14-4624

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

STATE OF NEW YORK, by and through ERIC T. SCHNEIDERMAN, Attorney General

Plaintiffs-Appellees,

v.

ACTAVIS plc AND FOREST LABORATORIES, LLC

Defendants-Appellants.

FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK
CASE NO. 14-CV-7473 (RWS)

REPLY BRIEF OF DEFENDANTS-APPELLANTS (REDACTED)

George T. Conway III
WACHTELL, LIPTON, ROSEN & KATZ
51 West 52nd Street
New York, NY 10019
Tel.: (212) 403-1000
Fax: (212) 403-2000

Lisa S. Blatt
Sarah M. Harris
ARNOLD & PORTER LLP
555 Twelfth Street, NW
Washington, DC 20004
Tel.: (202) 942-5000
Fax: (202) 942-5999

J. Mark Gidley
Peter J. Carney
Claire A. DeLelle
WHITE & CASE LLP
701 Thirteenth Street, N.W.
Washington, D.C. 20005
Tel.: (202) 626-3600
Fax: (202) 639-9355

Jack E. Pace III
Martin M. Toto
WHITE & CASE LLP
1155 Avenue of the Americas
New York, NY 10036
Tel.: (212) 819-8200
Fax: (212) 354-8113

Attorneys for Defendants-Appellants

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

New York's answering brief starkly reveals what this case is about: its attempt to hijack the Sherman Act to vindicate the spirit of its mandatory drug-substitution law. New York has conjured up an antitrust claim that turns on the vagaries of state laws. Its for-this-case-only theory imposes a duty on a branded drug manufacturer to abjure its patent rights before those rights end, just to maximize the effect of state substitution laws after patent exclusivity expires.

The result is an unprincipled and unprecedented injunction that compels a company to restart production of its older product and eviscerates the exclusive rights granted by federal patent law. The injunction aids competitors that already have plenty of help from state and federal drug laws. No appellate court has come anywhere close to imposing such a radical antitrust duty to aid competitors. This Court should not be the first.

I. The Heightened Injunctive Standard Applies

This injunction is improper under any standard, but is especially indefensible under the "heightened" standard applicable to preliminary relief that either is "mandatory" or "will provide … substantially all the relief sought" and "cannot be undone" even if Forest ultimately prevails. *Tom Doherty Assocs., Inc. v. Saban Entm't, Inc.*, 60 F.3d 27, 33-35 (2d Cir. 1995).

New York concedes (at 76) that the injunction affirmatively commands Forest to announce that it will keep IR on the market. That should end the matter.

If even "one provision … is arguably mandatory," the heightened standard applies. *Tom Doherty*, 60 F.3d at 35. But there is more. Although an injunction need not alter the *status quo* to be mandatory, Br. 24-25, this one does. It forces Forest to abandon business plans formulated in 2013, and to restart production of IR, *id.* 32-33, which it had already ceased making. SA-50; *infra* p. 7.

Further, because it extends 30 days past generic entry, the injunction is effectively permanent. That New York also seeks damages is irrelevant. The injunction is the gravamen of its complaint. JA-607. At minimum, the injunction affords New York "*substantially* all the relief sought" and renders a trial "*largely or partly* meaningless." *Tom Doherty*, 60 F.3d at 34, 35 (emphases added).

New York's suggestion (at 75) that a trial and final judgment could occur before July is fanciful. Time is of the essence for Forest's business plan. Moreover, damages discovery has barely begun; expert discovery has not started. The court has set no schedule for discovery or summary judgment, let alone trial.

II. The Balance of Hardships Favors Forest

A. There Is No Irreparable Harm

1. New York's purported harms are either remediable by damages or non-cognizable under antitrust law. Br. 27-32. Alleged financial harm to consumers and health plans from higher prices (which New York precisely computes at [redacted]) is quintessentially remediable by money damages. *Id.* 27-28. It

makes no difference that some standing rules limit indirect purchasers' ability to recover. New York seeks damages under New York law, which contains no such limits. *Cf.* NY Br. 57-58.

New York never explains how alleged damage to competition from generics' projected decreased market share (NY Br. 55-56) cannot be remedied with money damages. Br. 27-28. Nor does it explain how this harm is separate from consumer damages caused by generics' decreased projected market share. New York sues as *parens patriae* for consumers and for its own indirect losses—not for generic manufacturers, which can sue for themselves. *See* JA-608.

New York also asserts (at 53-56) a freestanding irreparable harm to consumer choice, which its expert classified as a "psychic cost[]." JA-872. But "limit[ing] consumer choice, in itself, does not amount to 'antitrust injury.'" *Somers v. Apple, Inc.*, 729 F.3d 953, 966 (9th Cir. 2013); Br. 50-51. An emotional reaction to diminished choice is not an injury "to business or property," 15 U.S.C. § 15(a), and thus cannot be a basis for injunctive relief. *Cargill Inc. v. Monfort of Colo., Inc.*, 479 U.S. 104, 109, 112 (1986). And any loss of choice resulting in higher prices would be fully remediable through damages.

2. New York's reliance (at 58-60) on purported medical harms similarly flouts the rule that antitrust injuries "exclude personal injuries" and other non-economic harms. *Reiter v. Sonotone Corp.*, 442 U.S. 330, 339 (1979); Br. 28, 48-

49; *accord Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 414 n.9 (3d Cir. 1997) (environmental harm); *Gutierrez v. E. & J. Gallo Winery Co.*, 604 F.2d 645, 646 (9th Cir. 1979) (work conditions); *In re Multidistrict Vehicle Air Pollution*, 538 F.2d 231, 236 (9th Cir. 1976) (air pollution).

It makes no difference if those supposed harms allegedly "flow[] from defendants' antitrust violation" or carry "financial consequences." NY Br. 60. The same could be said of all the non-economic harms courts have refused to recognize. New York cites (at 60) *Blue Shield of Virginia v. McCready*, 457 U.S. 465 (1982), and *Consolidated Gold Fields PLC v. Minorco, S.A.*, 871 F.2d 252 (2d Cir. 1989), but neither involved non-economic harm. And New York is wrong that medical harms "not directly cognizable as irreparable [antitrust] injury" count "as irreparable injury in the preliminary injunction calculus." NY Br. 60. The only "relevant harm" for "irreparable harm" is "harm that … occurs to the parties' *legal interests*"—here, economic interests only. *Salinger v. Colting*, 607 F.3d 68, 81 (2d Cir. 2010) (emphasis added).

Regardless, the district court's finding of medical risk is clearly erroneous. Br. 26, 28-32. New York has only Dr. Lah, whose "extensive experience" New York asserts in a footnote. NY Br. 59 & n.9. Extensive his experience was not. Lah's non-expert testimony about medical risk concededly "had no foundation or support," JA-243, his experience with switching was "very limited," JA-240, 816-

17, and he acknowledged that medical risk is "not a known concern." JA-243. Nor is there any foundation for New York's assertion that switching might increase pill administration errors. NY Br. 58-59. The court never found this, and the evidence overwhelmingly shows the opposite. *E.g.*, JA-392-94 (Polivka-West).

New York also disregards evidence about switching that no rational fact-finder could ignore. Br. 29-32. The FDA approved switching as safe. The 250,000 patients who uneventfully switched to XR confirms it. Five distinguished Alzheimer's experts testified there is no risk. *Id*. 29; JA-933 (Reisberg); Physician Br. 11-17; Caregiver Br. 18-19. And if any change in medication truly threatens patient welfare, New York has no business compelling pharmacists to switch patients to new, different-looking, and differently-absorbed generic IR come July. Br. 31; Caregivers Br. 18. New York also does not explain why Foundation Care distribution does not fully address any risk. Br. 30-31 & n.4; Physician Br. 17-19; JA-516-17, 938-39 (Kohrman); JA-571, 573-76 (Blakeley).

New York (at 13, 30) parrots the district court's statement that "[t]he benefits of a switch are often marginal." SA-54-56. But the court also made *contrary* findings that "once-daily dosing increases compliance"; that "[m]any controlled clinical trials" prove that once-daily extended-release pills reduce treatment costs and produce "better long-term clinical outcomes"; and that once-daily dosing especially benefits Alzheimer's patients, because many resist

medication later in the day. SA-35-36. Indeed, XR's once-daily benefits are so great that *not* switching may be medically irrational. Br. 29-30; JA-508-11 (Ferris); JA-933 (Reisberg); Physician Br. 3-11; Caregiver Br. 8-16. And the injunction hurts patients right now by delaying access to Namzaric. Br. 32-33.

New York stresses a purported "risk" that "[redacted] of all Namenda patients" may stop treatment. NY Br. 58; *see id.* 16, 21, 32. But the district court made no such finding; the opinion merely references (once) Forest projections from 2013. SA-95. The court never found that the projections were correct, and for good reason. These figures did not use Namenda-specific market research and assumed total discontinuation of IR, not limited distribution. JA-123-24. Meanwhile, Namenda-specific surveys projected *at most 4%* disruption if IR distribution were limited instead of stopped. JA-79, 89, 107. And even that figure does not account for Namzaric or the convenience of Foundation Care's door-to-door distribution. JA-423 (Saunders); JA-573 (Blakeley); JA-938-39 (Kohrman).

B. The Balance of Hardships

The injunction forced Forest to immediately start making a patented product it stopped producing, and to forfeit an unrecoverable [redacted] business opportunity. Br. 32-33. New York observes (at 61-63) that Forest "always manufactured [IR] in batches" and set no cap on Foundation Care's supply; that 500,000 patients were taking IR in December 2014; and that Forest considered

[redacted]. These points misunderstand the key fact that Forest stopped making IR in 2014 *after* it made enough to satisfy all expected demand. Before stopping production, Forest stockpiled and manufactured [redacted] the amount of IR it expected Foundation Care to distribute. JA-453 (Kane); JA-994 (Stewart). And if Forest made generic IR, it could produce it at its leisure—whereas the injunction compels immediate, disruptive, large-scale production.

III. New York Cannot Prevail on the Merits

A. Forest's Patent Rights Bar New York's Claims

1. The Supreme Court has long held that when a patentee exercises rights granted by the Patent Act, no antitrust liability can attach to that conduct. Br. 34-35; Bioscience Ass'ns Br. 5-7; IP Professors' Br. 7-11. This Court likewise "hold[s] that where a patent has been lawfully acquired, subsequent conduct permissible under the patent laws cannot trigger any liability under the antitrust laws." *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981); *accord In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 685 (2d Cir. 2009). That rule ends this case. Forest has undisputedly valid patent rights over IR and XR, including the right to refuse to distribute, make, or sell IR, and to prevent anyone else from doing so. Forest thus exercises core patent rights in limiting IR distribution. Br. 34-37. New York does not argue otherwise.

2. New York responds (at 47) that Forest cannot limit IR distribution now if doing so would "extend [its] monopoly past Namenda IR's exclusivity period." That contention fails at every level. Non-use of a patent is not "illegal extension of the patent right." 35 U.S.C. § 271(d)(4); *see* Br. 34-37. No case requires a patent-holder to exercise its patent so that after the patent term expires, competitors may flourish. The Federal Circuit rejected this theory. Br. 37-38 (citing *Roche Prods., Inc. v. Bolar Pharm. Co., Inc.*, 733 F.2d 858, 864 (Fed. Cir. 1984)). And New York's argument has no logical stopping point. New York never explains when in a patent term a patent-holder must sacrifice its rights to guarantee a certain competitive landscape later. Either New York has some undisclosed date in mind, or patent rights become meaningless: from Day 1 of the patent term, patent-holders face treble damages for raising prices, restricting output, or suing infringers if those actions could impair competitors' future opportunities.

New York claims Section 271(d)(4) creates a safe harbor for refusals to exercise patent rights only under the "separate and distinct" patent misuse doctrine, not antitrust law. NY Br. 48-49. But Section 271(d)'s text is unqualified. Conduct within Section 271(d)'s safe harbors thus "does not amount to a violation of the antitrust laws"—period. *Carpet Seaming Tape Licensing Corp. v. Best Seam Inc.*, 616 F.2d 1133, 1143 (9th Cir. 1980). "It would be absurd to assume that Congress intended to provide that the use of a patent that merited punishment as a

[Sherman Act] felony would not constitute 'misuse.'" *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 42 (2006). That is why a tying arrangement involving a patented product without market power, which is not patent misuse under Section 271(d)(5), is also not an antitrust violation. *Id.* at 42-43. Likewise, it would be "absurd to assume" that non-use of Forest's IR patent merits punishment under the Sherman Act when it does not "constitute 'misuse'" under Section 271(d)(4). As for the legislative history: notwithstanding New York's view (at 48-49), Congress "designed [the law] to confine patent misuse … to conduct having anticompetitive effects." *Princo Corp. v. Int'l Trade Comm'n*, 616 F.3d 1318, 1329-30 (Fed. Cir. 2010) (en banc). Congress expressly defined patent misuse to exclude non-use of a patent *because* Congress determined that such conduct is not anticompetitive. *Id.*

Forest has never argued that a patent immunizes *everything* a patent-holder does from antitrust scrutiny. NY Br. 45-46. Antitrust laws apply to conduct not authorized by the Patent Act—like tying or otherwise leveraging a patent to seize a monopoly in other markets. Br. 35. But conduct *concededly within the patent's scope* cannot trigger liability, and Forest's conduct undisputedly falls in this category. *Id.*

That is why *FTC v. Actavis*, 133 S. Ct. 2223 (2013), does not aid New York. *See* NY Br. 44-45. The Patent Act grants patentees the exclusive right to make,

use, and sell their inventions during the patent term, but it confers no right to pay competitors not to compete with products that may not infringe. "Reverse payment" settlements—where patent-holders make "large and unjustified" payments to alleged infringers to stay out of the market until the patent term ends—thus were not expressly or implicitly within the patent's scope. 133 S. Ct. at 2227, 2232-33, 2237. *Actavis* "held that the potentially significant anticompetitive effects of reverse payment settlements are not immune from antitrust scrutiny merely because [those anticompetitive effects] may fall within the scope of the exclusionary potential of the patent at issue." *In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 133 (2d Cir. 2014) (quotations omitted). "[S]uch settlements necessarily prevent the adjudication of a patent's validity—thereby *leaving open the question of the patent's actual preclusive scope*." *Id.* (emphasis added; quotations omitted). Here, no one disputes the patents' validity, or that limiting IR distribution *is* a core patent right.

SCM did not leave open "whether antitrust liability could arise from a patent holder's exercise of a certain legal prerogative." NY Br. 46-47. *SCM* reserved "whether damage liability can accrue to a [patent] holder for refusing to license patents that he subsequently abuses through pooling or otherwise." 645 F.2d at 1206 n.10. Thus, if, as here, the *only* conduct at issue is within the patent's scope, no liability can attach. *Id.* at 1206. But if (unlike here) the patent-holder *later*

engages in conduct outside the patent's scope (like pooling), that earlier refusal to license might lose its immunity from antitrust scrutiny.

B. There Is No Antitrust Violation Anyway

1. Forest's Conduct Is Not Exclusionary

a. That Forest's conduct in no way resembles common anticompetitive conduct should have given the district court pause about New York's claims. A monopolist is free to limit one of its products to favor another; thus, before July 2015, Forest's conduct cannot be exclusionary. Br. 41. New York does not dispute this. Limiting IR distribution also will not stop rivals from launching generic IR. Five generics are poised to enter in July, and seven more in October. NY Br. 11. New York does not dispute this either, or that generics have no barriers to production, entry, or distribution. They have gotten the full benefit of Hatch-Waxman's streamlined approval process. Br. 10-11. And there is no tying or predatory pricing.

New York's theory should have raised further red flags. The crux of New York's claim (and the decision below) is that antitrust law "requires [Forest] to allow generic competitors … to compete using state substitution laws," *i.e.*, to help generics attain an 80-90% market share through laws that pressure or compel pharmacists to unilaterally fill brand prescriptions with generics. SA-95-96; Br. 43; *see* JA-606, 613-14, 617, 636-37. New York now adds that Forest's conduct

would create "transaction costs" by requiring pharmacists to call physicians to switch patients to generic IR. NY Br. 1. But those "transaction costs" arise solely because generics cannot exploit substitution laws to automatically channel them massive sales, and must instead compete for prescriptions. *Id.* 27, 38.

Endorsing a novel requirement that a company must keep selling its product to guarantee competitors' sales would vitiate established antitrust principles. Br. 40-44; PhRMA Br. 23-25. "Antitrust law … does not require one competitor to give another a break just because failing to do so offends notions of fair play." *Twin Labs, Inc. v. Weider Health & Fitness*, 900 F.2d 566, 568 (2d. Cir. 1990). A monopolist "has no general duty to help its competitors," whether by letting them free-ride on advertising or "otherwise pulling its competitive punches." *Olympia Equip. Leasing Co. v. W. Union Tel. Co.*, 797 F.2d 370, 375 (7th Cir. 1986) (Posner, J.). That is so even if competitors "could not survive" without free-riding. *Id.* at 377. Even if consumers are hurt in the short run, "in the long run they will be hurt more if juries are allowed to burden a monopolist with a positive duty of assisting competitors." *Id.*

New York (at 50) claims this case just "is about conduct directed at consumers" and disclaims "seek[ing] to bolster the position of any particular competitor." But elsewhere (at 34, 37) New York calls Forest's conduct "actionable" for "imped[ing] generic competition" and generics' market share.

And seeking to bolster *all* generic competitors is just as impermissible as bolstering *one* of them. Either way, New York wants Forest to keep selling IR to facilitate generics' sales. New York also hypothesizes (at 50) a novel duty to deal with patients. But Forest deals with wholesalers, not patients. And antitrust law at very most recognizes refusals to deal with *rivals*. *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408-11 (2004).

New York posits that product switching is exclusionary if it "has the purpose and effect of coercing customer choice and impeding competition." NY Br. 36. That theory is incoherent, arbitrary, and unworkable. It bears emphasis that New York—a sovereign with enormous power, immense prosecutorial discretion, and a special duty to exercise care before jettisoning a company's business plans—has not answered basic questions about its position.

New York does not dispute that Forest could have lawfully achieved the same effects by aggressively hiking IR's price. But the Supreme Court (and rudimentary economics) dictates that raising prices and limiting supply are the same. Br. 45. If anything, raising prices "tenfold" (as New York's expert said Forest could do) constrains consumer choice far more than distribution through Foundation Care. *Id.* 44. New York's theory presumably would also force a company to advertise an older product if the only reason the company wanted to cease promotion was to hinder the market opportunities of the company's future

rivals. *Cf.* NY Br. 50 n.7. New York suggests that the problem here was that allegedly "only [redacted]" of IR patients would "voluntarily" switch to XR, *id.* 13, 54, but otherwise Forest could have withdrawn IR entirely if there was a "lack of demand." *Id.* 40. But this "consumer choice" test lacks a limiting principle. Would New York have a claim if consumer surveys reported 50% approval of a product withdrawal? 85%?

Likewise, how *long* before generic entry and how *much* Forest could limit IR distribution is anyone's guess. Br. 45. Why Forest must keep selling IR 30 days (not 5 or 60) after generic entry also remains a mystery. *Id.* Why withdrawing an old drug for the new is anticompetitive only if the two allegedly have "medically equivalent effects," (NY Br. 36), raises more imponderables. What studies comparing old and new drugs would suffice? How should courts classify benefits like improved patient adherence, reduced pill error, and dramatically reduced caregiver burden? Br. 46.

Even if it had satisfactory answers, New York cannot use the Sherman Act to enforce the "spirit" of federal and state drug laws. *Id.* 46-47. Antitrust law is not a vehicle to enforce other regulatory obligations. *Pac. Bell Tel. Co. v. LinkLine Commc'ns, Inc.*, 555 U.S. 438, 449-51 (2009); PhRMA Br. 25-29. Liability is even less warranted here given that Forest violates neither state nor federal drug laws. Br. 46-47. And the Supreme Court in *Actavis* did not exalt state substitution

laws, as New York misleadingly suggests. NY Br. 38. *Actavis* actually says: "*The Hatch-Waxman process*, by allowing the generic to piggy-back *on the pioneer's approval efforts*, speed[s] [generic entry] … thereby furthering drug competition." 133 S. Ct. at 2228 (emphases added; quotations omitted). Forest has done nothing to stop generics from fully achieving those objectives here.

New York ignores another dispositive issue. The Sherman Act is a uniform federal statute; conduct that violates the Sherman Act in New York has to violate the Sherman Act in Des Moines. Br. 47-48; *Miss. Band of Choctaw Indians v. Holyfield*, 490 U.S. 30, 43-44 (1989). But under New York's theory, whether limiting IR distribution violates federal law depends on the terms of states' substitution laws. Br. 47-48.

Limiting IR distribution purportedly thwarts competition because states have an "AB-rated" requirement allowing pharmacists to substitute a generic for a brand only if it has the same dosage. SA-25, 28, 80-81, 112. But New York concedes that up to *twenty* states impose no AB-rated requirement. NY Br. 9 n.2. Many of those states—Minnesota, for example—may allow pharmacists to substitute generic IR for *XR*. Br. 13, 59; Minn. Stat. Ann. § 151.21. If pharmacists can make *that* substitution, all "transaction costs" under New York's theory disappear, and there is no antitrust violation. SA-117-18; NY Br. 27, 38.

New York dismisses "any heterogeneity in state law [as] largely irrelevant." NY Br. 73. But it invokes sources describing the lack of practical difference between *mandatory* jurisdictions—which compel pharmacists to substitute generics—and *permissive* ones, where pharmacists have discretion. That misses the point. Forest does not dispute that either way, pharmacists in practice substitute generics for brands, with generics getting up to a 90% share. SA-25. The critical point, however, is that in up to 20 states—regardless of whether substitution is mandatory or permissive—pharmacists might also automatically substitute generic IR for XR. In those states, even withdrawing IR completely would not prevent automatic generic IR substitution—which shows that the problem New York sought to enjoin is of its own making. If New York truly believes its assertion that IR and XR are therapeutically equivalent, it could allow pharmacists to substitute them, like Minnesota does. Br. 47. New York cannot justify how Forest's conduct would violate the Sherman Act in some states but not others, or why New York's policy preferences should make otherwise legal conduct illegal under federal law.

b. New York's paucity of supporting authority speaks volumes. New York cites three circuit court opinions (at 36), including *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 287 n.39 (2d Cir. 1979). But New York ignores Forest's explanation of why they are inapposite. Br. 42 & n.10. New York invokes

"district courts and leading commentators." NY Br. 36-37. But those decisions are distinguishable for reasons New York does not dispute: they involved product withdrawals coupled with other conduct that actually *is* anticompetitive because it blocks generic entry. Br. 42 & n.10. New York's treatise acknowledges: "A pharmaceutical patent owner has no legal duty either to help its generic competitors or to continue selling a particular product," and "may argue with some justification … that [it] cannot be held liable." 1 Herbert Hovenkamp et al, *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* § 15.3c1 (2d ed. Supps. 2013 & 2014). And the FTC's views in a 2012 case share the flaws of New York's theory, while never addressing patent law. FTC *Amicus* Br., *Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd.*, No. 12-cv-3824 (E.D. Pa. Nov. 21, 2012).

2. New York Proved No Anticompetitive Effects

a. New York did not show that limiting IR distribution would hamper competition. If generics had no hope of competing effectively or patients never switched from a brand drug that works, no generic would enter the market. But at least *twelve* sophisticated companies are poised to launch generic IR, and clearly believe they can succeed in an extraordinarily crowded market. Br. 18, 21, 42; JA-796-97 (Hausman). And generics undisputedly often gain significant market share against differently-dosed brand drugs. Br. 53.

New York asserts that "price competition with [Forest's] Namenda drugs will be dramatically impeded" because "[t]hat was [Forest's] very motivation." NY Br. 34; *see id.* 27-34, 54-55. But New York's heavy reliance "on defendants' own documents and statements," *id.* 20, gets the law backwards. Section 2 requires "that both intent *and* effect be proven" as separate elements, because "[h]opes and dreams alone cannot support a Section 2 claim." *U.S. Football League v. Nat'l Football League*, 842 F.2d 1335, 1359 (2d Cir. 1988). It is "an antitrust commonplace, that if conduct is not objectively anticompetitive the fact that it was motivated by hostility to competitors … is irrelevant." *Olympia Equip.*, 797 F.2d at 379. "Most businessmen don't like their competitors, or for that matter competition," and know "getting a monopoly is one way of making a lot of money." *Id.* And they can freely do so no matter how cutthroat their stated motives, so long as they do not commit "an objectively anticompetitive act." *Id.* at 380; *accord Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d 227, 232 (1st Cir. 1983) (Breyer, J.).

New York's selective reliance on Forest's documents shows how isolated business statements "readily may be misunderstood." *A.A. Poultry Farms, Inc. v. Rose Acre Farms, Inc.*, 881 F.2d 1396, 1402 (7th Cir. 1989). New York never acknowledges Forest's statements that "blunt[ing] the force of [substitution] laws" is "the definition of competition," SA-71, or that "what we hoped for … [is]

patients and physicians and caregivers … view the innovation of XR important enough to pay for it," since "people will have that chance to vote with their wallets." JA-836 (Saunders).

New York instead cherry-picks quotes about "barriers or obstacles," NY Br. 27, and claims that Forest projected "only [redacted] of patients would voluntarily switch to []XR before generic entry." *Id.* 13; *see id.* 54. But New York omits *later* data showing that Forest [redacted] XR conversion, because XR was one of the industry's best-ever launches. JA-370-71 (Hausman); JA-855 (Saunders); JA-915-16 (Meury). In XR's first ten months—before XR production problems in summer 2014 disrupted conversion—over [redacted] of patients switched, and XR was on track to win an overwhelming majority by July 2015. JA-370-71.[1]

New York says Forest proceeded despite projections that "as many as [redacted] of current IR users" would stop taking memantine. NY Br. 32. Not so. *Supra* p. 6. Equally misleadingly, New York claims (at 31) that Forest predicted "less than 3% of current []IR users" could "continue taking the drug" through Foundation Care. Forest projected that less than 3% of patients would want or need to continue taking the drug. Br. 31 n.4; JA-453 (Kane). That is not because of a cap

[1] New York suggests (at 32) that Forest acted nefariously by purportedly "asking" CMS in early 2014 to remove IR from its reference list *in 2015* (by which point Forest planned to cease IR tablet distribution). JA-162-64; JA-271-73; SA-53. Removal of a discontinued drug from CMS's list avoids confusion, and would not stop plans from covering generic IR.

on supply (there is none) or transaction costs, which are minimal. JA-571, 573-76 (Blakeley). It is because XR is so beneficial that, as Alzheimer's experts testified, "there is not a situation where [IR] would be desirable." JA-595 (Reisberg).

New York cites Forest's projection that "only" [redacted] of patients on XR might migrate to generic IR after July 2015 as proof that "doctors are especially reluctant to disrupt … medical routines." NY Br. 55. But the more natural conclusion is that once patients and caregivers experience XR's benefits and convenience, they will opt against twice-daily generic IR *despite* the potentially lower cost. Br. 52.

b. Regardless, New York does not identify any actual competitive harms. New York argues that "price competition" is the only type of competition that matters, and that Forest's conduct makes it less likely that consumers will receive the lowest-price product. NY Br. 33; *see id.* 9, 27-28, 38, 53-54. But generics can offer generic IR at whatever price they want. And antitrust law does not exist to guarantee that the cheapest product wins. Competition encompasses "*all elements of a bargain*—quality, service, safety, and durability—and not just the immediate cost, [which] are favorably affected by the free opportunity to select among alternative offers." *Nat'l Soc. of Prof'l Eng'rs v. United States*, 435 U.S. 679, 695 (1978) (emphasis added). New York's simplistic equation of fewer generic sales with competitive harm is especially misguided in the pharmaceutical industry, where "[c]ompetition … takes place across multiple dimensions, e.g., improved

efficacy, reduced side effects, increased reliability and safety, greater ease of use, better value, etc." Business & Policy Profs. Br. 18. Come July, generics will compete on price, while XR will compete on benefits like once-daily administration.

New York (at 28) claims "the relevant regulatory context makes it inefficient and uneconomical for generic manufacturers to market." That is just another way of saying that generics prefer to free-ride on substitution laws instead of competing by marketing. It is no response to the settled principle that if rivals must advertise, that *fosters* competition. Br. 48. New York also never explains why the court's finding that generics do not advertise (SA-78-80) was not clear error when New York's *own* expert confirmed generics can and do advertise effectively. Br. 48; PhRMA Br. 9; JA-299-300 (Kolassa). And New York's assertion (at 29) that marketing would skyrocket generic prices is citation-free for a reason. Generics needn't take out Super Bowl ads to reach doctors and patients; they can and do advertise effectively against differently-dosed brand versions with [redacted] or less. JA-331-33 (Clark).

New York and its *amicus* AHIP argue that doctors and health plans may resist changing Alzheimer patients' treatment by switching from XR to generic IR. NY Br. 29; AHIP Br. 5. But stickiness in consumer preference is not an *anticompetitive* barrier; it is a fact of economic life. Antitrust law accepts that new

entrants bear the burden of getting consumers to switch, and that the first product on the market often enjoys an incumbency advantage. Br. 49. Nor does the fact that this case involves Alzheimer's patients create unique stickiness problems that distinguish Namenda from other drugs. That argument rests exclusively on Dr. Lah's irresponsible, non-expert, and concededly unfounded opposition to any change in medication. *Supra* p. 5; SA-55-56. Neither New York nor AHIP explains why doctors and health plans would be reluctant to switch patients from XR back to IR when thousands of patients did so safely when XR production was disrupted. Br. 29. Nor do they address expert testimony from Alzheimer's specialists that it is "scientifically implausible" for switching from XR to IR to cause harm, and that doctors would switch cost-conscious patients. JA-265 (Ferris); JA-279-81 (Jacobs); Physicians' Br. 11-19.

New York and AHIP relatedly assert that while healthcare plans and other influential third-party payors have powerful means of driving physicians, patients, and pharmacists to generics, they would not use them for Alzheimer's patients. NY Br. 29-30; AHIP Br. 12-13. The only record support for this premise that the district court credited was equivocal testimony from a pharmacist at a small regional plan. SA-87; Br. 50 n.11. And it strains credulity that these multibillion-dollar companies would stand idly by with an alleged [redacted] at stake. Overwhelming evidence shows the opposite. *E.g.*, JA-285-300 (Kolassa); JA-558-

59 (Cremieux); Antitrust Economists Br. 7-17. [redacted] JA-910-11 (Meury). So did another major plan. *Id*.

New York's claim (at 32) that Forest "knew that restricting access to Namenda IR offered no benefits" and "would hurt some patients tremendously" defies reality. *Supra* pp. 4-6. And as discussed, anticompetitive effects encompass *only* economic consequences from diminished competition, not purported medical risk or psychic costs from diminished choices. *Supra* p. 4. Furthermore, antitrust law allows a monopolist to freely limit consumers' choices between its own products. Br. 41.

New York calls it "well-settled" that Forest's willingness to accept temporarily lower profits from limiting IR distribution is "probative of anticompetitive purpose and effect." NY Br. 33. But New York's authority states that in a case "at or near the outer boundary of § 2 liability," the defendant's "unilateral termination of a voluntary (*and thus presumably profitable*) course of dealing … suggested a willingness to forsake short-term profits to achieve an anticompetitive end." *Trinko*, 540 U.S. at 409. This Court has never applied that reasoning outside that context. And no wonder: a company's willingness to sacrifice short-term profits for longer-term gains reveals nothing. Companies

legitimately do that all the time: they invest in advertising and R&D, and in switching new products for old ones. So too here: Forest's short-term costs primarily reflect its efforts to ensure that XR and IR have the same co-pays, so that patients could access and afford XR. Health plans required XR rebates of up to [redacted] to do this—so XR was less profitable to Forest than IR in the short term. JA-842-43, 856 (Saunders); JA-909 (Meury).

New York (at 34-35) invokes reduced projected generic market share. But that alone is insufficient. "The question whether … conduct may properly be characterized as exclusionary cannot be answered by simply considering its effect on [competitors]." *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 605 (1985). Nor has Forest even "bar[red] a substantial number of rivals" or "severely restrict[ed] the market's ambit"—New York's preferred test. NY Br. 35. At least twelve rivals may enter; they will have all the same outlets to distribute generic IR. And *Microsoft*'s relaxed market foreclosure test does not help New York; it is limited to exclusive contracts that foreclose an entire distribution channel. *United States v. Microsoft Corp.*, 253 F.3d 34, 70 (D.C. Cir. 2001).

3. Forest's Conduct Is Procompetitive

New York's claims independently fail because limiting IR distribution to maximize Forest's return on XR is procompetitive. Br. 51-54. New York has no answer to the extensive testimony (including from New York's own Dr. Lah) that

there is *no* market need for IR. *Id.* 51-52. Nor does New York disagree that withdrawing an old drug to better promote the new one is common throughout industries and fosters incentives to innovate. *Id.* 52-53; Business & Policy Profs. Br. 2-21. Incremental innovations often foster major medical breakthroughs—as AIDS treatment illustrates. Biosciences Ass'ns Br. 14-16; PhRMA Br. 6-7. So too here: maximizing returns on XR lets Forest invest in further innovations—like the new Namzaric, which undisputedly relies on XR's innovations. Br. 53-54; Caregivers Br. 4-7.

New York reiterates that "internal company documents and contemporaneous statements" prove Forest's "sole motive" was to "imped[e] generic competition." NY Br. 39. But it would make no sense to disregard the actual procompetitive effects of conduct unless defendants' executives expressly invoked them. Courts must always look at potential procompetitive effects, because only "conduct without a legitimate business purpose that makes sense only because it eliminates competition" is exclusionary. *Adderall*, 754 F.3d at 133. And here again, New York's theory makes no sense. New York concedes that Forest could have hiked prices for a bad motive without facing liability.

4. The Section 1 Claim Independently Collapses

New York's Section 1 theory independently fails because it rests on the illogical premise that Forest aggravates its alleged misconduct by distributing IR

exclusively through Foundation Care rather than withdrawing it entirely. But exclusive distributorships are "presumptively legal," because they rarely "have an actual adverse effect on competition." *Elecs. Commc'ns Corp. v. Toshiba Am. Consumer Prods., Inc.*, 129 F.3d 240, 244-45 (2d Cir. 1997).

New York never points to any anticompetitive effect *caused by* the Foundation Care agreement. Br. 54-55. New York must show that the agreement gives Forest some "monopolistic benefit … that it does not already enjoy and would not continue to enjoy if the exclusive distributorship were enjoined." *E&L Consulting, Ltd. v. Doman Indus. Ltd.*, 472 F.3d 23, 29 (2d Cir. 2006). That is impossible: this agreement has no conceivable anticompetitive effects *beyond* what Forest could achieve by unilaterally withdrawing IR altogether. *See* NY Br. 30-31; SA-70. Nor does New York refute that its argument would open the floodgates to liability and convert a Section 2 defendant's subsidiary agreements into *per se* Section 1 violations. Br. 56.

New York's purportedly contrary cases, *NCAA v. Board of Regents of the University of Oklahoma*, 468 U.S. 85 (1984), and *Polygram Holding, Inc. v. FTC*, 416 F.3d 29 (D.C. Cir. 2005), involved horizontal agreements between competitors to restrict output. Unlike the agreement here, such horizontal agreements are presumptively *anticompetitive*. *Polygram Holding*, 416 F.3d at 34-35; *see Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 888 (2007).

IV. The Injunction Is Vague, Overbroad, and Unprecedented

1. What it means for Forest to "make" IR "available on the same terms and conditions applicable since July 21, 2013," SA-137, is fatally unclear. Br. 57-59. Whether the injunction prohibits Forest from changing IR's price beyond a certain point, or changing distribution arrangements, no one knows. New York will not commit. The district court acknowledged "difficulties," but refused to "interpret" the injunction. JA-1017. Instead, the court wished Forest "[g]ood luck." *Id.*

New York suggests Forest could license generic IR to launch immediately. NY Br. 70. But the injunction requires Forest to make "Namenda IR" available; does that include generics with different inactive ingredients, colors, and shapes? Must generics offer IR at the same prices Forest did? Must licensing agreements guarantee that generics will make IR available using Forest's same distributors? New York never explains.

New York asserts (at 71) that Forest endorsed similar wording. But Forest opposed *any* injunction, and proposed language only because it lost. JA-996, 1003. And Forest's proposal omitted the ambiguous language that it make IR available "on the same terms and conditions … since July 21, 2013." *See* JA-1005.

New York claims (at 71 & n.18) to have found similar injunctions, but cites refusal-to-deal cases where defendants resumed specifically-defined relationships

and no one raised vagueness. *Bergen Drug Co. v. Parke, Davis & Co.*, 307 F.2d 725, 726 (3d Cir. 1962) (must sell and deliver merchandise to plaintiffs on same terms as other competitors); *Nat'l Screen Serv. Corp. v. Poster Exch., Inc.*, 305 F.2d 647, 649-50 & n.2 (5th Cir. 1962) (must provide plaintiff motion picture accessories, not only non-competitors). New York also invokes an Actavis merger agreement (at 71-72), but misleadingly quotes a snippet of a clause and omits all the caveats and safe harbors that give it meaning. Actavis SEC Filing at A37 § 5.1, http://www.sec.gov/Archives/edgar/data/1578845/000119312514182855/d686059d424b3.htm.

2. New York does not answer why Forest must offer IR to *new* patients until 30 days after generic entry on July 11, even though no alleged concerns about switching apply to them. Br. 59-60. New York also never explains how Forest's conduct could harm competition in states that *allow* pharmacists to switch XR for generic IR. *Id*. 59; *supra* pp. 16-17. Again, New York is wrong about waiver. JA-996, 1003, 1005 (preserving objections). And Forest does not oppose nationwide injunctions *per se*—just the incoherence and arbitrariness of enjoining Forest's conduct in the up-to-twenty states where its conduct may be lawful.

3. No court has ever compelled a company to start producing and selling a product it stopped making, and dictated the terms and conditions for selling that product. That sort of commandeering would be extraordinary for the political

branches to attempt, and is even more radical for the judiciary, which has no institutional competence to oversee such an order. Br. 60; Chamber Br. 3-14; Bioscience Ass'ns Br. 17-20.

New York's citations (at 68-69 & nn.14-17) confirm that the injunction breaks dangerous new ground. Most of New York's cases order defendants to transact with all comers on reasonable, nondiscriminatory terms—often with an express option to refrain from selling altogether. *E.g.*, *United States v. Glaxo Grp., Ltd.*, 410 U.S. 52, 62-64 (1973). Others order defendants to stop discriminating against distributors or competitors for anticompetitive reasons, *e.g.*, *Interphoto Corp. v. Minolta Corp.*, 417 F.2d 621, 622 (2d Cir. 1969) (per curiam); *Silver v. N.Y. Stock Exch.*, 373 U.S. 341, 347 (1963), to sell products individually rather than tying them together, *United States v. Loew's Inc.*, 371 U.S. 38, 53-55 (1962), or to perform preexisting contracts, *e.g.*, *Reuters Ltd. v. United Press Int'l, Inc.*, 903 F.2d 904 (1990); *Semmes Motors, Inc. v. Ford Motor Co.*, 429 F.2d 1197 (2d Cir. 1970).

New York's cases (at 68-69 & n.13) granting divestiture or dissolution remedies for unlawful mergers or conspiracies underscore what makes this injunction so anomalous. Courts favor structural remedies in such cases precisely because, *unlike* the injunction here, they are "relatively easy to administer," and

avoid embroiling judges in day-to-day supervision of business operations. *United States v. E.I. du Pont de Nemours & Co.*, 366 U.S. 316, 331 (1961).

CONCLUSION

Antitrust law demands predictable rules so that businesses know how to avoid treble damages and debilitating injunctions. But the decision below runs roughshod over long-settled, bright-line patent and antitrust rules and instead enshrines New York's limitless, incoherent, for-this-case-only approach. The injunction and the decision below should be vacated.

Dated: February 23, 2015

Respectfully submitted,

By: /s/ Lisa S. Blatt
Lisa S. Blatt
Sarah M. Harris
ARNOLD & PORTER LLP
555 Twelfth Street, NW
Washington, DC 20004-1206
Tel: (202) 942-5842
Fax: (202) 942-5999
lisa.blatt@aporter.com
sarah.harris@aporter.com

Jack E. Pace III
Martin M. Toto
WHITE & CASE LLP
1155 Avenue of the Americas
New York, New York 10036
Tel.: (212) 819-8200
Fax: (212) 354-8113
jpace@whitecase.com
mtoto@whitecase.com

J. Mark Gidley
Peter J. Carney
Claire A. DeLelle
701 Thirteenth Street, NW
Washington, DC 20005-3807
Tel.: (202) 626-3600
Fax: (202) 639-9355
mgidley@whitecase.com
pcarney@whitecase.com
claire.delelle@whitecase.com

George T. Conway III
WACHTELL, LIPTON, ROSEN & KATZ
51 W 52nd Street
New York, NY 10019
Tel: (212) 403-1260
Fax: (212) 403-2260
GTConway@wlrk.com

Counsel for Defendants-Appellants Actavis plc and Forest Laboratories, LLC

CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE 32(a)

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 6,852 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).
2. This brief complies with the typeface limitation of Fed. R. App. P. 32(a)(5) and the style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2007 in 14 point Times New Roman font.

/s/ Lisa S. Blatt
Lisa S. Blatt
ARNOLD & PORTER LLP
555 Twelfth Street, NW
Washington, DC 20004
Tel.: (202) 942-5000
Fax: (202) 942-5999
lisa.blatt@aporter.com

Counsel for Defendants-Appellants Actavis plc, Forest Laboratories, LLC

CERTIFICATE OF SERVICE

I hereby certify that I caused the foregoing Reply Brief for Defendants-Appellants Actavis PLC and Forest Laboratories, LLC to be served on counsel for Plaintiff-Appellee via Hand Delivery:

Eric T. Schneiderman
Karla Sanchez
Barbara D. Underwood
Eric J. Stock
Anisha S. Dasgupta
Andrew Kent
Elinor Hoffmann
Jeremy R. Kasha
120 Broadway
New York, NY 10271
(212) 416-8018

Attorneys for Plaintiff-Appellee
State of New York

I certify that six hard copies of the foregoing Reply Brief for Defendants-Appellants Actavis PLC and Forest Laboratories, LLC were sent via Hand Delivery to:

Clerk of the Court
United States Court of Appeals for the Second Circuit
Thurgood Marshall United States Courthouse
40 Foley Square
New York, New York 10007
(212) 857-8576

February 23, 2015

/s/ Lisa S. Blatt
Lisa S. Blatt