14-4624-cv
State of New York v. Actavis

In the
United States Court of Appeals
For the Second Circuit

———

AUGUST TERM, 2014

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

No. 14-4624

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

v.

ACTAVIS PLC, FOREST LABORATORIES, LLC,
Defendants-Appellants.

———

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

———

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

———

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

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

daily IR therapy would likely further ensure that Defendants would maintain their effective monopoly in the relevant drug market beyond the time granted by their IR patents.

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

———

LISA S. BLATT, Arnold & Porter LLP, Washington, D.C. (Sarah M. Harris, Robert A. DeRise, Arnold & Porter, LLP, Washington, D.C.; George T. Conway III, Wachtell, Lipton, Rosen & Katz, New York, N.Y.; J. Mark Gidley, Peter J. Carney, Claire A. DeLelle, White & Case LLP, Washington, D.C.;

Jack E. Pace III, Martin M. Toto, White & Case LLP, New York, N.Y., *on the brief*), *for Defendants-Appellants.*

ANISHA S. DASGUPTA, (Barbara D. Underwood, Andrew Kent, Eric J. Stock, Elinor R. Hoffmann, *on the brief*), *for* Eric T. Schneiderman, Attorney General of the State of New York, New York, N.Y., *for Plaintiff-Appellee.*

———

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

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

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

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

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

BACKGROUND

This case raises a novel question of antitrust law: under what circumstances does conduct by a monopolist to perpetuate patent exclusivity through successive products, commonly known as "product hopping,"[2] violate the Sherman Act, 15 U.S.C. §§ 1 and 2. This question is an issue of first impression in the circuit courts. Determining whether Defendants' actions are unlawfully anticompetitive requires some understanding of the idiosyncratic market characteristics of the complex and highly-regulated pharmaceutical industry, as well as some peculiar characteristics of treatment for Alzheimer's disease. We begin by describing several key features of the pharmaceutical industry.

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

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

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

In 1984, Congress amended the Federal Food, Drug, and Cosmetic Act by enacting the Drug Price Competition and Patent

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

Term Restoration Act (the "Hatch-Waxman Act" or "Hatch-Waxman"), Pub. L. No. 98-417, 98 Stat. 1585. Hatch-Waxman was designed to serve the dual purposes of both encouraging generic drug competition in order to lower drug prices and incentivizing brand drug manufacturers to innovate through patent extensions. To incentivize innovation, Hatch-Waxman grants brand manufacturers opportunities to extend their exclusivity period beyond the standard 20-year patent term: it allows a brand manufacturer to seek a patent extension of up to five years to compensate for time that lapsed during the FDA regulatory process, 35 U.S.C. § 156, and an additional six-month period of "pediatric exclusivity" if the manufacturer conducts certain pediatric studies, 21 U.S.C. § 355a. Defendants applied for, and received, both extensions for Namenda IR.

Hatch-Waxman also promotes competition from generic substitute drugs. It permits a manufacturer that seeks to market a generic version of an NDA-approved drug to file what is known as an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C.

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

A generic drug is bioequivalent to a brand drug if "the rate and extent of absorption" of the active ingredient is the same as that of the brand drug. 21 U.S.C. § 355(j)(8)(B)(i). In other words, two drugs are bioequivalent if they deliver the same amount of the same active ingredient content into a patient's blood stream over the same amount of time. By enabling generic manufacturers to "piggy-back" on a brand drug's scientific studies, Hatch-Waxman "speeds the introduction of low-cost generic drugs to market, thereby

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

furthering drug competition." *Actavis*, 133 S. Ct. at 2228 (internal quotation marks, alteration, and citation omitted); *see also* H.R. Rep. No. 98-857, pt. 2, at 9 (1984) (stating the Hatch-Waxman Act's "policy objective" was to "get[] safe and effective generic substitutes on the market as quickly as possible after the expiration of the patent").

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

---

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

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

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

All state drug substitution laws prohibit pharmacists from substituting generic drugs that are not therapeutically equivalent to the brand drug, but state laws do not all define therapeutic equivalence in the same way.[8] Thirty states, including New York and the District of Columbia, adopt the FDA's definition of therapeutically equivalent and only allow generic substitution if the FDA designates the generic as "AB-rated" in a publication commonly referred to as the "Orange Book."[9] N.Y. Education Law

---

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

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

[9] Some states explicitly require generic drugs to have an AB-rating, some states adopt the requirements of an AB-rating without using the term, some states develop formularies that list permissible or impermissible drug substitutes, and some states give discretion to individual pharmacists as long as

§ 6816-a(1); N.Y. Public Health Law § 206(1)(o). To receive an AB-rating, a generic must not only be bioequivalent but pharmaceutically equivalent to the brand drug, meaning it has the same active ingredient, dosage form, strength, and route of administration as the brand drug. U.S. Dep't of Health & Human Servs., FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations* vii-x (35th ed. 2015), *available at* http://1.usa.gov/1PzbMxF (the "Orange Book"). The AB-rating requirement is designed to provide guidance regarding which drugs are therapeutically equivalent, but, as has been observed, it also provides an opportunity for brand manufacturers to "game" the system.[10] S.A. 28.

---

the drugs are pharmaceutically equivalent. *See* Vivian, *Generic-Substitution Laws* tbl.2.

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

Hatch-Waxman and state substitution laws were enacted, in part, because the pharmaceutical market is not a well-functioning market. In a well-functioning market, a consumer selects and pays for a product after evaluating the price and quality of the product. In the prescription drug market, however, the party who selects the drug (the doctor) does not fully bear its costs, which creates a price disconnect. Moreover, a patient can only obtain a prescription drug if the doctor writes a prescription for that particular drug. The doctor selects the drug, but the patient, or in most cases a third-party payor such as a public or private health insurer, pays for the drug. As a result, the doctor may not know or even care about the price and generally has no incentive to take the price into account. *See* American Antitrust Institute *Amicus* Brief in Support of Appellee ("AAI Br.") at 6; *see also* Intellectual Property and Antitrust Professors *Amicus* Brief in Support of Appellee ("IP and Antitrust Prof. Br.") at 12. As the Federal Trade Commission has explained:

Appellee ("AAI Br.") at 6, 10-11 (explaining that branded manufacturers can game the system by changing the form of the brand product before generics enter the market).

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

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

II. The Relevant Market

The relevant market, undisputed on appeal, is the memantine-drug market in the United States. Defendants manufacture

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

Namenda, a memantine hydrochloride-based[12] ("memantine") drug designed to treat moderate-to-severe Alzheimer's disease. Namenda is currently available in two formulations: a twice-daily immediate-release drug, Namenda IR, and a once-daily extended-release drug, Namenda XR. When Forest introduced Namenda IR tablets in January 2004, Namenda IR was the first medication approved for individuals suffering from moderate-to-severe

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

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

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

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

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

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

The non-medical difference between IR and XR relates to their patent protection. Defendants' patents on Namenda IR prohibit any

---

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

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

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

manufacturer from marketing a generic version of IR until July 11, 2015 (Namenda IR's "exclusivity period").[16] The exclusivity period for Namenda XR does not expire until 2029. A brand drug's exclusivity period is significant because when that period ends and generic versions enter the market, the brand drug often loses more than 80 to 90% of the market within six months. This period following the end of patent exclusivity has been referred to in this litigation and throughout the industry as the "patent cliff."

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

Namenda IR and Namenda XR currently occupy the entire memantine-drug market. However, five generic versions of IR have tentative FDA approval to enter the market on July 11, 2015, and seven others may enter the market as early as October 2015. Because Namenda XR has a different strength and daily dosage regimen—Namenda IR involves two immediate-release tablets of 10mg each and Namenda XR involves one 28mg extended-release

[16] Defendants' patents on Namenda IR prohibit generic entry until October 2015. But in 2009 and 2010, in order to resolve patent litigation, Forest entered into licensing agreements permitting ten generic competitors to enter the market three months before Namenda IR's official exclusivity period ends.

capsule[17]—the generic IR versions that are poised to enter the market will be therapeutically equivalent under FDA regulations to Namenda IR, but not to Namenda XR. Therefore, pharmacists are prohibited from substituting generic IR for Namenda XR under most, if not all, state drug substitution laws.

When Defendants brought Namenda XR to market in July 2013 (approximately three years after it was approved), they adopted so-called "product extension" strategies to convert patients from Namenda IR to Namenda XR and, thus, to avoid the patent cliff. Initially, Defendants sold both Namenda IR and XR but stopped actively marketing IR. During that time, they spent substantial sums of money[18] promoting XR to doctors, caregivers, patients, and pharmacists. They also sold XR at a discounted rate, making it considerably less expensive[19] than Namenda IR tablets, and issued rebates to health plans to ensure that patients did not have to pay higher co-payments for XR than for IR. The parties have

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

[18] The original numbers have been redacted.

[19] The original numbers have been redacted.

referred to Defendants' efforts to transition patients to XR while IR was still on the market as the "soft switch," and we will adopt that term.

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

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

But before Defendants withdrew IR entirely, intervening events again prompted them to modify their plans. In September 2014, New York State filed a complaint alleging that Defendants' planned withdrawal of Namenda IR violated the antitrust laws. Defendants subsequently entered into an agreement with Foundation Care, a mail-order-only pharmacy, to provide for limited access to Namenda IR if medically required. Under the terms of the agreement, Foundation Care is authorized to dispense Namenda IR tablets only after receiving a form from a doctor stating that it is "medically necessary" for the patient to take Namenda IR. Defendants estimated internally that less than 3% of current Namenda IR users would be able to obtain IR through Foundation Care. S.A. 67. Although the agreement with Foundation Care makes IR available to a limited number of patients, Defendants' actions effectively withdrew Namenda IR from the market. The

parties have referred to Defendants' efforts to withdraw Namenda IR from the market as the "hard switch" or "forced switch," terms we also adopt. The hard switch began on February 14, 2014 with the announcement of Defendants' intention to withdraw Namenda IR and was suspended in September 2014 when Defendants agreed to a "standstill" during the litigation proceedings described below. Because a manufacturer does not simply withdraw a drug at once, absent pressing safety concerns, announcing the imminent discontinuation of a drug is tantamount to withdrawal.

IV. Procedural History

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

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

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

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

Based on those findings, the district court granted New York's request for a preliminary injunction. The district court concluded

that New York raised serious questions regarding the merits of its claims under Sections 1 and 2 of the Sherman Act and the Donnelly Act, demonstrated the potential for irreparable harm, and concluded that the balance of the equities favored an injunction. The injunction states:

> 1. During the Injunction Term . . . the Defendants shall continue to make Namenda IR (immediate-release) tablets available on the same terms and conditions applicable since July 21, 2013 . . .
> 2. Defendants shall inform healthcare providers, pharmacists, patients, caregivers, and health plans of this injunction . . . and the continued availability of Namenda IR . . .
> 3. The Defendants shall not impose a "medical necessity" requirement or form for the filling of prescriptions of Namenda IR during the Injunction Term.

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

DISCUSSION

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

On appeal, Defendants argue that (1) the district court applied the wrong legal standard for a preliminary injunction; (2) product hopping is not anticompetitive or exclusionary under § 2 of the Sherman Act; (3) Defendants' patent rights foreclose antitrust liability; (4) the agreement with Foundation Care does not violate § 1 of the Sherman Act; (5) New York failed to show irreparable harm; and (6) the injunction is vague and overbroad.

I. The Applicable Preliminary Injunction Standard

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

Section 16 of the Clayton Act entitles a party to obtain injunctive relief "against threatened loss or damage by a violation of the antitrust laws." *California v. Am. Stores Co.*, 495 U.S. 271, 280 (1990) (quoting 15 U.S.C. § 26). A party seeking a preliminary injunction must ordinarily establish (1) "irreparable harm"; (2) "either (a) a likelihood of success on the merits, or (b) sufficiently serious questions going to the merits of its claims to make them fair ground for litigation, plus a balance of the hardships tipping decidedly in favor of the moving party"; and (3) "that a preliminary injunction is in the public interest." *Oneida Nation of New York v. Cuomo*, 645 F.3d 154, 164 (2d Cir. 2011) (internal quotation marks omitted).

We have held the movant to a heightened standard where: (i) an injunction is "mandatory," or (ii) the injunction "will provide the movant with substantially all the relief sought and that relief cannot be undone even if the defendant prevails at a trial on the merits." *Tom Doherty Assocs., Inc. v. Saban Entm't, Inc.*, 60 F.3d 27, 33-34 (2d Cir. 1995). When either condition is met, the movant must show a "clear" or "substantial" likelihood of success on the merits, *Beal v. Stern*, 184 F.3d 117, 123 (2d Cir. 1999), and make a "strong showing" of irreparable harm, *Doe v. N.Y. Univ.*, 666 F.2d 761, 773 (2d Cir. 1981), in addition to showing that the preliminary injunction is in the public interest.

The injunction issued by the district court in this case remains in place until 30 days after generics enter the market, and therefore "grant[s] plaintiffs substantially all the relief they ultimately sought, in effect, as if the injunction had been permanent." *Eng v. Smith*, 849 F.2d 80, 82 (2d Cir. 1988). The district court found that Defendants' plan is contingent on switching patients to Namenda XR before generic IR enters the market. S.A. 20. The injunction, however, bars

Defendants from withdrawing IR, and thus forcing a switch, "until thirty days after July 11, 2015 (the date when generic memantine will first be available)." S.A. 138. Because the injunction prevents Defendants' hard switch from succeeding, the injunction "render[s] a trial on the merits largely or partly meaningless." *Tom Doherty Assocs.*, 60 F.3d at 35.[20] Accordingly, the heightened standard applies.

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

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

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

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

Section 2 of the Sherman Act makes it an offense to "monopolize, or attempt to monopolize . . . any part of the trade or commerce among the several States." 15 U.S.C. § 2; *see also Geneva Pharm. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 495 (2d Cir. 2004). To establish monopolization in violation of § 2, a plaintiff must prove not only that the defendant possessed monopoly power in the relevant market, but that it willfully acquired or maintained that power "as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004) (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966)). "To safeguard the incentive to innovate,

the possession of monopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive *conduct*." *Id.* In order to show attempted monopolization, the plaintiff must prove: "(1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power." *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993). Attempted monopolization, unlike monopolization, requires a finding of specific intent. *See, e.g., Delaware & Hudson Ry. Co. v. Consol. Rail Corp.*, 902 F.2d 174, 180 (2d Cir. 1990).

Defendants' patents on Namenda IR indisputably grant them a legal monopoly in the U.S. memantine-drug market until July 11, 2015.[21] The parties do not dispute the district court's factual findings that the relevant market is the memantine-drug market in the United States and that Namenda IR and XR represent 100% of that market. S.A. 108-10. Consequently, the parties do not dispute that Defendants possess monopoly power. *See Geneva Pharm.*, 386

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

F.3d at 500 (monopoly power can be "proven directly through evidence of control over prices or the exclusion of competition," or "inferred from a firm's large percentage share of the relevant market").

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

[22] *See also Mid-Texas Commc'ns Sys., Inc. v. Am. Tel. & Tel. Co.*, 615 F.2d 1372, 1389 n.13 (5th Cir. 1980) ("It is clear, however, that the analysis under section 2 is similar to that under section 1 regardless whether the rule of reason label is applied per se." (citing *Byars v. Bluff City News Co.*, 609 F.2d 843, 860 (6th Cir. 1979))); *Cal. Computer Prods., Inc. v. Int'l Bus. Machs. Corp.*, 613 F.2d 727, 737 (9th Cir. 1979) ("[U]nder § 2 attempt as with § 1 monopolization individual conduct is

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

a. Anticompetitive and Exclusionary Conduct

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

---

measured against the same 'reasonableness' standard governing concerted and contractual activity under § 1.").

Sportswear, Inc., 964 F.2d 186, 188-89 (2d Cir. 1992) (quoting *U.S. Football League v. Nat'l Football League*, 842 F.2d 1335, 1359 (2d Cir. 1988)).

Well-established case law makes clear that product redesign is anticompetitive when it coerces consumers and impedes competition.[23] The leading case in our circuit for § 2 liability based

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

on product redesign is *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263 (2d Cir. 1979). In that case, Kodak simultaneously introduced its new Kodacolor II film and new Kodak 110 camera, which was designed so that it could only be used with the Kodacolor II film (the "110 system"). *Id.* at 277-78. Kodak, which possessed a lawful monopoly in film but not in cameras, heavily advertised Kodacolor II film as "a remarkable new film," and for 18 months, Kodak made Kodacolor II film only for the 110 camera. *Id.* at 278. Berkey Photo, Inc. ("Berkey"), a smaller camera manufacturer, alleged that Kodak unlawfully used its monopoly in film to increase camera sales and monopolize the camera market. *Id.* We rejected that claim and held that the introduction of the 110 system and advertising of the Kodacolor II film did not violate the

---

1736957, at *13 (E.D. Pa. Apr. 16, 2015) (noting that because generics had already entered the market at the time of defendants' product reformulation, "doctors remained free to prescribe generic Doryx; pharmacists remained free to substitute generics when medically appropriate; and patients remained free to ask their doctors and pharmacists for generic versions of the drug"); *Walgreen Co. v. AstraZeneca Pharm. L.P.*, 534 F. Supp. 2d 146, 151 (D.D.C. 2008) (dismissing a case alleging attempted market monopolization because unlike in *Abbott Labs*, "there is no allegation that AstraZeneca eliminated any consumer choices. Rather, AstraZeneca . . . introduced a new drug to compete with already-established drugs—both its own and others'—and with the generic substitutes for at least one of the established drugs").

Sherman Act because "[Kodak's] success was not based on any form of coercion." *Id.* at 287. But, of significance to the case before us, we cautioned that "the situation might be completely different if, upon the introduction of the 110 system, Kodak had ceased producing film in the 126 size, thereby compelling camera purchasers to buy a Kodak 110 camera." *Id.* at 287 n.39.[24]

In this case, Defendants argue that withdrawing a product is not anticompetitive or exclusionary conduct, especially when the new product is superior to the old product.[25] Certainly, neither product withdrawal nor product improvement alone is anticompetitive. But under *Berkey Photo*, when a monopolist *combines* product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits, *id.* at 287, and to impede competition, *id.* at 274-75, its

[24] We also noted that restricting Kodacolor II to the 110 format for 18 months may have been anticompetitive conduct, but we did not decide the question because there was no proof of injury to Berkey. *Berkey Photo*, 603 F.2d at 290.

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

actions are anticompetitive under the Sherman Act.[26] *Cf. Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962) (noting that when an antitrust conspiracy involves multiple acts, "[t]he character and effect of [the] conspiracy are not to be judged by dismembering it and viewing its separate parts, but only by looking at it as a whole" (internal quotation marks omitted)). Here, Defendants' hard switch—the combination of introducing Namenda XR into the market and effectively withdrawing Namenda IR—forced Alzheimer's patients who depend on memantine therapy to switch to XR (to which generic IR is not therapeutically equivalent) and would likely impede generic competition by precluding generic substitution through state drug substitution laws.

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

i. Consumer Coercion

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

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

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

57. Defendants' hard switch was expected to transition 80 to 100% of Namenda IR patients to XR prior to generic entry, S.A. 81, and thereby impede generic competition.

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

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

the knowledge that transaction costs would make the reverse commute by patients from XR to generic IR highly unlikely.

ii. Impedes Competition

As the district court concluded, Defendants' hard switch would likely have anticompetitive and exclusionary effects on competition in the memantine market, creating a "dangerous probability" that Defendants would maintain their monopoly power after generics enter the market. *Spectrum Sports*, 506 U.S. at 456. Based on careful consideration of the unique characteristics of the pharmaceutical market, the district court found that "[p]rice competition at the pharmacy, facilitated by state substitution laws, is the principal means by which generics are able to compete in the United States." S.A. 26.

We agree with the district court's analysis. Forcing patients to switch to XR would prevent generic substitution because generic versions of IR are not AB-rated to Namenda XR. And if, as Defendants' own internal predictions estimate, the hard switch successfully converted 80 to 100% of IR patients to XR prior to

generic entry, there would be "few to no prescriptions" left for which generics would be eligible to compete. S.A. 82. Because Defendants' forced switch "through something other than competition on the merits[] has the effect of significantly reducing usage of rivals' products and hence protecting its own . . . monopoly, it is anticompetitive." *Microsoft*, 253 F.3d at 65.

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

[29] Formularies, tiered-drug structures, step programs, and prior-authorization requirements are all tools that third-party payors may use to incentivize patients to take less-expensive drugs. A formulary is a list of approved drugs that a health plan will pay for, either in whole or in part. S.A. 19. A tiered-drug structure divides the drugs listed on a plan's formulary into categories or "tiers." S.A. 20. Typically, health plans use a three-tiered system, which reserves tier 1 for generic drugs, tier 2 for preferred branded drugs, and tier 3 for non-preferred branded drugs. The portion of the cost of the drug that the patient is responsible for paying, known as the "co-payment" or "co-pay," increases with each tier. A step program requires a patient to first try a preferred, and usually less expensive, drug. Only if that treatment is unsuccessful will the health plan pay for the patient's drug of choice. S.A. 20. A prior authorization policy requires a patient to obtain the third-party payor's approval for payment prior to taking a particular drug. Antitrust Economists Br. at 14.

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

Although in theory, Alzheimer's patients would be free to switch back to IR therapy after generic entry, the district court found

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

that, in practice, such a reverse commute would be a highly unlikely occurrence. As one of Defendants' own executives explained during a January 21, 2014 earnings call: "if we do the hard switch and we convert patients and caregivers to once-a-day therapy versus twice a day, it's very difficult for the generics then to reverse-commute back." S.A. 51. This is because there are high transaction costs associated with reverse commuting. Any patient who wants to switch back to twice-daily IR therapy must first obtain a new prescription from a doctor. But, as the district court found, the nature of Alzheimer's disease makes moderate-to-severe Alzheimer's patients especially vulnerable to changes in routine, and makes doctors and caregivers very reluctant to change a patient's medication if the current treatment is effective. As a result, if Defendants forced patients to switch from twice-daily Namenda IR to once-daily XR, those patients would be very unlikely to switch back to twice-daily generic IR even if generic IR is more cost-effective.[31] Moreover, third-party payors are reluctant to require

[31] The Department of Health and Human Services ("HHS") reached this same

patients to switch from a drug they are currently taking to a new drug, so health plans would be unlikely to require patients to switch to less-expensive generic IR.

Defendants and their *amici* argue that the district court's focus on AB-ratings is misplaced because up to 20 states do not impose an AB-rating requirement and thus "*may* let pharmacists unilaterally substitute generic IR for Namenda XR." Defs. Br. at 13 (emphasis added). Defendants' argument, however, exaggerates the variance in state substitution laws. Many states that do not explicitly require generic drugs to have the same AB-rating effectively require the same degree of therapeutic equivalence. For example, Defendants cite Iowa Code § 155A.32 as an example of a state law that "do[es] not rely on the Orange Book." Defs. Br. at 13. Section 155A.32(1)

---

conclusion, explaining:

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

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

permits pharmacists to substitute a generic drug if it has the same "demonstrated bioavailability" as the brand drug, Iowa Code Ann. § 155A.32(1), but Section 155A.3(9) clarifies that a generic is only considered to have the same "demonstrated bioavailability" if it has the same "rate and extent of absorption of a drug or drug ingredient from a specified dosage form," Iowa Code Ann. § 155A.3(9). Because the dosage and absorption rates of generic IR differ from that of XR, the drugs are not bioequivalent under Iowa law. Moreover, because generic IR is manufactured in tablet form and Namenda XR is marketed in capsule form, they do not have the same dosage form.[32] As a result, as in New York and the 29 other states that require an AB-rating, Iowa pharmacists will not be permitted to substitute generic IR for XR.[33]

---

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

[33] Defendants argue that up to 20 states may allow pharmacists to substitute generic IR for Namenda XR; however, throughout their briefs, Defendants and their experts point to 21 different states. Of the states identified by Defendants and their experts, 16 require the same dose and/or dosage form and thus will not allow generic IR to be substituted for Namenda XR. *See* Ala. Code § 34-23-8; Alaska Stat. Ann. §§ 08.80.295(a), 08.80.480(11); Ark. Code Ann. §§ 17-92-503(a)(1), 17-92-101(6), (11); Cal. Bus. & Prof. Code §§ 4073(a), 4052.5(a), (f); Colo.

Defendants argue that their conduct was not anticompetitive because preventing "free riding" is a legitimate business purpose. But what Defendants call "free riding"—generic substitution by pharmacists following the end of Namenda IR's exclusivity period—is authorized by law; is the explicit goal of state substitution laws; and furthers the goals of the Hatch-Waxman Act by promoting drug competition, *Actavis*, 133 S. Ct. at 2228, and by preventing the "practical extension of [brand drug manufacturers'] monopoly

---

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

. . . beyond the expiration of the[ir] patent[s]," H.R. Rep. No. 98-857, pt. 2, at 4 (1984).

Defendants also argue that antitrust law is not a vehicle for enforcing the "spirit" of drug laws. Defs. Br. at 46. But the Supreme Court has made clear that "[a]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue." *Trinko,* 540 U.S. at 411. Leading antitrust authorities have encouraged courts to acknowledge market defects, such as a price disconnect and the exclusivity of patents, in their antitrust analysis.[34] And in other Hatch-Waxman contexts, this court has recognized that efforts to manipulate aspects of the Hatch-Waxman incentive structure to exclude competition could state an antitrust claim. *See, e.g., Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d

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

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

b. Procompetitive Justifications

All of Defendants' procompetitive justifications for withdrawing IR are pretextual. The record is replete with evidence showing that Defendants were, in the words of Defendants' own CEO, "trying to . . . put up barriers or obstacles" to generic competition. J.A. 132; *see also* S.A. 49 ("We need to transition volume to XR to protect our Namenda revenue from generic

penetration in 2015 when we lose IR patent exclusivity."); J.A. 155 ("[W]hat we're trying to do is make a cliff disappear and rather have a long—a prolonged decline. And we believe that by potentially doing a forced switch, we will hold on to a large share of our base users."); S.A. 49 ("Our mission is to convert to Namenda XR and lift the franchise . . . . We need to convert as much IR business to Namenda XR as quickly as possible."). Based largely on Defendants' own documents, New York has rebutted Defendants' procompetitive justifications.

c. Procompetitive Benefits v. Anticompetitive Harms

Because we have determined that Defendants' procompetitive justifications are pretextual, we need not weigh them against the anticompetitive harms. But in any event, New York has shown that whatever procompetitive benefits exist are outweighed by the anticompetitive harms. Defendants argue that their conduct is procompetitive because "[l]aunching a new product . . . advances competition by adding a better product to the market and by paving the way for further innovation." Defs. Br. at 51. While *introducing*

Namenda XR may be procompetitive, that argument provides no procompetitive justification for *withdrawing* Namenda IR.

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

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

S.A. 74.

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

In sum, we conclude that the combination of withdrawing a successful drug from the market and introducing a reformulated version of that drug, which has the dual effect of forcing patients to switch to the new version and impeding generic competition,

without a legitimate business justification, violates § 2 of the Sherman Act.

III. Patent Rights as a Defense to Liability

Defendants argue that their patent rights under Namenda IR and Namenda XR shield them from antitrust liability. To be sure, there is tension between the antitrust laws' objective of enhancing competition by preventing unlawful monopolies and patent laws' objective of incentivizing innovation by granting legal patent monopolies. *See In re Adderall*, 754 F.3d at 133; *see also SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1205 (2d Cir. 1981).

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

licensees under the patent grants with the prohibitions of the Sherman Act against combinations and attempts to monopolize").

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

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

333 U.S. 287, 308 (1948). Defendants have essentially tried to use their patent rights on Namenda XR to extend the exclusivity period for all of their memantine-therapy drugs. As explained above, it is the *combination* of Defendants' withdrawal of IR and introduction of XR in the context of generic substitution laws that places their conduct beyond the scope of their patent rights for IR or XR individually.

IV. The Sherman Act § 1 and the Donnelly Act

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

unreasonable restraint prong under § 2 does not necessarily violate § 1 absent evidence that the agreement furthers the anticompetitive conduct. *Id.* at 506.

V. Irreparable Harm

New York has made a "strong" showing that competition and consumers will suffer irreparable harm in the absence of the injunction. *Doe*, 666 F.2d at 773. Irreparable harm is "injury that is neither remote nor speculative, but actual and imminent and that cannot be remedied by an award of monetary damages." *Forest City Daly Hous., Inc. v. Town of N. Hempstead*, 175 F.3d 144, 153 (2d Cir. 1999) (internal quotation marks omitted). To obtain injunctive relief under § 16 of the Clayton Act, that injury must be an injury "of the type the antitrust laws were designed to prevent and that flows from that which makes defendants' acts unlawful." *Consol. Gold Fields PLC v. Minorco, S.A.*, 871 F.2d 252, 257 (internal quotation marks omitted), *amended by* 890 F.2d 569 (2d Cir. 1989).

As the district court concluded, "[p]ermanent damage to competition in the memantine market can . . . result from

Defendants' planned hard switch strategy."[35] S.A. 131. If generics cannot compete with Defendants' drugs via state substitution laws, they "cannot compete effectively for sales of a branded drug in the same class, such as Namenda XR, even if the price of the generics is much lower than the brand." S.A. 80-81; *see also* IP and Antitrust Prof. Br. at 13-14 (explaining that absent substitution at the pharmacy, "the market for generics will collapse"). Moreover, generics cannot simply move into the market for generic XR. To become substitutable for Namenda XR, generic manufacturers must develop new once-daily Namenda tablets, begin the ANDA-approval process all over again, and await the end of XR's patent exclusivity period in 2029. Because Defendants' conduct does not simply harm a competitor or two, but threatens to "reduce competition in the [memantine-drug] market[,] . . . [it] is precisely

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

the type that the antitrust laws were designed to protect against." *Consol. Gold*, 871 F.2d at 257-58.

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

Defendants argue that the district court erred in finding *irreparable* harm because any increase in costs to consumers and

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

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

third-party payors is "compensable and readily quantifiable." Defs. Br. at 26. But compensating the approximately 500,000 Alzheimer's patients who take Namenda IR tablets, and an unknown number of public and private third-party payors, for an ongoing harm would impose "the task of disentangling overlapping damages claims [which] is not lightly to be imposed upon potential antitrust litigants, or upon the judicial system." *Blue Shield of Va. v. McCready*, 457 U.S. 465, 475 n.11 (1982); *see also Salinger v. Colting*, 607 F.3d 68, 81 (2d Cir. 2010) ("Harm might be irremediable, or irreparable, for many reasons, including that a loss is difficult to replace . . . .").[38] In

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

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

Defendants also argue that they "had stopped making IR batches and ha[d] been implementing plans to limit distribution for months." Defs. Br. at 25. Ordering Defendants to manufacture IR, Defendants argue, impedes production of XR and delays the development of Namzaric, an even newer Alzheimer's drug, because the FDA has only certified one plant to produce IR, XR, and Namzaric. This argument is belied by the record. At the preliminary injunction hearing, one of Defendants' executives testified that the plant could manufacture IR while manufacturing XR. J.A. 533. Defendants also informed the district court that there was no cap on the amount of IR that would be supplied through

addition, many of the victims of Defendants' hard switch, such as patients and health plans, may be prevented from direct recovery for their antitrust losses because of the "indirect purchaser" rule, which bars those who do not directly purchase a product from recovering antitrust damages, thus further supporting New York's claim of irreparable injury. *See Illinois Brick Co. v. Illinois*, 431 U.S. 720, 745-46 (1977).

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

Foundation Care and that the supply could be "adjusted as necessary based on demand." J.A. 904. Another of Defendants' experts testified that the "biggest problem [Defendants] have with [manufacturing both IR and XR] is the labor force," but "the equipment is completely different equipment." J.A. 202. Defendants' expert clarified that they need skilled labor but, at most, he explained that there might be some delay caused by training employees to use the new XR equipment where employees who had manufactured IR would be able to transition more quickly. J.A. 203.

2004) ("[G]overnment action taken in furtherance of a regulatory or statutory scheme . . . is presumed to be in the public interest").

VI. The Preliminary Injunction

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

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

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

CONCLUSION

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