca Pharm. L.P.*, 534 F. Supp. 2d 146, 151 (D.D.C. 2008) (dismissing a case alleging attempted market monopolization because unlike in *Abbott Labs*, "there is no allegation that AstraZeneca eliminated any consumer choices. Rather, AstraZeneca . . . introduced a new drug to compete with already-established drugs—both its own and others'—and with the generic substitutes for at least one of the established drugs").

[24] We also noted that restricting Kodacolor II to the 110 format for 18 months may have been anticompetitive conduct, but we did

In this case, Defendants argue that withdrawing a product is not anticompetitive or exclusionary conduct, especially when the new product is superior to the old product.[25] Certainly, neither product withdrawal nor product improvement alone is anticompetitive. But under *Berkey Photo*, when a monopolist *combines* product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits, *id*. at 287, and to impede competition, *id*. at 274-75, its actions are anticompetitive under the Sherman Act.[26] *Cf. Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962) (noting that when an antitrust conspiracy involves multiple acts, "[t]he character and effect of [the] conspiracy are not to be judged by dismembering it and viewing its separate parts, but only by looking at it as

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not decide the question because there was no proof of injury to Berkey. *Berkey Photo*, 603 F.2d at 290.

[25] Whether XR is superior to IR is not significant in this case. When there is coercion, "the technological desirability of the product change . . . bear[s] on the question of monopolistic intent," *id*. at 287 n.39, rather than the permissibility of the defendant's conduct. Here, there is no genuine dispute that Defendants intended to avoid the patent cliff. *See, e.g.*, J.A. 132, 155.

[26] Several other courts have held that product redesign violates § 2 when combined with other conduct and the combined effect is anticompetitive or exclusionary. *See Allied Orthopedic*, 592 F.3d at 1000 (explaining that § 2 is violated when "some conduct of the monopolist associated with its introduction of a new and improved product design constitutes an anticompetitive abuse or leverage of monopoly power, or a predatory or exclusionary means of attempting to monopolize the relevant market" (internal quotation marks omitted)); *In re Suboxone*, 2014 WL 6792663, at *10 ("The key question is whether the defendant combined the introduction of a new product with some other wrongful conduct, such that the comprehensive effect is likely to stymie competition, prevent consumer choice and reduce the market's ambit.").

a whole" (internal quotation marks omitted)). Here, Defendants' hard switch—the combination of introducing Namenda XR into the market and effectively withdrawing Namenda IR—forced Alzheimer's patients who depend on memantine therapy to switch to XR (to which generic IR is not therapeutically equivalent) and would likely impede generic competition by precluding generic substitution through state drug substitution laws.

i. Consumer Coercion

Defendants' hard switch crosses the line from persuasion to coercion and is anticompetitive. As long as Defendants sought to persuade patients and their doctors to switch from Namenda IR to Namenda XR while both were on the market (the soft switch) and with generic IR drugs on the horizon, patients and doctors could evaluate the products and their generics on the merits in furtherance of competitive objectives.

By effectively withdrawing Namenda IR prior to generic entry, Defendants forced patients to switch from Namenda IR to XR—the only other memantine drug on the market.[27] S.A. 49; Tr. 183:22-184:17 (Stitt) ("So the unique thing [about the Namenda IR hard switch] I think is that there's really no place for prescribers to, to go with a drug to treat that condition."). In fact, the district court found that Defendants devised the hard switch because they projected that only 30% of memantine-therapy patients would voluntarily switch to Namenda XR prior to generic entry. S.A. 56-57. Defendants' hard switch was expected to transition 80

[27] As previously noted, the other available Alzheimer's drugs, all CIs, are not substitutes for Namenda because they perform different medical functions and are not designed to treat moderate-to-severe Alzheimer's disease.

to 100% of Namenda IR patients to XR prior to generic entry, S.A. 81, and thereby impede generic competition.

Defendants argue that courts should not distinguish between hard and soft switches. But this argument ignores one of *Berkey Photo*'s basic tenets: the market can determine whether one product is superior to another only "so long as the free choice of consumers is preserved." 603 F.2d at 287. Had Defendants allowed Namenda IR to remain available until generic entry, doctors and Alzheimer's patients could have decided whether the benefits of switching to once-daily Namenda XR would outweigh the benefits of adhering to twice-daily therapy using less-expensive generic IR (or perhaps lower-priced Namenda IR). By removing Namenda IR from the market prior to generic IR entry, Defendants sought to deprive consumers of that choice. In this way, Defendants could avoid competing against lower-cost generics based on the merits of their redesigned drug by forcing Alzheimer's patients to take XR,[28] with the knowledge that transaction costs would make the reverse commute by patients from XR to generic IR highly unlikely.

ii. Impedes Competition

As the district court concluded, Defendants' hard switch would likely have anticompetitive and exclusionary effects on competition in the memantine market, creating a "dangerous probability" that Defendants would maintain their monopoly power after generics enter the market. *Spectrum Sports*, 506 U.S. at 456. Based on careful consideration of the unique characteristics of the pharmaceutical market, the district court found that "[p]rice competition at the pharmacy,

[28] Alternatively, patients could discontinue memantine-therapy entirely.

facilitated by state substitution laws, is the principal means by which generics are able to compete in the United States." S.A. 26.

We agree with the district court's analysis. Forcing patients to switch to XR would prevent generic substitution because generic versions of IR are not AB-rated to Namenda XR. And if, as Defendants' own internal predictions estimate, the hard switch successfully converted 80 to 100% of IR patients to XR prior to generic entry, there would be "few to no prescriptions" left for which generics would be eligible to compete. S.A. 82. Because Defendants' forced switch "through something other than competition on the merits[] has the effect of significantly reducing usage of rivals' products and hence protecting its own . . . monopoly, it is anticompetitive." *Microsoft*, 253 F.3d at 65.

Defendants and their *amici* argue that generics can successfully compete by persuading third-party payors and prescription-benefit managers to promote generic IR through the use of formularies, tiered-drug structures, step programs, and prior-authorization requirements.[29] But, as the district court determined, competition through state drug substitution laws is the only

[29] Formularies, tiered-drug structures, step programs, and prior-authorization requirements are all tools that third-party payors may use to incentivize patients to take less-expensive drugs. A formulary is a list of approved drugs that a health plan will pay for, either in whole or in part. S.A. 19. A tiered-drug structure divides the drugs listed on a plan's formulary into categories or "tiers." S.A. 20. Typically, health plans use a three-tiered system, which reserves tier 1 for generic drugs, tier 2 for preferred branded drugs, and tier 3 for non-preferred branded drugs. The portion of the cost of the drug that the patient is responsible for paying, known as the "co-payment" or "co-pay," increases with each tier. A step program requires a patient to first try a preferred, and usually less expensive, drug. Only if that

cost-efficient means of competing available to generic manufacturers.[30] S.A. 78. For there to be an antitrust violation, generics need not be barred "from all means of distribution" if they are "bar[red] . . . from the cost-efficient ones." *Microsoft*, 253 F.3d at 64; *see also United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 191 (3d Cir. 2005) ("The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit."). Moreover, as the district court found, additional expenditures by generics on marketing would be impractical and ineffective because a generic manufacturer promoting a product would have no way to ensure that a pharmacist would substitute its product, rather than one made by one of its generic competitors.

Although in theory, Alzheimer's patients would be free to switch back to IR therapy after generic entry, the district court found that, in practice, such a reverse commute would be a highly unlikely occurrence. As one of Defendants' own executives explained during a

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treatment is unsuccessful will the health plan pay for the patient's drug of choice. S.A. 20. A prior authorization policy requires a patient to obtain the third-party payor's approval for payment prior to taking a particular drug. Antitrust Economists Br. at 14.

[30] The district court found that the regulatory context makes it impractical and uneconomical for generic manufacturers to market their products to doctors or pharmacists because, among other reasons, marketing costs severely impact generic manufacturers' ability to offer the lower prices upon which they compete. S.A. 78. Two other district courts confronted with product hopping cases concluded that plaintiffs plausibly alleged that the unique characteristics of the pharmaceutical industry "make generic substitution the cost-efficient means of competing for companies selling generic pharmaceuticals." *In re Suboxone*, 2014 WL 6792663, at *12; *see also Abbott Labs.*, 432 F. Supp. 2d at 423 (same).

January 21, 2014 earnings call: "if 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." S.A. 51. This is because there are high transaction costs associated with reverse commuting. Any patient who wants to switch back to twice-daily IR therapy must first obtain a new prescription from a doctor. But, as the district court found, the nature of Alzheimer's disease makes moderate-to-severe Alzheimer's patients especially vulnerable to changes in routine, and makes doctors and caregivers very reluctant to change a patient's medication if the current treatment is effective. As a result, if Defendants forced patients to switch from twice-daily Namenda IR to once-daily XR, those patients would be very unlikely to switch back to twice-daily generic IR even if generic IR is more cost-effective.[31] Moreover, third-party payors are reluctant to require patients to switch from a drug they are currently taking to a new drug, so health plans would be unlikely to require patients to switch to less-expensive generic IR.

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[31] The Department of Health and Human Services ("HHS") reached the same conclusion, explaining:

> The unique nature of this patient population—Alzheimer's patients with moderate-to-severe dementia—makes it likely that a switch from the twice-daily Namenda IR to the once-daily Namenda XR would be a permanent one for practical purposes, as providers, patients, and families would be reluctant to switch back to twice-a-day therapy even if they believed that it represented a better value.

HHS, Office of the Assistant Sec'y for Planning and Evaluation, *Some Observations Related to the Generic Drug Market 5 (2015), available at* http://aspe.hhs.gov/sp/reports/2015/GenericMarket/ib_GenericMarket.pdf (HHS, *Some Observations*).

Defendants and their *amici* argue that the district court's focus on AB-ratings is misplaced because up to 20 states do not impose an AB-rating requirement and thus "*may* let pharmacists unilaterally substitute generic IR for Namenda XR." Defs. Br. at 13 (emphasis added). Defendants' argument, however, exaggerates the variance in state substitution laws. Many states that do not explicitly require generic drugs to have the same AB-rating effectively require the same degree of therapeutic equivalence. For example, Defendants cite Iowa Code § 155A.32 as an example of a state law that "do[es] not rely on the Orange Book." Defs. Br. at 13. Section 155A.32(1) permits pharmacists to substitute a generic drug if it has the same "demonstrated bioavailability" as the brand drug, Iowa Code Ann. § 155A.32(1), but Section 155A.3(9) clarifies that a generic is only considered to have the same "demonstrated bioavailability" if it has the same "rate and extent of absorption of a drug or drug ingredient from a specified dosage form," Iowa Code Ann. § 155A.3(9). Because the dosage and absorption rates of generic IR differ from that of XR, the drugs are not bioequivalent under Iowa law. Moreover, because generic IR is manufactured in tablet form and Namenda XR is marketed in capsule form, they do not have the same dosage form.[32] As a result, as in New York and the 29 other

[32] Generic IR is manufactured in 5 and 10 mg tablet dosage formulations whereas Namenda XR is marketed in 7, 14, 21, and 28 mg capsule dosage formulations. J.A. 673 n.57. As Dr. Ernest R. Berndt, Ph.D. explains in his declaration, "tablets and capsules are not the same 'dosage form.'" *Id*.

states that require an AB-rating, Iowa pharmacists will not be permitted to substitute generic IR for XR.[33]

Defendants argue that their conduct was not anti-competitive because preventing "free riding" is a legitimate business purpose. But what Defendants call

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[33] Defendants argue that up to 20 states may allow pharmacists to substitute generic IR for Namenda XR; however, throughout their briefs, Defendants and their experts point to 21 different states. Of the states identified by Defendants and their experts, 16 require the same dose and/or dosage form and thus will not allow generic IR to be substituted for Namenda XR. *See* Ala. Code § 34-23-8; Alaska Stat. Ann. §§ 08.80.295(a), 08.80.480(11); Ark. Code Ann. §§ 17-92-503(a)(1), 17-92-101(6), (11); Cal. Bus. & Prof. Code §§ 4073(a), 4052.5(a), (f); Colo. Rev. Stat. Ann. §§ 12-42.5-122(1)(a), *as amended by* 2015 Colo. Legis. Serv. Ch. 77 (S.B. 15-071), 12-42.5-102(40); Conn. Gen. Stat. Ann. § 20-619(b); Fla. Stat. Ann. §§ 465.025(2), (1)(b); Ga. Code Ann. § 26-4-81(a); Mo Ann. Stat. § 338.056(1); Mont. Code Ann. § 37-7-505(1); Neb. Rev. Stat. §§ 71-5403(1), 71-5402(1), (5), (6), *as amended by* 2015 Nebraska Laws L.B. 37; N.C. Gen. Stat. Ann. §§ 90-85.28(a), 90-85.27(1); Or. Rev. Stat. Ann. § 689.515(2)(a); R.I. Gen. Laws Ann. §§ 21-31-16.1(a), 5-19.1-2(k); S.C. Code Ann. § 39-24-30a. Mich. Comp. Laws Ann. § 333.17755(1) allows for substitution of "generically equivalent" drugs, which courts in Michigan have interpreted to require "chemical equivalence," meaning that the drugs "contain the same active ingredients and are identical in strength, dosage form and route of administration." *Pennwalt Corp. v. Zenith Labs., Inc.*, 472 F. Supp. 413, 417 (E.D. Mich. 1979). Oklahoma prohibits substitution "without authority of the prescriber or purchaser," so we cannot determine whether generic IR will be substituted for Namenda XR under Oklahoma law. *See* Okla. Stat. Ann. tit. 59, § 353.13(D). Of the states that allow pharmacists to substitute generic drugs without consulting the prescribing physician, four states *may*—but will not necessarily—allow substitution of generic IR for Namenda XR. *See* Minn. Stat. Ann. § 151.21 Subd. 3; Minn. R. 9505.0340 Subp.3(H); N.D. Cent. Code Ann. §§ 19-02.1-14.1(3), (1)(g); Vt. Stat. Ann. tit. 18, § 4605(a), 4601(4); Wash. Rev. Code Ann. § 69.41.120; 69.41.110(4). Those four states account for less than 6% of the U.S. population. J.A. 673.

"free riding"—generic substitution by pharmacists following the end of Namenda IR's exclusivity period—is authorized by law; is the explicit goal of state substitution laws; and furthers the goals of the Hatch-Waxman Act by promoting drug competition, *Actavis*, 133 S. Ct. at 2228, and by preventing the "practical extension of [brand drug manufacturers'] monopoly . . . beyond the expiration of the[ir] patent[s]," H.R. Rep. No. 98-857, pt. 2, at 4 (1984).

Defendants also argue that antitrust law is not a vehicle for enforcing the "spirit" of drug laws. Defs. Br. at 46. But the Supreme Court has made clear that "[a]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue." *Trinko*, 540 U.S. at 411. Leading antitrust authorities have encouraged courts to acknowledge market defects, such as a price disconnect and the exclusivity of patents, in their antitrust analysis.[34] And in other Hatch-Waxman contexts, this court has recognized that efforts to manipulate aspects of the Hatch-Waxman incentive structure to exclude competition could state an antitrust claim. *See, e.g., Arkansas*

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[34] *See* IIIB Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 776c, at 297 (3d ed. 2008); Herbert Hovenkamp et al., *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* § 15.3, at 25 (2012); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1557 (2006) ("A particular regulatory regime sets the boundaries of feasible anticompetitive conduct."); Jonathan Jacobson, et al., *Predatory Innovation: An Analysis of Allied Orthopedic v. Tyco in the Context of Section 2 Jurisprudence*, 23 Loy. Consumer L. Rev. 1, 8 (2010) ("There are two scenarios where an exclusionary redesign may be especially harmful: (a) in the context of networked markets . . . and (b) in pharmaceutical markets . . . .").

Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98, 106 (2d Cir. 2010) ("[A] plaintiff can have antitrust claims" where a pharmaceutical manufacturer "manipulate[s] the [Hatch-Waxman-conferred] 180-day exclusivity period in a manner that bars subsequent challenges to the patent or precludes the generic manufacturer from marketing non-infringing products unrelated to the patent."), *abrogated on other grounds by Actavis*, 133 S. Ct. at 2231. Therefore, we conclude that the district court appropriately considered the unique market characteristics of the pharmaceutical industry in concluding that antitrust law "requires [Defendants] to allow generic competitors a fair opportunity to compete using state substitution laws." S.A. 95-96.

b. Procompetitive Justifications

All of Defendants' procompetitive justifications for withdrawing IR are pretextual. The record is replete with evidence showing that Defendants were, in the words of Defendants' own CEO, "trying to . . . put up barriers or obstacles" to generic competition. J.A. 132; *see also* S.A. 49 ("We need to transition volume to XR to protect our Namenda revenue from generic penetration in 2015 when we lose IR patent exclusivity."); J.A. 155 ("[W]hat we're trying to do is make a cliff disappear and rather have a long—a prolonged decline. And we believe that by potentially doing a forced switch, we will hold on to a large share of our base users."); S.A. 49 ("Our mission is to convert to Namenda XR and lift the franchise . . . . We need to convert as much IR business to Namenda XR as quickly as possible."). Based largely on Defendants' own documents, New York has rebutted Defendants' procompetitive justifications.

c. Procompetitive Benefits v. Anticompetitive Harms

Because we have determined that Defendants' procompetitive justifications are pretextual, we need not weigh them against the anticompetitive harms. But in any event, New York has shown that whatever procompetitive benefits exist are outweighed by the anticompetitive harms. Defendants argue that their conduct is procompetitive because "[l]aunching a new product . . . advances competition by adding a better product to the market and by paving the way for further innovation." Defs. Br. at 51. While *introducing* Namenda XR may be procompetitive, that argument provides no procompetitive justification for *withdrawing* Namenda IR.

Defendants argue that withdrawing IR was procompetitive because it would maximize their return on their investment in XR. But in deciding to take IR off the market, Defendants were willing to give up profits they would have made selling IR—Forest's best-selling drug. This "willingness to forsake short-term profits to achieve an anticompetitive end" is indicative of anticompetitive behavior. *In re Adderall*, 754 F.3d at 135 (internal quotation marks omitted). Moreover, Defendants fail to explain why the potential [redacted] in additional XR sales that they stood to earn—which is less than the approximately $1.5 billion in annual sales they have made from Namenda IR in recent years—makes economic sense in the absence of the benefit derived from eliminating generic competition. *See id*. at 133 (stating that anticompetitive effects could be shown where defendants' conduct "makes sense only because it eliminates competition"). As a result, we agree with the district court that:

> Defendants' short-term loss of [redacted] in IR sales, translating to [redacted] in income, is most rationally construed as an investment in moving the memantine market in [their] favor [through impeding generic competition], yielding [D]efendants [redacted] in income over the course of the next [redacted] years.

S.A. 74.

Finally, Defendants have presented no evidence to support their argument that antitrust scrutiny of the pharmaceutical industry will meaningfully deter innovation. To the contrary, as the American Antitrust Institute *amici* argue, immunizing product hopping from antitrust scrutiny may deter significant innovation by encouraging manufacturers to focus on switching the market to trivial or minor product reformulations rather than investing in the research and development necessary to develop riskier, but medically significant innovations.

In sum, we conclude that the combination of withdrawing a successful drug from the market and introducing a reformulated version of that drug, which has the dual effect of forcing patients to switch to the new version and impeding generic competition, without a legitimate business justification, violates § 2 of the Sherman Act.

III. Patent Rights as a Defense to Liability

Defendants argue that their patent rights under Namenda IR and Namenda XR shield them from antitrust liability. To be sure, there is tension between the antitrust laws' objective of enhancing competition by preventing unlawful monopolies and patent laws' objective of incentivizing innovation by granting legal patent monopolies. *See In re Adderall*, 754 F.3d at 133;

see also SCM Corp. v. Xerox Corp., 645 F.2d 1195, 1205 (2d Cir. 1981).

But in its recent landmark antitrust case, *F.T.C. v. Actavis, Inc.*, the Supreme Court made clear that "patent and antitrust policies are both relevant in determining the scope of the patent monopoly—and consequently antitrust law immunity—that is conferred by a patent." 133 S. Ct. at 2231 (internal quotation marks omitted); *see also United States v. Gypsum Co.*, 333 U.S. 364, 390–91 (1948) (indicating that courts must "balance the privileges of [the patent holder] and its licensees under the patent grants with the prohibitions of the Sherman Act against combinations and attempts to monopolize").

The Court's decision in *Actavis* reaffirmed the conclusions of circuit courts that a patent does not confer upon the patent holder an "absolute and unfettered right to use its intellectual property as it wishes," *Microsoft*, 253 F.3d at 63, and "[i]ntellectual property rights do not confer a privilege to violate the antitrust laws," *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1325 (Fed. Cir. 2000). *See also Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 998 (9th Cir. 2010) ("[C]hanges in product design are not immune from antitrust scrutiny and in certain cases may constitute an unlawful means of maintaining a monopoly under Section 2.").

Defendants argue that their conduct does not violate antitrust law because they have merely "exercised rights afforded by the Patent Act." Defs. Br. at 34. But patent law gives Defendants a temporary monopoly on individual drugs—not a right to use their patents as part of a scheme to interfere with competition "beyond the limits of the patent monopoly." *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948). Defendants

have essentially tried to use their patent rights on Namenda XR to extend the exclusivity period for all of their memantine-therapy drugs. As explained above, it is the *combination* of Defendants' withdrawal of IR and introduction of XR in the context of generic substitution laws that places their conduct beyond the scope of their patent rights for IR or XR individually.

IV. The Sherman Act § 1 and the Donnelly Act

In light of New York's substantial likelihood of success on the merits of its monopolization and attempted monopolization claims, we need not address the merits of its Sherman Act § 1 or Donnelly Act claims, which are based on the agreement between Defendants and Foundation Care. We do note, however, that an agreement related to a party's violation of § 2 does not trigger liability under § 1 unless the agreement *itself* unreasonably restrains trade, *Geneva Pharm.*, 386 F.3d at 506, and there is mutual anticompetitive intent, *see id*. at 507 ("[L]ack of intent by one party . . . precludes a conspiracy to monopolize."). Conduct that satisfies the unreasonable restraint prong under § 2 does not necessarily violate § 1 absent evidence that the agreement furthers the anticompetitive conduct. *Id*. at 506.

V. Irreparable Harm

New York has made a "strong" showing that competition and consumers will suffer irreparable harm in the absence of the injunction. *Doe*, 666 F.2d at 773. Irreparable harm is "injury that is neither remote nor speculative, but actual and imminent and that cannot be remedied by an award of monetary damages." *Forest City Daly Hous., Inc. v. Town of N. Hempstead*, 175 F.3d 144, 153 (2d Cir. 1999) (internal quotation marks omitted). To obtain injunctive relief under § 16 of the Clayton Act, that injury must be an injury "of

the type the antitrust laws were designed to prevent and that flows from that which makes defendants' acts unlawful." *Consol. Gold Fields PLC v. Minorco, S.A.*, 871 F.2d 252, 257 (internal quotation marks omitted), *amended by* 890 F.2d 569 (2d Cir. 1989).

As the district court concluded, "[p]ermanent damage to competition in the memantine market can . . . result from Defendants' planned hard switch strategy."[35] S.A. 131. If generics cannot compete with Defendants' drugs via state substitution laws, they "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." S.A. 80-81; *see also* IP and Antitrust Prof. Br. at 13-14 (explaining that absent substitution at the pharmacy, "the market for generics will collapse"). Moreover, generics cannot simply move into the market for generic XR. To become substitutable for Namenda XR, generic manufacturers must develop new once-daily Namenda tablets, begin the ANDA-approval process all over again, and await the end of XR's patent exclusivity period in 2029. Because Defendants' conduct does not simply harm a competitor or two, but threatens to "reduce competition in the [memantine-drug] market[,] . . . [it] is precisely the type that the antitrust laws were designed to protect against." *Consol. Gold*, 871 F.2d at 257-58.

The district court also found that, in addition to harming consumer choice, Defendants' hard switch would

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[35] *See also LePage's Inc. v. 3M*, 324 F.3d 141, 159 (3d Cir. 2003) ("When a monopolist's actions are designed to prevent one or more new or potential competitors from gaining a foothold in the market by exclusionary, i.e. predatory, conduct, its success in that goal is not only injurious to the potential competitor but also to competition in general.").

cause economic harm to consumers. Based on Defendants' own data, the district court found that consumers would pay almost $300 million more and third-party payors would pay almost $1.4 billion more for memantine therapy if Defendants were permitted to switch patients to Namenda XR before generic IR entry. And HHS reports that Defendants' withdrawal of Namenda IR prior to generic entry would cost Medicare and its beneficiaries a minimum of $6 billion over the next ten years.[36] "Threaten[ed] economic harm to . . . consumers . . . is plainly sufficient to authorize injunctive relief." *Am. Stores Co.*, 495 U.S. at 283.[37]

Defendants argue that the district court erred in finding *irreparable* harm because any increase in costs to consumers and third-party payors is "compensable and readily quantifiable." Defs. Br. at 26. But compensating the approximately 500,000 Alzheimer's patients who take Namenda IR tablets, and an unknown number of public and private third-party payors, for an ongoing harm would impose "the task of disentangling overlapping damages claims [which] is not lightly to be imposed upon potential antitrust litigants, or upon the judicial system." *Blue Shield of Va. v. McCready*, 457 U.S. 465, 475 n.11 (1982); *see also Salinger v. Colting*, 607 F.3d 68, 81 (2d Cir. 2010) ("Harm might be irremediable, or irreparable, for many reasons,

[36] HHS, *Some Observations*, at 7.

[37] Given that we conclude that the district court did not abuse its discretion in granting a preliminary injunction based on the harm to competition and economic harm to consumers, we need not consider whether the district court's findings related to medical harm to patients provided a basis for injunctive relief.

including that a loss is difficult to replace . . . .").[38] In addition, many of the victims of Defendants' hard switch, such as patients and health plans, may be prevented from direct recovery for their antitrust losses because of the "indirect purchaser" rule, which bars those who do not directly purchase a product from recovering antitrust damages, thus further supporting

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[38] Defendants also argue that the district court erred in discounting the harm that they will suffer as a result of the injunction. We need not consider the balance of the hardships given that New York has demonstrated a substantial likelihood of success on the merits. In any event, we agree with the district court that the balance of the hardships tips decidedly in New York's favor.

Defendants argue that they will be injured if they cannot convert patients to Namenda XR prior to July 2015, but that argument begets the question of whether their conduct is lawful. Certainly, courts do not consider the harm a party suffers from being prevented from violating the law.

Defendants also argue that they "had stopped making IR batches and ha[d] been implementing plans to limit distribution for months." Defs. Br. at 25. Ordering Defendants to manufacture IR, Defendants argue, impedes production of XR and delays the development of Namzaric, an even newer Alzheimer's drug, because the FDA has only certified one plant to produce IR, XR, and Namzaric. This argument is belied by the record. At the preliminary injunction hearing, one of Defendants' executives testified that the plant could manufacture IR while manufacturing XR. J.A. 533. Defendants also informed the district court that there was no cap on the amount of IR that would be supplied through Foundation Care and that the supply could be "adjusted as necessary based on demand." J.A. 904. Another of Defendants' experts testified that the "biggest problem [Defendants] have with [manufacturing both IR and XR] is the labor force," but "the equipment is completely different equipment." J.A. 202. Defendants' expert clarified that they need skilled labor but, at most, he explained that there might be some delay caused by training employees to use the new XR equipment where employees who had manufactured IR would be able to transition more quickly. J.A. 203.

New York's claim of irreparable injury. *See Illinois Brick Co. v. Illinois*, 431 U.S. 720, 745-46 (1977).

Additionally, we agree with the district court, and the parties do not dispute, that the preliminary injunction serves the public's interest in a competitive market for memantine drugs. *See United States v. Siemens Corp.*, 621 F.2d 499, 506 (2d Cir. 1980) (finding that the government represents the public's interest in a competitive marketplace in seeking to enjoin a merger under § 7 of the Clayton Act); *see also Register.com, Inc. v. Verio, Inc.*, 356 F.3d 393, 424 (2d Cir. 2004) ("[G]overnment action taken in furtherance of a regulatory or statutory scheme . . . is presumed to be in the public interest").

VI. The Preliminary Injunction

Defendants argue that the injunction provision requiring them to make Namenda IR tablets available on the same terms and conditions applicable since July 21, 2013 is vague because the terms and conditions have shifted over the past 17 months. We disagree. The injunction plainly prohibits Defendants from charging more for Namenda IR than it did during the specified timeframe and from restricting access to IR. If Defendants need additional clarification, they can seek it in the district court.

Defendants also argue that the injunction is overbroad because there is no antitrust violation in the 20 states in which drug substitution laws *might* allow pharmacists to substitute generic IR for Namenda XR. Defendants did not raise this argument before the district court, and therefore have forfeited it. *See, e.g., Zalaski v. City of Hartford*, 723 F.3d 382, 395 (2d Cir. 2013) ("[P]laintiffs failed to raise the argument in the district court, thereby forfeiting it on appeal."). In any

event, that argument is not persuasive because, as explained above, it exaggerates the extent to which state substitution laws differ. Defendants have not brought to our attention a single state in which drug substitution laws will definitively allow pharmacists to submit generic IR for Namenda XR, and have thus failed to identify any state for which there is no antitrust violation.

CONCLUSION

For the reasons stated above, we AFFIRM the District Court's order granting New York's motion for a preliminary injunction.

APPENDIX B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

[Filed: 12/11/14]

14 Civ. 7473

THE PEOPLE OF THE STATE OF NEW YORK,

Plaintiff,

-against-

ACTAVIS, PLC, and FOREST LABORATORIES, LLC,

Defendants.

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REDACTED OPINION*

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,

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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.

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.[2]

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[2] 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) 1 7; Lah Decl. (PX85) 1 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) 1 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 payers 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) 1 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]. 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

/s/ Robert W. Sweet
Robert W. Sweet
U.S.D.J

APPENDIX C

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

[Filed: 12/15/14]

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14 Civ. 7473

THE PEOPLE OF THE STATE OF NEW YORK,

Plaintiff,

against

ACTAVIS, PLC, and
FOREST LABORATORIES, LLC,

Defendants.

ORDER

Upon the findings of fact and conclusions of law set forth in the Opinion of this Court dated December 11, 2014, it is hereby ORDERED that:

1. During the Injunction Term as defined below, the Defendants shall continue to make Namenda IR (immediate-release) tablets available on the same terms and conditions applicable since July 21, 2013 (the date Namenda XR entered the market).

2. On or before December 23, 2014, Defendants shall inform healthcare providers, pharmacists, patients, caregivers, and health plans of this injunction (and provide a copy of the injunction or other means to easily view the injunction) and the continued availability of Namenda IR in the same or substantially similar

manner in which they informed them of Defendants' plan to discontinue Namenda IR in February 2014.

3. The Defendants shall not impose a "medical necessity" requirement or form for the filling of prescriptions of Namenda IR during the Injunction Term.

4. In order to allow for an orderly transition, this injunction shall be effective from the date of issuance until thirty days after July 11, 2015 (the date when generic memantine will first be available) (the "Injunction Term").

New York, NY
December 15, 2014

/s/ Sweet
ROBERT W. SWEET
U.S.D.J.

APPENDIX D

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

[Filed: 08/07/2015]

Docket No: 14-4624

PEOPLE OF THE STATE OF NEW YORK, by and through ERIC T. SCHNEIDERMAN, Attorney General of the State of New York,

Plaintiff-Appellee,

v.

ACTAVIS PLC, FOREST LABORATORIES, LLC,

Defendants-Appellants.

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Thurgood Marshall United States Courthouse, 40 Foley Square, in the City of New York, on the 7th day of August, two thousand fifteen.

ORDER

Appellants, Actavis PLC and Forest Laboratories, LLC, filed a petition for panel rehearing, or, in the alternative, for rehearing *en banc*. The panel that determined the appeal has considered the request for panel rehearing, and the active members of the Court have considered the request for rehearing *en banc*.

IT IS HEREBY ORDERED that the petition is denied.

FOR THE COURT:

/s/ Catherine O'Hagan Wolfe
Catherine O'Hagan Wolfe, Clerk