14-4624

United States Court of Appeals for the Second Circuit

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.

On Appeal from the United States District Court
for the Southern District of New York

FINAL BRIEF FOR APPELLEE

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TABLE OF CONTENTS

Page

TABLE OF CONTENTS (cont'd)

Page

TABLE OF CONTENTS (cont'd)

Page

TABLE OF CONTENTS (cont'd)

Page

TABLE OF AUTHORITIES

Cases **Page**

TABLE OF AUTHORITIES (cont'd)

Cases **Page(s)**

TABLE OF AUTHORITIES (cont'd)

Cases **Page(s)**

TABLE OF AUTHORITIES (cont'd)

Cases **Page(s)**

TABLE OF AUTHORITIES (cont'd)

Cases **Page(s)**

TABLE OF AUTHORITIES (cont'd)

Cases **Page(s)**

Laws

TABLE OF AUTHORITIES (cont'd)

Laws **Page(s)**

Miscellaneous Authorities

TABLE OF AUTHORITIES (cont'd)

Miscellaneous Authorities **Page(s)**

PRELIMINARY STATEMENT

This case is about an attempt by a monopolist drug company to insulate itself from competition by manipulating the supply and distribution of its products. Defendant-appellant Actavis plc and its wholly owned subsidiary Forest Laboratories, LLC, make and market Namenda—a drug that uses memantine to treat moderate-to-severe Alzheimer's disease. As their twice-daily instant release (IR) formulation of Namenda neared the end of its exclusivity period, defendants launched a once-daily extended-release formulation (XR). The two drugs are the only ones in their class (NMDA antagonists) and have the same therapeutic effect, but Namenda IR's exclusivity period—during which it is insulated from generic competition—ends on July 11, 2015, whereas Namenda XR's exclusivity runs until 2029.

Defendants determined that if they could restrict patient access to Namenda IR, existing users would be forced to switch to XR, and transaction costs would be created that would hinder those patients from switching to a lower-cost memantine therapy when generic versions of IR become available in July 2015. Defendants were willing to absorb [redacted]—and to

sacrifice future sales to the appreciable percentage of patients who would be so badly disrupted as to discontinue memantine treatment altogether—in expectation of the vastly greater profits they would obtain by impeding generic competition.

The district court made extensive factual findings concerning the anticompetitive motives and effect of defendants' conduct, including the irreparable harm that would result to competition, consumer choice, and the medical routines of vulnerable Alzheimer's patients. Those findings were largely based on defendants' contemporaneous business records and statements, and defendants have not shown that they were clearly erroneous.

Defendants similarly cannot show that it was an abuse of discretion for the district court to take at face-value their repeated testimony that they could easily meet future market demand for Namenda IR. The district court likewise did not abuse its discretion when crafting the specific terms of an injunction that uses recognized antitrust remedies to preserve the status quo during the litigation. This Court should affirm in all respects.

ISSUES PRESENTED

1. Whether a pharmaceutical manufacturer's efforts to create a shortage of a drug product, for an anticompetitive purpose and with anticompetitive effect, can result in liability under the antitrust laws.

2. Whether New York demonstrated irreparable harm by showing that the manufacturer's conduct would irreversibly impede competition and significantly disrupt the medical treatment plans of approximately 500,000 Alzheimer's patients.

3. Whether the district court properly determined that the preliminary injunction it entered was necessary to preserve the status quo of Namenda IR availability pending a determination of the merits.

STATEMENT OF THE CASE

A. The Regulatory Structure Governing Competition in the Pharmaceutical Industry

"Antitrust analysis must sensitively recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies." *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004) (quotation marks and alterations omitted). In a pharmaceutical case, that setting consists of the unique

economic characteristics of the prescription drug market and the "key features of the relevant drug-regulatory framework." *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2227 (2013).

Government regulation of the pharmaceutical industry seeks to balance several policy goals that are often in tension with each other—ensuring that drugs are safe and effective, encouraging development of new drugs, and lowering drug costs. The resulting economic and legal setting contains certain features that diminish the effectiveness of traditional mechanisms for competition.

First, regulatory requirements for safety and efficacy testing create significant barriers to entry for firms and individual drug products. *See, e.g.*, *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2470-71 (2013). Patent protection and regulatory exclusivity allow brand-name drug producers to charge supracompetitive prices for a limited time, thus encouraging investment in new drugs, but lower-cost alternatives cannot automatically enter the market when that exclusivity period ends.

Second, after a new drug is approved for sale, laws designed to safeguard public health may prohibit a consumer from purchasing a

drug without a prescription from a doctor. Third, because most pharmaceuticals are paid for by private or public insurance, the parties who select and use a drug do not fully bear its costs. These latter two features can diminish the effectiveness of price competition because the party paying for the drug is often not the party selecting it. *See e.g.,* Br. for the FTC as Amicus Curiae at 6, *Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd.*, No. 12-cv-3824 (E.D. Pa. Nov. 21, 2012), ECF No. 116-2; Steve D. Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 Rutgers L.J. 1, 9-12 (2009) (summarizing economic research). (*See also* Special App'x ("SA") 3.)

1. The Federal Hatch-Waxman Act

Generic competition plays an important role in controlling prescription drug costs by providing consumers with therapeutically equivalent alternatives to brand-name drugs at far lower prices. Generic drugs are generally 85% cheaper than their brand-name equivalents, and typically generate well over $100 billion in annual savings for the United States healthcare system. *See* U.S. GAO, Research on Savings from Generic Drug Use 10 (No. GAO-12-371R 2012); FTC *Mylan* Amicus Br., *supra*, at 7.

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act ("Hatch–Waxman Act") to "'speed[ ] the introduction of low-cost generic drugs to market,' thereby furthering drug competition." *Actavis*, 133 S. Ct. at 2228 (quoting *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012)). The Act modified the "costly and time-consuming" process for new generic drug approval, *id.* (quotation marks omitted), in an effort to mitigate that process's "serious anti-competitive effects," H.R. Rep. No. 98-857, pt. 2 at 4 (1984), which too frequently enabled brand-name drug producers to receive a "practical extension of the[ir] monopoly position . . . beyond the expiration of the[ir] patent," *id.* Congress's "policy objective" was to "get[] safe and effective generic substitutes on the market as quickly as possible after the expiration of the patent." *Id.* at 9.

Hatch-Waxman provides for accelerated approval of a generic drug that can show it is equivalent to a branded drug—that is, it has the same active ingredients, dosage form, rate and extent of absorption, among other characteristics. *Mutual Pharm.*, 133 S. Ct. at 2471 (discussing 21 U.S.C. § 355(j)(2)(A)(ii)-(v), (8)(B)). As an offsetting benefit to brand-name manufacturers, the Act allows brand-name manufacturers

to apply for an up-to-five-year extension of their twenty-year patent term to compensate for time required to secure FDA approval, *see* 35 U.S.C. § 156, and six months of regulatory exclusivity after patent expiration if the manufacturer conducts pediatric testing, *see* 21 U.S.C. § 355a.

2. State drug substitution laws

Hatch-Waxman was enacted against the backdrop of state drug substitution laws, which seek to lower transaction costs and other barriers to price competition in the pharmaceutical industry. Drug regulations require physician prescriptions before consumers may purchase most pharmaceutical products. Although beneficial for safety reasons, this requirement raises transaction costs for consumers considering switching products at the point of sale. State substitution laws reduce or eliminate these transaction costs by allowing (or requiring) a pharmacist to fill a prescription written for a brand-name drug with a lower-cost equivalent, unless the physician has directed otherwise. State substitution laws thus allow price competition among equivalent drugs to proceed uninhibited at the point of sale.

All fifty States have enacted such laws,[1] and the federal government has recognized that they form an important complement to Congress's efforts to encourage competition on the basis of price after the expiration of the applicable exclusivity period. *See* United States Government, Generic Pharmaceuticals 2, OECD No. DAF/COMP/WD (2014)51. Where generics are able to enter a market and compete on the basis of price at the pharmacy, they can capture as much as 90% of brand-name sales within the first year. FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 8 (2010).

New York's drug substitution law requires pharmacists to "substitute a less expensive drug product" if, among other things, it "contain[s] the same active ingredients, dosage form and strength as the drug product prescribed." N.Y. Education Law § 6816-a(1). Substitution of the lower-cost drug cannot occur unless it is "AB-rated" (or therapeutically equivalent) to the more expensive drug that was prescribed—that is, has the same active ingredients, and the same

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[1] HHS, Office of the Ass't Sec'y for Planning and Evaluation, ASPE Issue Brief: Expanding the Use of Generic Drugs, appx. A (Dec. 2010).

dosage form, strength, and route of administration. *Id.*; N.Y. Public Health Law § 206(1)(o); FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations* vii-x (34th ed. 2014). The requirement of AB-rating or a similar measure of therapeutic equivalence is intended to protect the physician's role in selecting the appropriate drug for his or her patient,[2] but it also provides a means by which brand-name manufacturers can "game" the system and avoid facing direct price competition with generics.

[2] New York, twenty-nine other States, and the District of Columbia incorporate by reference the federal AB-rated metric into their substitution laws, while the remaining States determine therapeutic equivalence in other ways. *See* Jesse C. Vivian, *Generic-Substitution Laws*, 33 U.S. Pharmacist 30 (June 2008).

B. Defendants' Efforts to Exploit the Relevant Regulatory Framework to Prevent Generic Competition with Their Namenda Products

1. Forest introduces Namenda IR, the only Alzheimer's treatment in its class

More than five million Americans, including about 380,000 New Yorkers, suffer from Alzheimer's disease. (SA13-14.) In 2000, Forest[3] acquired an exclusive license to sell a drug that treats Alzheimer's disease through the use of a compound called memantine HCL, which is the only FDA-approved treatment for moderate-to-severe Alzheimer's disease in its class (NMDA antagonists). (SA16-17, 30-31.) Since 2004, Forest has manufactured and marketed a twice-daily dosage memantine Alzheimer's therapy under the brand name Namenda Instant Release ("IR"). (SA30, 32.) Namenda IR is produced in tablet and liquid form. (SA32.)

Forest sought and in 2009 received a five-year patent extension under the Hatch-Waxman Act for the primary patent covering Namenda IR, extending its period of market exclusivity until April 11, 2015. (SA30-31; JA29.) Forest then secured from the FDA a further six-

[3] Forest was purchased by Actavis in July 2014. (SA12.)

month extension of non-patent-based market exclusivity (until October 11, 2015) by testing whether memantine could be approved for pediatric uses. (SA33-34.) In 2009 and 2010, Forest resolved patent litigation with potential generic competitors by agreeing to allow them to enter the market three months early, in July 2015. (SA33.) Five generic manufacturers have received tentative approval from the FDA to market generic versions of Namenda IR starting on July 11, 2015, and seven other generic manufacturers may enter the market as early as October. (SA33.)

During its exclusivity period, Namenda IR has been Forest's best-selling drug. In both 2012 and 2013, it generated at least $1.4 billion in annual sales. (SA34.)

2. As generic competition with Namenda IR approaches, Forest launches an extended-release version, Namenda XR

Soon after Namenda IR launched, Forest began developing an extended-release, once-daily version—Namenda XR. (SA35.) The active ingredient in IR and XR is the same, the drugs have "the same therapeutic effect," and "[n]o studies have been done to show that Namenda XR is more effective than Namenda IR." (SA17, 39, 54.) But

Namenda XR's different strength and dosage regimen (once-daily instead of twice-daily) means that the generic versions of Namenda IR that are poised to enter the market will not be therapeutically equivalent to Namenda XR (AB-rated or deemed substitutable by a similar metric, see *supra* 8-9 and n.2), and thus not substitutable under most state drug substitution laws. (SA25, 80; JA824 [114:15-20, 115:19-25], 840 [223:1-4].)

Although Namenda XR was approved by the FDA in June 2010, Forest waited over three years, until July 2013, to bring Namenda XR to market. (SA37-38.) Based on defendants' contemporaneous documents and statements, the district court found that Namenda XR was being used as part of a broader "product extension" strategy to protect defendants' Namenda drugs from generic competition. (SA47; *see also* SA 39.) Namenda XR's exclusivity rights run until 2029 and defendants recognized that if they could switch enough patients to Namenda XR before generic versions of Namenda IR entered the market in July 2015, they could use the dosage regimen differences between those drugs to defeat AB-substitutability and thereby impede

price-based competition from generic drugs for many more years. (SA48-49, 58.)

3. Defendants' plan to force Alzheimer's patients to switch from Namenda IR to Namenda XR

Forest spent approximately [redacted] on efforts designed to convince patients, caregivers, healthcare providers and pharmacists that patients should be switched from IR to XR. (SA39.) But this sales and marketing did not result in sufficient switching from IR to XR because Alzheimer's patients "are extremely sensitive to changes in routine" (SA89), and "[p]hysicians and caregivers are reluctant to disrupt patients' medical routines without a medical reason to do so" (SA87; *see also* SA54-57, 90, 92). The benefits of XR over IR are marginal to nonexistent for many Alzheimer's patients, who often already take other pills throughout the day. (SA54-56.)

After several months of selling Namenda IR and Namenda XR concurrently, Forest projected that only [redacted] of patients would voluntarily switch to Namenda XR before generic entry. (SA38-39, 56-57.) Forest therefore devised a plan to *force* the remaining patient population onto Namenda XR, by creating a shortage of Namenda IR.

(SA49-50, 54, 72-73.) If patients could not obtain IR, physicians would have no choice other than to switch them to XR.

Defendants at first contemplated discontinuing IR entirely, and made public announcements claiming they would cease to sell it as of late summer or fall of 2014. (SA51-52, 63.) They also sought to have the Centers for Medicare and Medicaid Services remove Namenda IR from the reference list that health plans serving Medicare patients use to determine which drugs to approve for payment. (SA53.)

Subsequently, defendants decided that severely restricting the distribution of Namenda IR would be an equally effective means of forcing a switch from IR to XR. (SA67.) In [redacted] defendants began to discuss a restrictive distribution plan with Foundation Care, a mail-order-only pharmacy, that would have the effect of eliminating IR from all retail store shelves. (SA64-65.)

C. Prior Proceedings

1. This litigation and defendants' undertakings to continue to make Namenda IR available

In September 2014, the New York State Attorney General brought this lawsuit, challenging defendants' planned "forced switch" under the Sherman Act (15 U.S.C. §§ 1, 2), New York's Donnelly Act (General Business Law § 340 *et seq.*), and Executive Law § 63(12). New York also moved for a preliminary injunction to preserve the status quo during the litigation.

Defendants agreed to a "standstill" under which they would maintain the status quo for Namenda IR availability during the preliminary injunction proceedings in the district court. (JA1014 [33:7-13].) At the time, defendants were supplying enough Namenda IR to meet the needs of the approximately 500,000 patients taking it twice-daily nationwide. (SA15.)

In November 2014, defendants announced their signing of a contract to distribute Namenda IR exclusively through Foundation Care beginning in January 2015. (SA65-66.) The agreement requires that patients seeking to purchase Namenda IR must provide, in addition to a prescription, a physician certification that it is medically necessary for

them to take IR specifically (*i.e.*, instead of XR). (SA66-67; JA845 [241:11-18].) Defendants projected that the transaction costs for patients, caregivers, and physicians—and the lack of any demonstrated difference in efficacy between Namenda IR and XR—would ensure that less than 3% of current IR users obtained IR under the Foundation Care arrangement. (SA70.) Defendants had also earlier projected that the confusion and disruption arising from a discontinuance or limited distribution of IR could result in as many as [redacted] of all Namenda patients discontinuing memantine treatment entirely. (SA95.)

During the preliminary injunction proceedings, defendants represented that they were still supplying enough Namenda IR to meet the daily needs of the 500,000 patients taking it nationwide (JA1014 [33:7-13]); *see also* Defs.-Appellants' Emergency Mot. for a Stay Pending Appeal Mem. 7, ECF No. 67 ("Defs.' CA2 Stay Mem.")), and that their agreement with Foundation Care imposed no limit on how much Namenda IR they could continue to make and ship (JA847 [255:18-20].) Defendants' executives had also testified that [redacted]. (JA532-533 [73:2-20,

75:12-18, 76:5-7], 202 [168:21-169:16], 205 [291:3-10].) Indeed, defendants' CEO testified at his deposition that defendants were [redacted] (JA421 [307:8-10], 424 [350:2-3]; *see also* JA502 [171:25-173:10]. *But see* JA844 [238:12-239:14].)

2. The district court's entry of a preliminary injunction to preserve the status quo

The district court held a five-day hearing on the preliminary injunction, during which it received live or written testimony from twenty-four witnesses and reviewed over 1400 exhibits. (SA11.) On December 11, 2014, the court issued a written opinion granting New York's request for a preliminary injunction to preserve the status quo. (SA129.)

The court first found that defendants' Namenda drugs currently represent "100% of the market" for a unique class of Alzheimer's treatments, and "there is no competition." (SA17, 110.) The court then found that defendants' forced-switch scheme had the intended purpose and likely effect of impeding competition with defendants' Namenda

drugs after the expiration of Namenda IR's exclusivity period. (SA38-39, 50-51, 56-60, 64-70, 120.)

The court determined that a preliminary injunction maintaining the status quo with respect to Namenda IR availability was necessary to avert the irreparable harm that defendants' conduct threatens to inflict on competition and on vulnerable Alzheimer's patients. (SA129-36.) On the other side of the balance, the court found that defendants "have not demonstrated any harm resulting from their continuing the same IR distribution strategy they have been using since 2004." (SA132-133.) After receiving proposed preliminary injunctions from the parties and hearing argument on these, the court on December 15, 2015, imposed a preliminary injunction requiring defendants to "continue to make [IR] tablets available on the same terms and conditions applicable since July 21, 2013" and to inform consumers about the continued availability of Namenda IR. (SA137.)

3. The district court and this Court deny defendants' request to stay the preliminary injunction

Defendants moved in the district court and then this Court to stay the injunction, claiming for the first time that they "no longer make[]" Namenda IR and that having to "restart" production and distribution would cause them irreparable injury. Defs.' CA2 Stay Mem. 11. They also asserted that being unable to force a switch from IR to XR before generic IR becomes available in July 2015 would irreparably harm them. This Court denied their request for a stay but granted their request for expedited briefing of their preliminary injunction appeal.

STANDARD OF REVIEW AND SUMMARY OF ARGUMENT

This Court reviews the grant of a preliminary injunction for abuse of discretion, *see Faiveley Transp. Malmo AB v. Wabtec Corp.*, 559 F.3d 110, 116 (2d Cir. 2009), and sustains a district court's judgment that a preliminary injunction was warranted unless the decision "cannot be located within the range of permissible decisions," or was based on a clearly erroneous assessment of the factual evidence, or an error of law, *In re Sims*, 534 F.3d 117, 132 (2d Cir. 2008) (quotation marks omitted).

The preliminary injunction that the district court entered here was an entirely proper exercise of its discretion. The court's fact-finding rested primarily on defendants' own documents and statements, and its legal analysis and chosen remedies are well-grounded in established antitrust cases and authorities.

As the district court found, defendants' immediate-release (IR) and extended-release (XR) Namenda drugs currently represent 100% of the market for a unique class of Alzheimer's treatments. Exploiting their current monopoly position and certain unique features of the relevant economic and regulatory context, defendants developed a plan to create a shortage of IR in order to force current users onto XR, with the ultimate aim of impeding the competition they will face when generic IR enters the market in July 2015.

Defendants projected that this scheme would succeed because patients forcibly switched to XR now would face substantial transaction costs switching back to the IR formulation when a less expensive generic version became available. It was not an abuse of discretion for the district court to rely on defendants' market projections and admissions of anticompetitive intent when finding that this scheme

could violate the Sherman Act's prohibitions on monopolization and concerted restraints on trade. The abundant direct evidence as to both anticompetitive intent and anticompetitive effects makes this case unusual as a factual matter but straightforward legally.

The record also contains abundant evidence that irreparable harm would result from the consummation of defendants' plan. Defendants predicted that their scheme's disruptive effects would cause [redacted] of current IR users to cease taking their needed medication. The district court did not err in crediting that estimate and finding that it, together with defendants' intended damage to competition and consumer choice, established irreparable harm warranting a preliminary injunction.

In view of these multiple, serious irreparable harms and New York's strong showing of likelihood of success on the merits, the district court properly concluded that the balance of equities favored entering a preliminary injunction to preserve the status quo. In making that determination, the district court was entitled to rely on defendants' representations as to the status quo of Namenda IR's availability. Although defendants now assail the injunction on the ground that it forces them to manufacture a product they have allegedly ceased

producing, they repeatedly represented to the district court that they were currently satisfying market demand for 500,000 daily users of Namenda IR and could continue to do so in the future.

Defendants mistakenly suggest that their possession of a patent immunizes their conduct from antitrust scrutiny. It is well settled that antitrust liability may be imposed on a patentee for conduct that seeks to extend its monopoly beyond the scope or term of its patent.

ARGUMENT

POINT I

NEW YORK IS LIKELY TO SUCCEED ON THE MERITS

Defendants' scheme to force Alzheimer's patients to switch from Namenda IR to Namenda XR to impede generic competition likely violates the Sherman Act's prohibition on agreements in restraint of trade, 15 U.S.C. § 1, and its prohibitions on monopolization and attempted monopolization, *id.* § 2. The factual record is replete with contemporaneous acknowledgements by defendants' executives that the *sole* reason for the forced switch is to thwart generic competition and thereby maintain defendants' monopoly in the relevant market. The district court correctly found that the harm to competition that

defendants' conduct will cause, and the lack of any procompetitive business purpose, make out a core § 2 claim. These same factors, combined with defendants' facially restrictive distribution agreement with Foundation Care, make out a core § 1 claim. The wealth of direct evidence as to anticompetitive intent and effects makes this case factually unusual but legally straightforward.

Defendants seek to avoid these conclusions with strikingly overbroad claims that their patents grant them immunity from antitrust scrutiny. That is not the law, as the district court correctly found. Nor are defendants correct that withdrawals of a patented product can never violate the Sherman Act. Finally, defendants' argument that the introduction of a new product should be immune from antitrust scrutiny is simply irrelevant. New York challenges defendants' anticompetitive actions to restrict Namenda IR availability, not defendants' introduction of Namenda XR.

A. Defendants' Conduct Likely Violates § 2 of the Sherman Act.

The elements of a § 2 monopolization claim are "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966); *accord Trinko*, 540 U.S. at 407. A claim for attempted monopolization requires "(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). New York's showing amply satisfies the elements of both its monopolization and attempted monopolization claims.

Defendants do not dispute the district court's factual finding that the relevant product and geographic market here is the market for memantine in the United States (SA103-107), and that their Namenda products currently represent 100% of that market (SA17, 108-110). Indeed, defendants expressly relied on these facts when formulating their forced-switch scheme, predicting that discontinuing IR was likely

to force patients onto XR because "'there are no alternatives' to Namenda." (SA47 (citing PX15).)

Where the existence of a monopoly has been established, the next question is whether the defendant willfully sought to maintain monopoly power through exclusionary or "anticompetitive conduct"—that is, "conduct without a legitimate business purpose that makes sense only because it eliminates competition." *In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 133 (2d Cir. 2014) (quotation marks omitted); *see also Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 482-83 (1992); *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 605 n.32 (1985).

Courts have developed specific tests for types of anticompetitive conduct that arise frequently, such as tie-ins, predatory pricing, exclusive dealing, termination of distributorships, and efforts to deceive regulators. *See Novell, Inc. v. Microsoft Corp.*, 731 F.3d 1064, 1072 (10th Cir. 2013). But "anticompetitive conduct comes in too many forms and shapes to permit a comprehensive taxonomy." *Id.* Less common conduct alleged to violate § 2 is generally evaluated by (1) asking whether exclusionary actions occurred and whether they had an anticompetitive

effect, and (2) balancing that harm to competition against any non-pretextual, procompetitive business justifications offered by the defendant. *See Trans Sport, Inc. v. Starter Sportswear, Inc.*, 964 F.2d 186, 188-89 (2d Cir. 1992).[4] Although the primary focus is on the conduct and its effects, *see Trinko*, 540 U.S. at 407, intent can help illuminate "whether the challenged conduct is fairly characterized as 'exclusionary' or 'anticompetitive,'" *Aspen Skiing,* 472 U.S. at 602; *Grinnell*, 384 U.S. at 571; *Geneva Pharm. Tech. Corp. v. Barr Labs.*, 386 F.3d 485, 504 (2d Cir. 2004).[5]

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[4] *See also Eastman Kodak*, 504 U.S. at 483; *United States v. Microsoft Corp.*, 253 F.3d 34, 58-59 (D.C. Cir. 2001) (en banc) (per curiam); *United States v. Dentsply Int'l Inc.*, 399 F.3d 181, 196-97 (3d Cir. 2005).

[5] *See Chicago Bd. of Trade, Inc. v. United States*, 246 U.S. 231, 238 (1918); *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 288 (2d Cir. 1978); *see also* Herbert Hovenkamp, *Federal Antitrust Policy: The Law of Competition and Its Practice* 300 (4th ed. 2011) ("considerations of subjective intent are sometimes essential" to determining if ambiguous conduct was exclusionary under § 2).

1. The intended purpose and likely effect of defendants' conduct is to create transaction costs that discourage patients from using lower-cost generic IR.

Defendants' effort to restrict supply and distribution of their product in order to impede competition is paradigmatic exclusionary conduct. (SA113-119.) As the district court found, the sole purpose and likely effect of defendants' conduct was to forcibly switch as many patients as possible from Namenda IR to Namenda XR, in order to create transaction costs that would discourage patients from using lower-cost generic IR when it became available in July 2015. (SA38-39, 71-75, 117-120.) Defendants' CEO has stated that the purpose of the forced switch was to create "barriers or obstacles" to generic competition. (JA132; *see also* SA51, 72, 120.)

Price competition for pharmaceutical products is inhibited by the fact that switching to a less-expensive prescription drug generally requires physician permission. State drug substitution laws reduce the transaction costs to price competition among therapeutically equivalent drugs at the point of sale, by permitting (or requiring) a pharmacist to dispense the least expensive equivalent for a prescribed drug without

the need for physician intervention. *See, e.g.*, N.Y. Education Law § 6816-a(1).

Defendants sought to ensure that price competition with their Namenda drugs would not take place even after generic IR becomes available, by trying to switch all current IR users to Namenda XR. Because generic IR will not be AB-rated to Namenda XR, consumers and healthcare payors seeking a lower-cost memantine Alzheimer's therapy will not be in a position to benefit from the reduction in transaction costs provided by state drug substitution laws. Instead, each and every switch by a patient to generic IR will require a physician's intervention. (SA24-26, 77.)

As defendants recognized (SA72), the need for physician intervention to switch a patient from XR to IR will particularly hinder price competition because the relevant regulatory context makes it inefficient and uneconomical for generic manufacturers to market in the same manner as a brand-name manufacturer would. Although physicians select the drug to be prescribed, pharmacists select which equivalent of that drug to substitute. Thus, as the district court found: "'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.'" (SA78-80 (quoting JA865 [328:5-11] (Mylan executive).) Moreover, requiring generic manufacturers to engage in costly marketing and physician detailing would result in significantly higher prices for generic drugs, thus undermining the regulatory framework's aim of furthering price competition.

Defendants' plan also relies on the creation of another type of transaction cost. The burdens associated with switching drugs are especially high for Alzheimer's patients. Alzheimer's patients "are extremely sensitive to changes in routine" (SA89), and their doctors (and health plans) are exceptionally reluctant to switch their medications without a strong medical reason to do so (SA56, 87, 90-91). Even small changes in an Alzheimer's patient's medication can raise the risk of an adverse event for the patient. (SA92.) A patient who has been forcibly switched from Namenda IR to Namenda XR is therefore unlikely to undertake a second switch back when generic IR becomes

available. (SA83, 89 (citing JA179).) By contrast, if Namenda IR remains available until generic entry, current users and their doctors will be in a position to freely choose between the cost savings of generic IR and any potential convenience associated with switching to XR's once-daily formulation.

As the district court found, defendants studied all of these phenomena when developing their forced-switch plan and defendants' executives expressly cited them when explaining in internal and external communications—including to investors—why the forced switch scheme would be effective. (SA72 (citing JA840 [223:25-224:4], 155.)

Defendants had at first attempted to encourage Namenda IR users to switch to XR through an "aggressive marketing and pricing" campaign. (SA38-39, 56-57.) But they failed to achieve sufficient switching through these "soft" tactics because physicians and caregivers would not disrupt patient routines without a strong medical reason (SA87; *see also* SA54-56, 90, 92), and the benefits of XR over IR are marginal to nonexistent for many Alzheimer's patients, who often already take other pills throughout the day (SA54-56).

Defendants accordingly decided to force a "hard switch" (SA51, 120) to Namenda XR by taking action to severely limit patient access to Namenda IR. Defendants at first considered discontinuing IR entirely, but ultimately determined that they could achieve their desired result by continuing to make IR available under restrictive terms and conditions that would prevent most patients from accessing it. (SA49-50, 64-67.) Defendants therefore executed a contract to make Namenda IR available to patients only through a single mail-order pharmacy (Foundation Care) under a standard of medical necessity. (SA65-67.) See *supra* 15-16. Defendants knew that few patients would be able to obtain IR through the Foundation Care arrangement because, among other things, it would be difficult for any doctor to certify that a patient needed to take IR specifically. The active ingredient in IR and XR is the same and the drugs have "the same therapeutic effect." (SA17, 39, 54.)

Defendants predicted that in the face of transaction costs and the medical necessity requirement, less than 3% of current Namenda IR users would be able to continue taking the drug. (SA70.) As defendants' CEO testified, the "medical necessity" requirement was adopted for "competitive" rather than "medical" reasons. (SA68.) The district court

thus correctly found it to be an "artificial roadblock[] to patient access to Namenda IR" that defendants "designed . . . to protect their profits." (SA68.)

Defendants also took other affirmative steps to block patient access to Namenda IR. In February 2014, they asked the Centers for Medicare and Medicaid Services to remove Namenda IR from the reference list that health plans serving Medicare patients consult when determining which drugs to include in their formularies. (SA53 (citing JA162-165).)

Defendants knew that restricting access to Namenda IR offered no benefits for patients, physicians, or caregivers. In fact, it would hurt some patients tremendously. [redacted] that constraining patient access to IR would be so disruptive that as many as [redacted] of current IR users would "cease memantine treatment entirely." (SA95 (citing JA70, 123, 36).) Where no consumer benefit can be shown for conduct (SA71), a finding of anticompetitive exclusion is straightforward. *See* 3 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 651a, at 97 (3d ed. 2008).

Defendants' conduct "makes sense only because it eliminates competition." *Adderall*, 754 F.3d at 133 (quotation marks omitted). The district court found that defendants could not explain how any purported operational savings from limiting IR distribution [redacted]" (SA75.) The court also observed that defendants' contemporaneous documents and statements did not identify cost-savings as a motive for the forced switch. (SA75.)

As the district court found, [redacted] that they would not have had absent a forced switch. (SA73-74.) That increased revenue does not reflect improvements in quality, efficiency, or other factors making defendants' products more attractive. Instead, it reflects the increased sales that defendants can make if they do not face price competition.

It is well-settled that a monopolist's willingness to sacrifice short-term profits to stave off long-term competition can be probative of

anticompetitive purpose and effect. *Trinko*, 540 U.S. at 409; *Aspen Skiing*, 472 U.S. at 610-11. And conduct such as that at issue here, which was undertaken "plainly and explicitly for [the] single purpose" of maintaining a monopoly, is exclusionary under § 2. *Grinnell*, 384 U.S. at 571.

2. Defendants' conduct is anticompetitive and actionable under the antitrust laws.

Defendants cannot dispute that price competition with their Namenda drugs will be dramatically impeded if defendants' "forced switch" scheme is permitted to proceed. That was the very motivation for the scheme. (SA51 (citing JA155); SA71-73 (citing inter alia JA841 [228:13-15], 139-157, 840 [223:25-224:4]).)

Defendants projected that, absent a forced switch, generic IR would be able to compete so effectively on the basis of price with defendants' Namenda drugs that it would account for [redacted] of all prescriptions in the relevant market in 2016, leaving defendants with only a [redacted] market share. (SA84.) But they predicted that if they could implement a forced switch from IR to XR prior to generic entry, generic competition would be so impeded that generics would fill only [redacted] of

prescriptions, leaving brand-name Namenda (IR and XR together) with an [redacted] market share. (SA84 (citing JA967).) As the district court found, "[p]ermanent damage to competition in the memantine market" will result from defendants' planned forced switch. (SA131.)

To demonstrate an anticompetitive effect for purposes of a § 2 claim, it is not necessary that all competition be entirely foreclosed. Rather, the test is "whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." *Dentsply*, 399 F.3d at 191. Thus, a § 2 claim can be proved based on market foreclosure that is "less than the roughly 40% or 50% share usually required in order to establish a § 1 violation." *Microsoft*, 253 F.3d at 70. New York has clearly made that showing here.

Defendants assert (Final Br. for Defs.-Appellants ("Br.") 40-41) that product withdrawal can never be a basis for antitrust liability, regardless of facts, economic and regulatory context, and intent. That claim is untenable. In particular, defendants ignore the importance of consumer choice to the antitrust inquiry when they incorrectly assert (Br. 45) that, if a soft switch—using marketing, advertising, and other persuasive techniques to convince Namenda IR users to switch to XR—

"is not exclusionary, a fortiori a so-called 'hard switch' with the same effect is not either." The distinction between the soft and hard switch—between free consumer choice versus coercion and artificial limits on choice—is precisely the line that antitrust laws are designed to police.

This Court has suggested that § 2 may be violated where a monopolist's withdrawal of a product has the purpose and effect of coercing customer choice and impeding competition. *See Berkey Photo*, 603 F.2d at 287 & n.39; *see also Glen Holly Entm't v. Tektronix Inc.*, 352 F.3d 367, 374 (9th Cir. 2003); *Microsoft*, 253 F.3d at 64. And district courts and leading commentators have endorsed application of that theory to pharmaceutical manufacturers who attempt to defeat generic competition by forcing a switch to a reformulation with medically equivalent effects but a later patent expiration. *See In re Suboxone Antitrust Litig.*, MDL No. 2445, 2014 WL 6792663, at *12 (E.D. Pa. Dec. 3, 2014); *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 420-24 (D. Del. 2006); 1 Herbert Hovenkamp, Mark D. Janis, Mark A. Lemley & Christopher R. Leslie, *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* § 15.3c1, at 15-77–15-80 (2d ed. Supps. 2013 & 2014); *see also Walgreen Co. v.*

AstraZeneca Pharm., L.P., 534 F. Supp. 2d 146, 151 (D.D.C. 2008) (no § 2 violation by manufacturer that introduced a reformulation with nearly identical clinical effects just prior to expiration of its original drug's patent because manufacturer left prior version of drug on the market and did not seek to "eliminate[] any consumer choices").

The FTC has similarly recognized that refusal to sell a drug can harm competition. The FTC recently opined that a § 2 claim could be stated by allegations that a manufacturer seeking to impede generic competition reformulated a drug prior to generic entry and then "discontinu[ed] the sale of the prior version." FTC *Mylan* Amicus Br., *supra*, at 14. And in a 2005 suit, the FTC sought a preliminary injunction to prevent a manufacturer from withdrawing a tablet version of the drug Ovcon after introducing a chewable version. The FTC noted that the manufacturer was attempting to convert consumers to the new product prior to generic entry in order to avoid competition, and that such a strategy would indeed have thwarted competition. J. Thomas Rosch, FTC Comm'r, *The Antitrust/Intellectual Property Interface: Remarks Before World Generic Medicine Conference* 15 (Nov. 17, 2010) (describing events in *FTC v. Warner Chilcott Holdings Co. III,* 05-cv-

2179 (D.D.C.)). The FTC accordingly sued for a preliminary injunction requiring the manufacturer "to continue to make tablet Ovcon." *Id.* Rather than litigate the issue, the manufacturer agreed to allow a generic manufacturer to immediately market the tablet version. *Id.*

Defendants seek to avoid the implications of their conduct by characterizing price competition through lower-cost drug substitution at the pharmacy as illegitimate "free riding" by generic manufacturers. Br. 5, 19, 40-41, 43, 52. But as the FTC has explained, "[w]hatever 'free-riding' occurs is the intended result of the legislative framework of the Hatch-Waxman Act and the state substitution laws." FTC *Mylan* Amicus Br., *supra*, at 7; *see also Actavis*, 133 S. Ct. at 2228 (generic "piggy-back[ing]" on brand-name drugs "further[s] drug competition" intended by Congress). Drug substitution laws lower the transaction costs that interfere with price competition at the point of sale. What defendants term free-riding is thus what Congress, the Supreme Court, the FTC, and the States have determined is desirable—indeed, indispensable—to competition in the relevant market.

Defendants' complaint is particularly inapt because, as the district court noted, they have for a decade reaped the benefits of the

exclusivities conferred on their Namenda drugs by the applicable statutory framework, securing many billions of dollars in sales at supracompetitive, monopoly prices, as well as a five-year patent extension under Hatch-Waxman. (SA34, 95-96 (citing JA875-876 [417:17-418:22]).) Having received the benefits of the legal framework's compromise between innovation and competition, they cannot now be heard to complain that they must face the precise forms of competition that framework envisions.

3. Defendants lack any non-pretextual, procompetitive justification for their conduct.

If there were any non-pretexual, efficiency-related, procompetitive justification for defendants' exclusionary conduct, it would be weighed against the anticompetitive effects of the conduct to determine whether § 2 liability is appropriate. See *supra* 25-26. But here the district court found, based on internal company documents and contemporaneous statements by defendants' executives, that impeding generic competition was defendants' sole motive when they devised the forced switch. (SA71 (citing JA841 [228:13-15]); *see also* SA48-49, 51, 72-75, 120 (citing JA30, 139-157, 855 [286:18-287:9]).)

Indeed, this lack of any legitimate business purpose for defendants' product withdrawal is one of the characteristics that set this case apart from other product withdrawals that may take place in this and other industries. It may make sense for a manufacturer to discontinue old models of a product when the lack of demand or high burden of support make continuing to support that model uneconomical. But here, defendants' conduct made business sense only because it impeded competition. They did not demonstrate *any* legitimate, procompetitive reason for their withdrawal of Namenda IR, and in fact repeatedly acknowledged that the sole purpose of their conduct was to impede generic competition.

B. Defendants' Facially Restrictive Distribution Agreement with Foundation Care Likely Violates § 1 of the Sherman Act.

"To prove a § 1 violation, a plaintiff must demonstrate: (1) a combination or some form of concerted action between at least two legally distinct economic entities that (2) unreasonably restrains trade." *Geneva*, 386 F.3d at 506. The rule of reason "weighs all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition."

Cont'l T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36, 49 (1977); *see also Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 885-86 (2007) (§ 1 claims involving conduct not deemed per se illegal are evaluated under the rule of reason).

There can be no dispute that defendants' express agreement with Foundation Care satisfies the first element for § 1 liability. (SA124-125.) Thus the only question is whether the district court correctly determined that the agreement was an unreasonable restraint because it would have the effect of "denying current memantine patients access [to] the IR tablets and driving up the average price of memantine following generic entry," without any offsetting procompetitive justification. (SA126.) Defendants cannot show that the court's factual findings are clearly erroneous.

The arrangement makes Foundation Care, a mail-order-only pharmacy, the sole distributor of Namenda IR nationwide and requires it to obtain a medical necessity certification from a patient's physician (in addition to an ordinary prescription) before it can dispense IR. (SA68 (citing JA903 [549:2-10]).) The transaction costs to patients and physicians are clear. (SA67-68.) Defendants themselves projected that

less than 3% of the patients currently taking Namenda IR would have access to IR under the Foundation Care arrangement. (SA67.) That dramatic reduction in patient access was intentional, as was the increased burden the scheme imposes on physicians and patients. Based partly on testimony from defendants' CEO, the district court found that defendants "designed those roadblocks" solely to restrict patient access and thus "to protect their profits." (SA68 (citing JA845-846 [244:23-245:2]).)

The core purpose of rule of reason analysis is to distinguish "between restraints with anticompetitive effect that are harmful to the consumer and restraints stimulating competition that are in the consumer's best interest." *Leegin*, 551 U.S. at 886. Here, there is no consumer welfare or procompetitive justification to be weighed in the rule of reason calculus. Consumers self-evidently do not benefit from increased prices combined with reduced choice, and the sole purpose for the limited distribution plan was to coerce patients into switching medicines as a means of impeding generic competition. The evidence shows a likely violation of § 1.

Defendants contend that no antitrust liability can lie where a firm limits access to one of its own products for the benefit of another of its products (Br. 41, 50), but that misstates the law. The Supreme Court has found that agreements intended to suppress one product in favor of another *can* violate the antitrust laws where the effect is to reduce competition. *See Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of the Univ. of Oklahoma*, 468 U.S. 85, 106-07, 115-17 (1984). In *NCAA*, the NCAA sought to restrict consumer access to one of its products (televised football games) to protect another product (tickets to live football games) it deemed "insufficiently attractive to consumers." *Id.* at 117. The Supreme Court noted that was "inconsistent with the basic policy of the Sherman Act." *Id.* Similarly, the D.C. Circuit has affirmed an FTC decision that the antitrust laws were violated by an agreement under which two joint-venture partners suppressed sales of certain products (old "Three Tenors" albums) in order to drive sales to a new product (a new "Three Tenors" album). *Polygram Holding, Inc. v. FTC*, 416 F.3d 29, 31, 37-38 (D.C. Cir. 2005).

Defendants argue (Br. 55) that only "actual" as opposed to "predicted" restraints on trade can violate § 1, unless the conduct being

challenged is *per se* anticompetitive. But the remedial provision of the statute expressly authorizes injunctions based on "a significant threat of injury from an impending violation of the antitrust laws," *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 129-33 (1969) (glossing 15 U.S.C. § 26's "threatened loss or damage" language), whether or not a *per se* violation has been alleged.

C. Defendants' Patents Do Not Insulate Them from Antitrust Liability.

The abundance of direct evidence of anticompetitive purpose and effects makes this case distinctive as a factual matter. But the § 1 and § 2 analysis applicable to such conduct is straightforward. See *supra* Point I.A and B.

Defendants seek to avoid that analysis through extraordinarily overbroad claims about the supposed antitrust immunity that their patent for Namenda IR gives them. Br. 22, 32, 36, 38. To be sure, a valid patent may create a legal monopoly for a time. But contrary to defendants' claims (Br. 4, 32), a patentee is not automatically immune from antitrust scrutiny simply because its challenged conduct is within the scope of what patent law would allow. The Supreme Court recently

reaffirmed this point, noting that the fact that alleged "anticompetitive effects fall within the scope of the exclusionary potential of the patent" does not "immunize" an anticompetitive "agreement from antitrust attack." *Actavis,* 133 S. Ct. at 2230 (quotation marks omitted). A court cannot "answer the antitrust question" by simply looking at "what the holder of a valid patent could do" under the patent law. *Id*. at 2230-31.

Actavis did not make new law in this regard. As the Court has observed many times, patent rights "do not give any more than other rights a universal license against positive prohibitions," such as those contained in the Sherman Act. *Hartford-Empire Co. v. United States*, 323 U.S. 386, 406 (1945) (quotation marks omitted); *see also United States v. Nat'l Lead Co.*, 332 U.S. 319, 334-35 (1947) (noting court's obligation to "give effect" to both patent and antitrust laws).

Based on the Supreme Court's cases, other courts and leading commentators have rejected the argument that "antitrust law does not or should not constrain the scope of intellectual property rights," instead recognizing that "[i]t is possible to use an intellectual property right to obtain unwarranted market power or interfere with competition in a variety of ways, and antitrust law properly addresses conduct of

that sort." 1 Hovenkamp et al., *IP and Antitrust*, *supra*, § 1.3b, at 1-14–1-15. Indeed, the same argument that defendants make here about "unfettered," "absolute" and "unqualified" intellectual property rights (Br. 32, 36, 38) has been expressly rejected by both the Federal Circuit and the D.C. Circuit. The Federal Circuit has observed that "[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). And the D.C. Circuit has noted that a patentee's claim of "an absolute and unfettered right to use its intellectual property as it wishes . . . is no more correct than the proposition that use of one's personal property, such as a baseball bat, cannot give rise to tort liability." *Microsoft,* 253 F.3d at 63.

Defendants quote out of context this Court's decision in *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981), to suggest that any conduct that a holder of a valid patent may perform under the patent laws *ipso facto* cannot violate the antitrust laws. Br. 35. That contention is plainly foreclosed by the Supreme Court's cases and in any event mischaracterizes *SCM*. In *SCM*, the Court noted and reserved the question of whether antitrust liability could arise from a patent holder's

exercise of a certain legal prerogative—there, a refusal to license pooled patents. 645 F.2d at 1206 n.10.

1. Defendants' patent rights are not impaired by the preliminary injunction.

Defendants contend (Br. 32) that the preliminary injunction "obliterates" their patent rights. That is incorrect. The injunction seeks to prevent defendants from manipulating the supply of their product in order to extend their monopoly past Namenda IR's exclusivity period. *See generally* 1 Hovenkamp et al., *IP and Antitrust*, *supra*, § 1.3b, at 1-15 (stating that antitrust law is "concerned not with the legitimate exercise of an intellectual property right granted by the government, but with efforts to *expand* the scope of that right, either to new products, or temporally, or by conditioning access to the right on restrictions of competition" (emphasis in original)). The injunction preserves defendants' legal exclusivity over Namenda IR manufacturing and ability to charge monopoly prices until July 2015.[6]

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[6] In any event, defendants' patent rights are irrelevant after April 2015, because their Namenda IR patent will have expired and they have only non-patent regulatory exclusivity after that date.

2. Conduct that is not patent misuse can nevertheless violate the antitrust laws.

Defendants' reliance on 35 U.S.C. § 271(d)(4) conflates the question of antitrust liability with the separate and distinct question of patent misuse. Section 271(d)(4) provides that a patent holder shall not be denied relief for infringement or contributory infringement simply because he has "refused to license or use any rights to the patent." The legislative history of the statute rejects the view advanced here by defendants (Br. 37)—that § 271(d)(4) requires antitrust law to defer entirely when conduct is authorized by patent laws. Congress declined to enact a proposed version of the statute that would have aligned patent misuse doctrine entirely with antitrust doctrine, and the bill ultimately codified as § 271(d)(4) addresses only patent misuse. 134 Cong. Rec. H10647-48 (daily ed. Oct. 20, 1988) (statement of primary sponsor Rep. Kastenmeier); *see also Patent Licensing Reform Act of 1988; Hearing on H.R. 4086 Before Subcomm. on Courts, Civil Liberties, and Admin. of Justice of the H. Comm. on the Judiciary,* 100th Cong. 12 (1988) (statement of Charles F. Rule, Assistant Attorney General, DOJ, Antitrust Div.) (noting that although some anticompetitive conduct "may escape misuse condemnation" as a result

of § 271(d)(4), "there would still be the antitrust laws to condemn such practices"); Br. for the United States as Amicus Curiae at 12 n.6, *CSU, LLC v. Xerox Corp.*, 531 U.S. 1143 (2001) (rejecting the argument that § 271(d)(4) confers antitrust immunity); U.S. DOJ & FTC, *Antitrust Enforcement and Intellectual Property Rights* 25-27 (2007) (same).

D. New York Neither Challenges the Introduction of a New Product Nor Seeks to Impose a Duty to Assist Rival Firms.

Defendants repeatedly mischaracterize the issues in this case. For example, they describe New York's suit as a challenge to the introduction of a new product. Br. 22-23, 51-54. It is not. New York's antitrust claims do not rest on any challenge to the merits of Namenda XR or assertion that defendants' introduction of XR was unlawful. Rather, New York challenges only defendants' efforts to severely limit patient access to Namenda IR in an attempt to eliminate consumer choice and impede future competition. In other words, the question presented is not whether defendants had a good reason for introducing Namenda XR, but whether they had a legitimate reason for their actions with respect to IR.

Defendants also mischaracterize this case as involving a supposed duty to assist rival firms. Br. 44. That too is incorrect. This case is not about "a refusal to cooperate with rivals." *Trinko*, 540 U.S. at 409. Instead, it is about conduct directed at consumers with the aim of impeding competition. New York does not seek to bolster the position of any particular competitor.[7] But even if this Court framed the case in this way New York's showing satisfies the test set forth in *Trinko*. Defendants' conduct here plainly involves "'[t]he unilateral termination of a voluntary (and thus presumably profitable) course of dealing'"—in this case their profitable sales of Namenda IR to their patients—"'suggest[ing] a willingness to forsake short-term profits to achieve an anticompetitive end.'" *Adderall*, 754 F.3d at 135 (quoting *Trinko*, 540 U.S. at 409). See *supra* 32-34.

[7] Defendants claim (Br. 44) that New York's theory requires them to help its competitors "through advertising or other indirect assistance." To the contrary, New York has never challenged defendants' decision (SA76), to cease advertising and marketing Namenda IR, and nothing in the preliminary injunction requires defendants to advertise anything.

POINT II

THE DISTRICT COURT DID NOT ABUSE ITS DISCRETION IN DETERMINING THAT THE FACTS AND EQUITIES STRONGLY FAVORED ENTRY OF A PRELIMINARY INJUNCTION

Section 16 of the Clayton Act entitles "[a]ny person," including a State, to obtain injunctive relief "against threatened loss or damage by a violation of the antitrust laws" under the same conditions and principles a court of equity would apply when considering injunctive relief in any other type of case. *California v. Am. Stores Co.*, 495 U.S. 271, 280-81 (1990) (quoting 15 U.S.C. § 26). Under these traditional rules, the irreparable harm to be found by the court "must be . . . imminent, not remote or speculative, and the alleged injury must be one incapable of being fully remedied by monetary damages." *Reuters Ltd. v. United Press Int'l, Inc.*, 903 F.2d 904, 907 (2d Cir. 1990) (affirming preliminary injunction in antitrust action). Whether this Court applies a preliminary injunction standard requiring "irreparable harm" or instead "extreme or very serious damage," *see Innovative Health Sys., Inc. v. City of White Plains*, 117 F.3d 37, 43 (2d Cir. 1997); *see infra* Point III.C, the facts found by the district court establish that New York's showing is sufficient.

As the district court found, the balancing of hardships and equities strongly favors the injunction. Competition, consumer choice, and the financial and nonfinancial interests of consumers will be irreparably harmed if defendants are able to force a switch before generic entry and before a court can resolve this case on the merits. On the other hand, the court found that no cognizable harm would come to defendants from a temporary injunction. (SA132-133.) Defendants have represented that they will immediately take action to force a switch if the preliminary injunction is lifted (Defs.' CA2 Stay Mem. 19-20), and they have shown no reason why the merits of this action cannot be resolved before generic IR enters the market in July 2015.

A. The District Court Correctly Found That Defendants' Conduct Threatens Irreparable Harm to Consumer Choice, Competition, and Consumers' Financial and Nonfinancial Interests.

To obtain a § 16 injunction the plaintiff "must show a threat of antitrust injury, that is, 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 (2d Cir. 1989) (quoting *Cargill, Inc. v. Monfort of Colo., Inc.*,

479 U.S. 104, 109, 113 (1986) (quotation marks omitted)). "[Antitrust] law's mission is to preserve, improve, and reinforce the powerful economic mechanisms that compel businesses to respond to consumers." Robert Bork, *The Antitrust Paradox* 91 (1978). "The primary goal of antitrust law is to maximize consumer welfare by promoting competition among firms." *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 308 (3d Cir. 2007).

Thus, "threatened harm to . . . consumers" may be enjoined, *Am. Stores*, 495 U.S. at 282, as may actions that will "reduce competition in the relevant market," *Consol. Gold Fields*, 871 F.2d at 257-58. The essence of defendants' scheme here is to make a well-established product unavailable solely in order to force current users to switch to a new product that they do not prefer, and thereby to prevent price competition from lower-cost equivalents to defendants' original product.

1. The forced switch irreparably harms consumer choice and competition.

Defendants' expert in the district court proceedings estimated that approximately [redacted] of physicians would prefer to keep their patients on IR, if given the choice. (SA94; *see also* (SA93 (citing JA497, 467, 476)

(defendants' internal surveys "show that many physicians, caregivers, and pharmacists are concerned about the potential harm to patients from the forced switch").) And defendants' internal projections show that in the absence of conduct to force a switch, defendants "would only be able to switch [redacted] of Namenda IR prescriptions to Namenda XR prior to generic entry." (SA82 (citing JA839 [217:25-218:5]); *see also* SA81.) Namenda XR has been on the market since mid-2013, with extensive marketing and sales force support. (SA38-39.) Consumers who prefer XR over IR have had abundant opportunities to switch—and, if not, could still switch under the preliminary injunction.

Thus, there is more than ample support for the district court's factual finding that defendants' conduct (but not the preliminary injunction) will deprive some large number of Alzheimer's patients of a drug that they and their physicians prefer them to take. (*See also* SA57.) There is also no dispute, because defendants' CEO repeatedly stated it, that defendants' withdrawal strategy aimed to create transaction costs that would impede price competition by generic IR. See *supra* 27, 29-31, 41-42. These strong negative impacts on consumer choice are classic antitrust injuries. And there can be no dispute that

this type of injury is irreparable in the sense of being irremediable by money damages alone.

Defendants assert that these harms will be cured when generic IR becomes available in July 2015. Br. 42. But this ignores the projections of permanent damage to competition and consumer choice that defendants developed and indeed relied upon when formulating their forced-switch scheme. Defendants predicted that because of unique characteristics of the pharmaceutical market, and because doctors are especially reluctant to disrupt the medical routines of Alzheimer's patients, only 5-30% of the patients who are forcibly switched to Namenda XR will ultimately switch back to IR, even after lower-cost generics are available. (SA83 (citing JA178-179); see also *supra* 29-30. Indeed, the CEO of Actavis identified the difficulties of a "reverse-commute back" to generic IR as a reason why defendants' forced switch was likely to be successful. (SA51 (citing JA155); SA73 (citing JA855 [286:18-287:9]); SA91.)

Defendants predicted that without a forced switch, in 2016 their Namenda products would have a [redacted] share of the relevant market and generic drugs would have [redacted]. (SA84-85 (citing JA967).) But they

predicted that with the forced switch, they could limit generic competition sufficiently to capture [redacted] of the relevant market in that year. (SA84-85.) Defendants have not shown—nor can they—that the district court's reliance on their own projections was in any way erroneous, let alone clearly so.

2. The additional irreparable harms to consumers and the public.

The district court found that at least two additional kinds of irreparable injury would result from defendants' conduct, if it were not enjoined. Those harms are (1) financial harms that cannot be fully or easily recouped, and (2) nonfinancial harms to consumers and to the public. Both kinds of harm constitute cognizable antitrust injury in that they flow from harms to consumer choice and competition that defendants specifically anticipated and sought.

a. Financial harms to consumers.

Based on defendants' own data, the district court found that defendants' exclusion of lower-cost competitors from the market will result in patients paying almost $300 million more for memantine Alzheimer's therapy and health plans paying nearly [redacted] extra.

(SA132; *see also* SA90 (citing JA680-683).) Defendants do not dispute these numbers, but instead contend that "[b]y definition, quantifiable harm is not irreparable harm." Br. 27. That is not so.

Defendants' position ultimately seems to be that "antitrust law only remedies economic loss," and "monetary loss" by definition may be remedied with damages. Br. 2-3. But Congress has a different view, having decided to authorize injunctions "against *threatened* loss or damage by a violation of the antitrust laws." 15 U.S.C. § 26 (emphasis added). That congressional judgment recognizes that damages are not an adequate remedy for the injury inflicted by antitrust violations. For example, parties that the district court found would be financially injured—patients and health plans—do not directly purchase drugs from defendants and so are barred by the "indirect purchaser" rule from pursuing antitrust damage claims under federal law. *See Ill. Brick Co. v. Illinois*, 431 U.S. 720, 745-46 (1977). *See generally Blue Shield of Va. v. McCready*, 457 U.S. 465, 475 n.11 (1982) ("[T]he task of disentangling multiple damages claims is not lightly to be imposed upon potential antitrust litigants, or upon the judicial system."). And although some States (including New York) permit indirect purchaser damages

actions, many do not.[8] Moreover, even in the States allowing such actions, the challenges of proving which patients have been harmed and by how much would be substantial. The financial harm likely to result from defendants' conduct is thus not easily remedied by an action for damages.

b. Nonfinancial harm to consumers and the public.

The district court found a serious risk of a number of nonfinancial harms that would flow from defendants' conduct if it is not enjoined. There is a risk that disrupted Alzheimer's patients will not take their needed medicine. Specifically, defendants themselves projected that [redacted] of all Namenda patients" would not be able to cope with the forced switch but instead would "cease memantine treatment entirely." (SA95 (citing JA70, 123, 36).)

There is also a risk that the disruption in patients' routines and need to reeducate caregivers will result in mistakes in the administration of medication—for example, a mistaken double dose of

[8] *See, e.g.*, *Abbott Labs., Inc. v. Segura*, 907 S.W.2d 503, 507 (Tex. 1995).

XR by a caregiver accustomed to twice-daily administration. (JA827-828 [132:23-133:22].) Based on physician testimony, the district court recognized that even if switching from IR to XR is safe for most patients, there are still attendant medical risks of "an adverse event," compounded here by the fact that Alzheimer's sufferers "are an especially vulnerable group of patients." (SA92 (citing JA212 [¶24], 810 [58:5-15]); *see also* SA55-56 (citing inter alia JA813 [78:21-79:1]).)[9]

Defendants have two responses. First, they assert that the district court's factfinding about medical harm is clearly erroneous. Second, they assert that, as a matter of law, nonfinancial harms cannot constitute irreparable injury for purposes of the preliminary injunction because "antitrust law only remedies economic harms." Br. 28 (citing *Cargill*, 479 U.S. at 109, 112). Defendants' claim about the facts is plainly incorrect for the reasons set forth above. And their arguments

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[9] Defendants' attacks on New York's physician witness are meritless. Br. 28-29. Dr. Lah's testimony was based on his extensive experience treating Alzheimer's patients and the concerns he has as a treating physician of this patient population. (JA807-808 [46:25-52:8] (setting out Dr. Lah's experience and qualifications).)

about the law fare no better. Each of the nonfinancial harms at issue clearly "flows" from defendants' antitrust violation because it is "inextricably intertwined with the injury the [defendants] sought to inflict". *McCready,* 457 U.S. at 484; *see also Consol. Gold Fields*, 871 F.2d at 259-60 & n.6 (emphasizing *Cargill*'s limited relevance to claims for injunctive relief).

Even if this Court decides that the nonfinancial harms to patients found by the district court are not *directly* cognizable as irreparable injury in an antitrust action, they are still includable *indirectly* as irreparable injury in the preliminary injunction calculus. The nonfinancial, primarily medical harms to patients will of course have financial consequences, and individuals, families, and insurers will bear the financial costs. But none of these indirect costs are likely to be recovered in a private treble damages action.

B. The District Court Correctly Found That Defendants Have Not Shown They Will Suffer Cognizable Harms from the Preliminary Injunction.

The district court found that defendants have not demonstrated they would suffer any cognizable harms from "continuing the same IR distribution strategy they have been using since 2004." (SA133.) Defendants assert (Br. 32-33) they will be injured if they cannot complete their forced-switch scheme far enough in advance of generic entry to make it successful. But that is essentially a complaint about having to compete on the merits to attract consumers. The Supreme Court has repeatedly held that alleged injuries stemming from having to compete in the market are not cognizable in antitrust suits. *See Cargill*, 479 U.S. at 116-17; *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977).

Defendants also now claim (Br. 32-33) that they no longer make Namenda IR and will be injured by having to restart production because this competes with manufacturing and distributing other products. But defendants have always manufactured Namenda IR in batches (JA531 [42:16-18], 1020 [58:20-23]), so the fact that defendants

may need to create another batch of IR is an ordinary occurrence (and has been for over a decade), not an injury or change in the status quo.

In any event, defendants repeatedly represented to the district court that even under their arrangement with Foundation Care they could supply all market demand for Namenda IR. (JA845 [241:21-242:6].) As their stay papers to this Court declare: "There is 'no cap' on how many Namenda IR prescriptions Foundation Care can fill." Defs.' CA2 Stay Mem. 9; *see also* Br. 56 (denying "that Forest agreed with Foundation Care to cap IR sales"). According to the testimony of an Actavis executive, the quantity of IR that defendants supplied to the market through Foundation Care could be readily "adjusted as necessary based on demand, up or down." (JA904 [551:14-552:4].)

As of the date the district court entered the preliminary injunction, defendants represented that they were supplying enough Namenda IR to meet the needs of 500,000 United States patients taking two pills per day. (JA1014 [33:7-13]); Defs' CA2 Stay Mem. 7.) Also, at the time of the district court's ruling, defendants were manufacturing enough Namenda XR for 240,000 other patients. Defs' CA2 Stay Mem. 7. Senior Actavis executives had testified that defendants would have

no problem manufacturing IR while also continuing to sell XR. They stated that defendants could meet all market demand for IR (JA532 [73:2-9], 533 [76:5-7]), and could readily produce IR while making XR (JA533 [75:12-18]). *See also* JA205 [291:3-10] ("[W]e always have been in a position to make whatever . . . they needed" and it is "easier to make" IR than XR); JA202 [168:21-169:16] (IR and XR are made with different equipment).) Defendants also indicated that they were "carefully considering" [redacted]. (JA421 [307:8-10], 424 [350:2-4], 502 [171:25-173:10].)

Defendants cannot now change course and contend that they would be harmed by having to comply with the terms of a preliminary injunction crafted in light of their representations to the district court.

Defendants are also wrong in their contention (Br. 32) that an inability to exercise patent rights in exactly the way they now want should result in an automatic finding of irreparable harm to them. The Supreme Court has explained that a patent holder has no absolute right to enforce its patents in any manner whatsoever. *See eBay Inc. v. MercExchange, L.L.C.,* 547 U.S. 388, 391-94 (2006); *see also id.* at 396

(Kennedy, J., concurring) (patent holder may not enforce its patents in a way that would result in unfair and "exorbitant" costs beyond those intended by the patent laws).

POINT III

THE DISTRICT COURT'S PRELIMINARY INJUNCTION USES TRADITIONAL ANTITRUST REMEDIES TO PRESERVE THE STATUS QUO

A. The Preliminary Injunction Requires Defendants to Maintain the Status Quo with Respect to the Market Availability of Namenda IR.

In the preliminary injunction proceedings, defendants repeatedly represented that they were supplying all market demand for Namenda IR. Prior to this litigation, in June 2014, defendants announced that they would continue to supply IR at least "[i]nto the fall of 2014." (JA189-190; SA63.) When New York brought this suit and request for a preliminary injunction in September 2014, defendants agreed to a standstill under which they would maintain the then-current availability of Namenda IR until the date the district court ruled on the preliminary injunction motion. (JA1014 [33:7-11].) At the time the district court entered the preliminary injunction, defendants represented that they were supplying enough Namenda IR to meet the

daily needs of approximately 500,000 U.S. patients, planned to continue meeting market demand, and anticipated being able to do so without logistical problems. See *supra*, II.B. The district court took these representations at face-value and entered a preliminary injunction that prohibits defendants from changing the availability of Namenda IR pending resolution of the merits.

The first provision of the preliminary injunction requires defendants to make Namenda IR available "on the same terms and conditions as applicable since July 21, 2013 (the date Namenda XR entered the market)." (SA137.) The third provision of the injunction similarly maintains the status quo, by providing that "defendants shall not impose a 'medical necessity' requirement or form for the filling of prescriptions of Namenda IR during the Injunction Term." (SA138.)

The second provision of the preliminary injunction aimed to safeguard the status quo for Namenda IR users by requiring defendants to update past public statements regarding the withdrawal of IR by informing the market that the drug is still available. (SA51-52, 63.) The parties agreed to delay the notices required under this provision while this Court considered defendants' motion to stay the preliminary

injunction, but after the stay motion was denied, defendants complied with the provision.

B. The Preliminary Injunction's Terms Are Proper.

1. The injunction applies a recognized antitrust remedy.

Defendants characterize as "unprecedented" and "dangerous" the preliminary injunction's requirement they continue supplying IR to patients. Br. 60. But that overlooks nearly a century of similar and analogous injunctions approved by the Supreme Court and the federal courts of appeals. Similarly, to the extent the preliminary injunction delays any planned future changes to defendants' business plans, that is no different from every injunction that temporarily restrains a merger in antitrust litigation under the Clayton Act.

Courts have repeatedly upheld antitrust injunctions requiring firms to engage in business transactions they wish to avoid for anticompetitive reasons—including transactions implicating their capital, facilities, intellectual property and personnel. "Mandatory selling on specified terms" is a "recognized antitrust remed[y]." *United States v. Glaxo Group Ltd.*, 410 U.S. 52, 64 (1973); *accord Besser Mfg.*

Co. v. United States, 343 U.S. 444, 447 (1952) (describing "compulsory sale provision of the judgment" as "a recognized remedy"). Thus, approved antitrust injunctions have routinely compelled defendants to sell their products.[10] Injunctions have also required antitrust defendants to restart and continue sales and other business relationships they previously terminated,[11] and to allow uses of their real and other property that they had previously prohibited.[12]

Antitrust injunctions also frequently restrain and control planned future uses of capital, facilities, personnel, or products of antitrust defendants. For instance, the Supreme Court has ordered an antitrust violator to create a new company with sufficient assets and personnel to

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[10] *See also Aspen Skiing*, 472 U.S. at 598 n.23; *Otter Tail Power Co. v. United States*, 410 U.S. 366, 375 (1973); *Grinnell*, 384 U.S. at 578-79.

[11] *See, e.g.*, *Jacobson & Co. v. Armstrong Cork Co.*, 548 F.2d 438, 440 (2d Cir. 1977); *Semmes Motors, Inc. v. Ford Motor Co.*, 429 F.2d 1197, 1201 (2d Cir. 1970) (Friendly, J.); *Interphoto Corp. v. Minolta Corp.*, 417 F.2d 621, 622 (2d Cir. 1969) (per curiam).

[12] *See, e.g., Standard Oil Co. v. United States*, 412 U.S. 924 (1973), *aff'g* 362 F. Supp. 1331, 1333, 1341 (N.D. Cal. 1972); *Silver v. N.Y. Stock Exch.*, 373 U.S. 341, 345-46 (1963); *Int'l Boxing Club of N.Y., Inc. v. United States*, 358 U.S. 242, 255 (1959); *Lorain Journal Co. v. United States*, 342 U.S. 143, 157-59 (1951).

compete against it. *See Utah Public Serv. Comm'n v. El Paso Natural Gas Co.*, 395 U.S. 464, 467-72 (1969). And the Court has approved a district court's preliminary injunction requiring the defendant "to hold and operate separately" the assets and businesses of a competitor it had purchased, pending final adjudication of the merits. *Am. Stores*, 495 U.S. at 276, 295-96.[13]

The presence or absence of patents or other intellectual property does not limit a court's equitable power to order appropriate preliminary or permanent relief. Antitrust injunctions have required the sale or lease of products made with patented components,[14] and compelled the licensing of patents,[15] the distribution of copyrighted

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[13] *See also United States v. E.I. DuPont de Nemours & Co.*, 366 U.S. 316, 329-31 (1961); *Hartford-Empire*, 323 U.S. at 426; *Standard Oil Co. of N.J. v. United States*, 221 U.S. 1, 77-79 (1911).

[14] *See, e.g., Int'l Salt Co. v. United States*, 332 U.S. 392, 398 n.7 (1947); *Hartford-Empire*, 323 U.S. at 419 (same); *Image Tech. Servs., Inc. v. Eastman Kodak Co.*, 125 F.3d 1195, 1226 (9th Cir. 1997).

[15] *See, e.g., Glaxo Group*, 410 U.S. at 62; *United States v. U.S. Gypsum Co.*, 340 U.S. 76, 93-94 (1950); *Nat'l Lead*, 332 U.S. at 335-36, 328 n.4, 348.

materials,[16] and the sale or other distribution of intellectual property.[17] The Supreme Court has confirmed repeatedly that an antitrust decree can, if necessary, "limit the rights normally vested in the owners of patents," rejecting arguments that "mandatory sales and compulsory licensing" requirements "deny . . . an essential ingredient" of the patent holder's "rights under the patent system." *Glaxo Group*, 410 U.S. at 59.

In short, even accepting as true defendants' new assertion that they "no longer make" IR and that restarting production will be disruptive, a century of antitrust injunctions shows that the provisional remedy here is not remotely "unprecedented" and certainly not tantamount to unlawful "commandeer[ing]" of defendants' property (*see* Br. 60).

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[16] *See, e.g.*, *United States v. Loew's Inc.*, 371 U.S. 38, 53-55 (1962), *overruled in part on other grounds by Ill. Tool Works, Inc. v. Indep. Ink, Inc.*, 547 U.S. 28 (2006).

[17] *See, e.g., Nat'l Lead*, 332 U.S. at 353-54, 358; *Reuters*, 903 F.2d at 905, 907.

2. Defendants may comply with the injunction by permitting others to supply the market.

The preliminary injunction does not expressly require defendants to manufacture Namenda IR. If defendants are truly concerned about their ability to simultaneously produce and distribute IR, XR and any other products, they may comply with the preliminary injunction by licensing another firm to produce and sell brand-name IR for them, or by licensing generic IR to enter the market straightaway. Permitting immediate generic entry was the solution adopted by Warner Chilcott when the FTC sought a preliminary injunction requiring it to continue marketing the drug Ovcon. See *supra* 38.

3. The preliminary injunction is not vague.

Defendants' complaints about supposed vagueness in the language of the preliminary injunction lack credibility. Defendants claim that the requirement they continue to make Namenda IR "available on the same terms and conditions applicable since July 21, 2013 (the date Namenda XR entered the market)" is "unintelligible" and confusing, because the terms and conditions upon which they have supplied IR to the market since July 2013 have changed somewhat over time. Br. 57, 58.

The injunction does not fix specific terms and conditions concerning price or other business matters in order to give defendants flexibility to do business in a manner "consistent with what [they] have been doing" with Namenda IR since introducing Namenda XR in mid-2013. (JA1017 [47:20-22].) In that respect, it closely tracks a proposed injunction term submitted by defendants: "The Defendants shall continue to make Namenda IR (immediate-release) tablets available and shall not implement a 'hard switch' . . . ." (JA1005.)

Courts of appeals have approved preliminary injunctions requiring a defendant to continue doing business on "the same terms and conditions" as it previously had.[18] And indeed such language is common in the business world. A standard clause in merger agreements—including multiple agreements entered into by defendants—requires merging firms to carry on their business "in all material respects in the ordinary course of business consistent with

[18] *See, e.g.*, *Bergen Drug Co. v. Parke, Davis & Co.*, 307 F.2d 725, 726-29 (3d Cir. 1962); *Nat'l Screen Serv. Corp. v. Poster Exch., Inc.*, 305 F.2d 647, 649, 650 (5th Cir. 1962).

past practice" during the period between the execution of the merger agreement and the closing of the merger.[19]

4. The nationwide scope of the preliminary injunction is appropriate.

Lastly, defendants contend (Br. 59) that the preliminary injunction is "fatally overbroad" because it is "nationwide" in scope. Defendants never raised this objection to the district court during the hearing on the injunction, and in fact the proposed injunction they submitted to the court contained no state-specific limitations. (JA1005.) Accordingly, that contention is not properly preserved for appeal. *See Aslanidis v. U.S. Lines, Inc.*, 7 F.3d 1067, 1077 (2d Cir. 1993).

In any event, there is nothing inherently wrong with an injunction restraining violations of federal law beyond the boundaries of the State where the federal court sits. *See generally Steele v. Bulova Watch Co.*, 344 U.S. 280, 289 (1952); *City of N.Y. v. Mickalis Pawn Shop, LLC*, 645

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[19] *See* Actavis SEC Filing, at 120, A37, http://www.sec.gov/Archives/edgar/data/1578845/000119312514182855/d686059d424b3.htm (describing Actavis-Forest merger agreement).

F.3d 114, 145 & n.30 (2d Cir. 2011). Nationwide injunctions are common where there is nationwide illegality.[20]

Defendants here do business throughout the United States, and there is no dispute that the relevant geographic market is the entire United States. (SA48.) Moreover, New York pays for drug costs not only for citizens residing in the State, but also for retired state employees living nationwide. And New York residents, for travel or other reasons, may purchase their drugs in other States. A nationwide temporary injunction is clearly appropriate here.

Defendants suggest (Br. 13, 47) that the injunction should be geographically limited to account for differences in state drug substitution laws, asserting that "[u]p to 20" states "may" allow pharmacists to substitute generic IR for XR. Br. 13. But as the record evidence showed, any heterogeneity in state law is largely irrelevant in practice. (JA673 [¶47], 868 [343:11-14], 840 [223:1-4].) Defendants' forced

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[20] *See, e.g.*, *Hartford-Empire*, 323 U.S. at 410; *CBS Broad., Inc. v. EchoStar Commc'ns Corp.*, 450 F.3d 505, 523-27 (11th Cir. 2006); *McLendon v. Cont'l Can Co.*, 908 F.2d 1171, 1182 (3d Cir. 1990).

switch was intended to create transaction costs in all States nationwide—and indeed will do so. See *supra* Points I.A, II.A.

C. A Heightened Legal Standard Does Not Apply Here Because the Preliminary Injunction Maintains the Status Quo and Does Not Provide Complete Relief.

A district court has discretion to issue a preliminary injunction upon a showing of irreparable harm and either a "likelihood of success on the merits" or a "sufficiently serious questions going to the merits" coupled with "a balance of hardships tipping decidedly toward the party requesting the preliminary relief." *UBS Fin. Servs., Inc. v. W. Va. Univ. Hosps., Inc.*, 660 F.3d 643, 648 (2d Cir. 2011) (quotation marks omitted). But a more demanding test applies if the preliminary injunction would alter the status quo or grant the movant complete relief. *Beal v. Stern*, 184 F.3d 117, 122-23 (2d Cir. 1999). The movant must show either "a 'clear' or 'substantial' likelihood of success," *id.* at 123, or demonstrate "that extreme or serious damage would result absent the relief," *Innovative Health*, 117 F.3d at 43.

For the reasons set forth above (Points II.B, III.A), there can be no dispute that the preliminary injunction preserves the status quo. The

only question, therefore, is whether the preliminary injunction provides New York with complete relief. It plainly does not. First, New York's complaint also seeks disgorgement, civil penalties, and damages for the harms that defendants' conduct has already caused. (JA643-644.) Second, defendants have represented that they will immediately take action to force a switch if the preliminary injunction is lifted, and they have shown no reason why a decision on the merits cannot be resolved before generic IR enters the market in July 2015.

Defendants assert (Br. 23-25) that even if the preliminary injunction preserves the status quo and does not grant complete relief, a heightened standard is required because the injunction is "mandatory." The Supreme Court has described the distinction between prohibitory and mandatory injunctions as often "illusory," *Am. Stores*, 495 U.S. at 282-83, and this Court has recognized that it can often be "more semantical than substantive," *Innovative Health,* 117 F.3d at 43 (quotation marks omitted). *See also Jolly v. Coughlin*, 76 F.3d 469, 474 (2d Cir. 1996). For example, "an injunction ordering the union: 'Do not strike,'" could also phrased as "ordering the union: 'Continue working.'" *Int'l Union, United Mine Workers of Am. v. Bagwell*, 512 U.S. 821, 835

(1994). Similarly, an injunction terminating imprisonment could be viewed as mandating a prisoner's release or as prohibiting continued confinement. *Jolly*, 76 F.3d at 474.

To be sure, the second provision of the preliminary injunction requires an affirmative act—notice regarding Namenda IR's continued availability. But this Court has held on multiple occasions that a heightened standard is unnecessary where a preliminary injunction orders an affirmative act merely to maintain or restore the status quo.[21] Other courts have done the same.[22]

In sum, defendants can show no clear error in the district court's factual findings that the preliminary injunction preserves the status quo and does not provide New York with complete relief. (SA100-102.) But even if a heightened standard were to apply, New York's showing easily meets that standard, as set forth in Points I and II above.

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[21] *See, e.g.*, *Reuters*, 903 F.2d at 904-07; *Johnson v. Kay*, 860 F.2d 529, 536, 540-41 (2d Cir. 1988); *Semmes Motors*, 429 F.2d at 1201, 1205-06, 1208; *see also Eng v. Smith*, 849 F.2d 80, 80, 82 (2d Cir. 1988).

[22] *See, e.g.*, *Dominion Video Satellite, Inc., v. EchoStar Satellite Corp.*, 269 F.3d 1149, 1155 (10th Cir. 2001).

CONCLUSION

For the reasons given below, the Court should affirm the district court's preliminary injunction.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a)(7)(C) of the Federal Rules of Appellate Procedure, Oren L. Zeve, an employee in the Office of the Attorney General of the State of New York, hereby certifies that according to the word count feature of the word processing program used to prepare this brief, the brief contains 13,845 words and complies with the type-volume limitations of Rule 32(a)(7)(B).

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