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)

FINAL FORM 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

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

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

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

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, the undersigned counsel for Defendants Actavis plc and Forest Laboratories, LLC respectfully submits the following corporate disclosure statement:

Forest Laboratories, LLC is a wholly owned subsidiary of Actavis plc, a public limited company incorporated in Ireland. No publicly held company owns 10% or more of the stock of Actavis plc.

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INTRODUCTION

The nationwide injunction in this case creates an unprecedented and unworkable antitrust rule. The court below compelled a company to start producing a patented drug it no longer makes, and to keep doing so for the next seven months on judicially-dictated terms and conditions to ease the way for competitors. Forest Laboratories, LLC and its parent company Actavis plc (together "Forest") must "continue to make" Forest's ten-year-old, patented Alzheimer's drug, twice-daily Namenda IR® tablets, "available on the same terms and conditions applicable since July 21, 2013." SA-137. Forest had stopped making IR so that physicians would transition patients to Namenda XR®, a new and improved once-daily capsule using the same active ingredient, memantine. Starting in January 2015, patients would take Forest's next-generation drug XR, but would decide, with their physicians, whether to remain on XR or switch to generic IR in July 2015.

The nominally preliminary injunction instead forces Forest to keep offering patients the older drug through August 10, 2015. Because of its patent rights, Forest is now the only company selling memantine-based drugs. In July 2015, Forest's patent and regulatory exclusivities on IR end, and at least five generic manufacturers are poised to enter the market with generic versions. If Forest cannot transition patients to XR now, and must instead keep up IR production and

distribution, state drug laws in July will automatically convert 80-90% of current Namenda IR prescriptions into generic IR sales at the pharmacy. In other words: the more IR prescriptions Forest is forced to foster before July 2015, the more sales Forest guarantees its generic competitors.

How Forest is to comply with this injunction is anyone's guess. No antitrust court has entered an injunction like this before. The "terms and conditions applicable" to IR have varied over the 17 months. Yet the court rejected pleas for clarification: "I am not unaware of the difficulties that this creates …. You will have to see what you think [the injunction] means. I think I know what it means, but we will see. … Good luck." JA-1017.

This injunction never should have issued. The decision justifying this injunction includes *seventy-seven* paragraphs copied virtually verbatim from New York's filings. Its reasoning contravenes every prerequisite for injunctive relief. There is no irreparable harm to prevent. New York's antitrust suit alleges that Forest tried to monopolize the memantine drug market and unlawfully exclude competition. Federal and state antitrust laws provide treble damages. New York's expert economist estimated damages at a remarkably precise [redacted], with the overwhelming majority attributable to healthcare plans. JA-682-83 (Berndt). To repeat that figure is to demonstrate just how reparable the alleged

antitrust harm is. Yet the district court inexplicably deemed this monetary loss irremediable. SA-95, SA-131.

The injunction also rested on the court's finding that limiting IR distribution and getting physicians to migrate patients to XR would create potential medical risk for certain existing Alzheimer's patients. SA-55-56, SA-131. That holding is legally and factually indefensible. Antitrust law precludes a court from granting an antitrust injunction based on irreparable harm that is not cognizable under antitrust law. New York chose to bring an antitrust suit, and antitrust law only remedies economic loss.

Moreover, the claim of patient harm is an outrageous fiction. The *FDA* considers switching from IR to XR entirely safe. Hundreds of thousands of patients already switched from IR to XR; New York identified not *one* who suffered harm. Had New York any evidence that any patient has been put at any risk by switching from IR to XR, New York could have, would have, and should have offered it. The court should have demanded such evidence before charging Forest with putting patients at risk. But New York presented *no* expert medical testimony, and the court relied on Dr. James Lah, who was not (and disclaimed being) an expert. He admitted that he "ha[s] *no foundation* or basis on which to conclude that … an individual patient will have greater adverse effects going to XR from IR. It's a potential concern, *not a known concern.*" JA-243 (Lah)

(emphasis added). And Namenda XR is improving the lives of countless Alzheimer's patients and caregivers—as the district court's opinion recognized elsewhere. Were that not enough, if a patient's doctor says that staying on IR is medically necessary, Forest (through a mail-order pharmacy) will ensure IR's availability to that patient. Irresponsible speculation that does not even allege a known risk is no basis for finding irreparable harm.

The district court's holdings on the merits are equally untenable. Bedrock principles of patent and antitrust law foreclose any likelihood that New York will succeed on the merits. At issue here is Forest's right under patent law to control whether to make, distribute, and sell a product to which Forest has valid patent rights—Namenda IR. Since 1790, federal patent law has struck a fundamental bargain with innovators: if they invest time and money in developing a novel product, a patent will guarantee them, for up to 20 years, the exclusive right to decide how much or how little of the patented product to make, distribute, and sell. After that, anyone can copy and sell competing versions. For over a century, the rule in America has been that patent law modifies antitrust law and relieves patent-holders of antitrust liability if they are exercising core rights within the scope of their patent. Yet the court inexcusably failed to even analyze this issue, and assumed Forest's patent rights were irrelevant.

There is more. A Section 2 monopolization claim requires a finding of exclusionary conduct that impairs competition, not competitors. Forest has done nothing exclusionary—it has not blocked generic competitors' access to suppliers or distributors, or their ability to enter the market come July. All that Forest's plans to reduce sales of Namenda IR would do is reduce its future rivals' ability to use state generic substitution laws to free-ride on Namenda IR prescriptions.

The district court created a new duty to comply with the "spirit" of federal and state laws so that competitors take over up to 90% of the market. That rule, if left undisturbed, would transform antitrust law's clear rules into an unmanageable series of imponderable questions. Forest sought to move patients from IR to XR by withdrawing IR from general distribution in the face of imminent generic entry. But, according to New York's expert, Forest could have *raised* the price of IR with antitrust impunity. Or perhaps Forest could have withdrawn IR a year earlier. And had New York deemed XR—in New York's words—"truly" better than IR, New York would not have sued. Left unexplained is how a court can or should determine whether a product is innovative enough to avoid treble damages.

Forest's actions are *pro*competitive. Forest has invested hundreds of millions of dollars to develop a new product, one that makes patients' and caregivers' lives better. And Forest has responded to generic competition with more competition: it sought to pit its newer, improved, and concededly beneficial

once-daily drug against generics' older, but likely cheaper, twice-a-day version, and let consumers decide which they prefer. XR eliminates any market need for IR by providing more convenient and beneficial once-a-day dosing. Nor are Forest's actions unusual: its conduct is common throughout the pharmaceutical industry. It is only under the district court's upside-down view that competition is furthered by maximizing the effect of state drug substitution laws and relieving generic manufacturers of the task of competing.

Left undisturbed, the decision below will insert courts into precisely the types of judgments for which they are least suited: whether an innovation is sufficiently novel to escape antitrust liability, and how businesses should set prices, terms, and conditions for their products. It must be reversed.

STATEMENT OF JURISDICTION

The district court has jurisdiction over New York's federal claims under 28 U.S.C. §§ 1331 and 1337, and jurisdiction over state-law claims under 28 U.S.C. § 1367(a). Forest seeks review of the district court's December 11, 2014 opinion granting a preliminary injunction (SA-1-136), and the December 15, 2014 preliminary injunction order (SA-137-38). Forest timely filed its notice of appeal on December 16, 2014. JA-1022-23. This Court has jurisdiction under 28 U.S.C. § 1292(a)(1).

STATEMENT OF THE ISSUES

1. Whether the district court erred by entering an injunction without finding a clear likelihood of success on the merits and a strong showing of irreparable harm.

2. Whether the court erred in finding that New York showed irreparable harm based on compensable monetary harms and an unsubstantiated and legally irrelevant risk of medical harm.

3. Whether the Sherman Act requires a company to exercise its patent rights by selling its patented product, and to do so to facilitate sales of its competitors' products.

4. Whether the nationwide injunction ordering a company to make a product "available on the same terms and conditions applicable since" 17 months ago is overly vague and broad.

STATEMENT OF THE CASE

On September 15, 2014, New York sued Forest, seeking declaratory relief, an injunction, disgorgement, restitution, and damages under the theory that Forest violated federal and state antitrust law by limiting distribution of IR in favor of XR. SA-6-8. On December 11, after an expedited hearing, the district court (Sweet, J.) granted New York a preliminary injunction. SA-2, SA-136. The court held that Forest engaged in exclusionary conduct that would lower generic

manufacturers' future market share by depriving generics of the advantage of state substitution laws. SA-113-19. The court found irreparable harm based on higher prices for memantine and the risk of medical harm to patients. SA-130-32; *see* SA-55-56. That decision will be reported. *New York v. Actavis*, 2014 WL 7015198 (S.D.N.Y. Dec. 11, 2014).

On December 15, the court ordered Forest to "continue to make [IR] tablets available on the same terms and conditions applicable since July 21, 2013." SA-137. The injunction is effectively permanent; it does not expire after a trial (none is scheduled), and will only be lifted "[30] days after July 11, 2015 (the date when generic memantine will first be available)." SA-138. On January 6, this Court granted expedited briefing but declined Forest's motion to stay the injunction. Dkt. No. 101.

STATEMENT OF FACTS

A. Regulatory and Industry Background

Brand drug manufacturers produce virtually all advances in prescription drugs. They do so both by developing new classes of drugs and incremental, yet meaningful, pharmaceutical innovations that significantly improve patients' lives. "[T]he vast majority of clinically important drugs … have resulted from … multiple, small, successive improvements within a pharmacological class," commonly called incremental innovations. JA-301 (Kolassa) (internal quotations

omitted). "[I]mproved formulations, delivery methods and dosing protocols may also … improve[] patient compliance, [provide] greater efficacy … reverse[] adverse effects or … treat new patient populations." Ernst R. Berndt et al., *The Impact of Incremental Innovation on Biopharmaceuticals: Drug Utilization in Original and Supplemental Indications*, 24 Pharmacoeconomics (Suppl. 2) 69, 71 (2006).

It usually takes over a decade and $2.6 billion to get FDA approval for a new class of drug, and profits from that drug rarely cover those costs. Tufts Center for the Study of Drug Development, *Cost to Develop and Win Marketing Approval for a New Drug is $2.6 Billion* (Nov. 18, 2014), http://bit.ly/1Hfvx6G. Incremental advances also require significant effort and innovation. And revenues from incremental innovations are essential to investments in developing breakthrough drugs. Albert Wertheimer & Thomas Santella, *Pharmacoevolution: The Advantages of Incremental Innovation*, at 12-13 (Int'l Policy Network Working Paper 2005); Berndt, *supra*, at 71.

While generic drugs play an important role in the practice of medicine, generic manufacturers do not significantly invest in new drugs or incremental innovation. Rather, they copy brand drugs, and usually enter the market after the product's patent term and regulatory exclusivity period ends. *See* 21 U.S.C. § 355(j)(2)(A)(vii).

1. The Hatch-Waxman Act

Until the 1984 Drug Price Competition and Patent Term Restoration Act, better known as Hatch-Waxman, federal law generally required generics to undertake the same cumbersome and expensive drug approval process as brands. Hatch-Waxman now "allow[s] [a] generic to piggy-back on the … approval efforts" made by brand drug manufacturers, *FTC v. Actavis*, 133 S. Ct. 2223, 2228 (2013), if the generic is "bioequivalent"—meaning (for most drugs) that the body absorbs the active ingredient at a rate and extent that is 80% to 125% of the reference brand drug—and has the same dosage form and other characteristics. FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations* (34th ed.), at vii–x, http://1.usa.gov/1ypXL8s ("Orange Book"). Generic manufacturers thus spend "a few million dollars" to get a generic to market. Henry G. Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries*, 8 Geo. Pub. Pol'y Rev. 7, 13 (2003).

Through the "[P]aragraph IV" certification process, Hatch-Waxman also incentivizes generic manufacturers to challenge brand-drug patents and can give the first successful challenger a "180-day period of exclusivity [sometimes] 'worth several hundred million dollars.'" *Actavis*, 133 S. Ct. at 2228-29 (citation omitted). But nothing in Hatch-Waxman guarantees generics a set market share, or dictates what happens when they enter. Indeed, even during a first generic's 180-

day exclusivity period, the brand manufacturer can itself introduce a competing generic. *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 52 (D.C. Cir. 2005).

2. States' Varied Generic Substitution Laws

Historically, physicians, in consultation with patients, decided which drug to dispense. But since the 1970s, states have encouraged, and—like New York—even forced, pharmacists to substitute lower-priced generics for brand drugs. State substitution laws, *not* Hatch-Waxman, prompt "automated switching" of generics for brands at pharmacies, so that generics capture 80-95% of sales. JA-824 (Stitt); JA-870 (Berndt).

States decide when generics can be substituted for brand drugs. Many states' laws incorporate the FDA's "Orange Book," which contains informal, non-binding "information and advice" on drugs the FDA considers similar enough to be substitutes. Orange Book, *supra*, at iv. The Orange Book designates generics as "AB-rated," and thus substitutable, if they are "therapeutically equivalent" to specific brand drugs referenced by generic applicants. *Id*. at vii. The Orange Book treats two drugs as "therapeutic equivalent[s]" if they "contain identical amounts of the same active drug ingredient in the same dosage form," among other criteria. *Id*. The FDA does *not* consider drugs therapeutically equivalent if they provide different dosages, regardless of therapeutic effect. *Id.* But the FDA deems two drugs therapeutically equivalent even if they differ in "shape, scoring

configuration, … colors, flavors, [or] preservatives," and even though consumers might consider these differences important. *Id.*; *accord* 44 Fed. Reg. 2932 (1979).

In New York, generic substitution is mandatory. Pharmacists must "substitute a less expensive drug product"—usually a generic—"[for] the drug product prescribed"—usually a brand—if the drug is on the state's list of acceptable substitutes. N.Y. Educ. Law § 6816-a (SA-185). New York lists generics as substitutes only if (1) the Orange Book "evaluated such drug product as pharmaceutically and therapeutically equivalent," *i.e.*, AB-rated, and (2) the generic contains "the same active ingredients, dosage form and strength as the drug product prescribed." *Id.*; N.Y. Pub. Health Law § 206(1)(o)(2) (SA-191-92).

When these conditions are met, New York compels pharmacies to disregard the physician's prescription and to substitute whatever "equivalent" costs least. N.Y. Educ. Law § 6816-a (SA-185). As New York's pharmacist witness, David Stitt, observed, "the element of choice is taken out of the equation by [New York's] law." JA-824 (Stitt). Only if the physician specifies "Dispense As Written" on the prescription, or if there is a medical emergency and the generic is unavailable, may pharmacists provide the brand drug. *See* N.Y. Educ. Law § 6816-a (SA-185).

But New York legislators realize New York may have gone too far. Aware that consumers lack information about "the drawbacks … of taking a generic drug"

and should "have the right to … decide … whether the generic product is appropriate for them," the state's legislature has been considering a partial repeal of the mandatory substitution law. S. 6739, 2013-2014 N.Y. Sess. Laws, http://bit.ly/1tzJlA2. Legislators cited the generic version of the antidepressant Wellbutrin®: although the FDA initially deemed it equivalent to the brand, consumers reported significant side effects, the FDA reconsidered, and the generic was withdrawn. *See id.*

Thirty-nine states reject mandatory substitution: they allow pharmacists to substitute a cheaper generic, but if the pharmacist, patient, or physician prefers the brand, the pharmacist can dispense it.[1] *See* SA-24-25. And, critically, many states, unlike New York, do not rely on the Orange Book.[2] Arkansas permits generic substitution within a therapeutic class, even if the generic comes in a different dose. Code Ark. Reg. § 07-00-0010. Some states even allow pharmacists to substitute an entirely different class of drug if it has therapeutically similar effects.[3] Up to 20 states may let pharmacists unilaterally substitute generic IR for Namenda XR. JA-347 (Cremieux); JA-673 (Berndt).

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[1] *See* Jesse C. Vivian, *Generic-Substitution Laws*, U.S. Pharmacist, at tbl.2 (June 19, 2008), http://www.uspharmacist.com/content/s/44/c/9787.

[2] *E.g.*, Code Ark. Reg. § 07-00-0010; Iowa Code Ann. §§ 155A.32, § 155A.3; Mich. Comp. Laws Ann. § 333.17755; Minn. Stat. Ann. § 151.21; Ohio Rev. Code Ann. §§ 3715.01, 4729.38; N.D. Cent. Code Ann. § 19-02.1-14.1; S.C. Code Ann. §§ 40-43-30, 40-43-86; Wash. Admin. Code §§ 246-899-030, 182-530-1050.

[3] Jesse C. Vivian, *Legal Aspects of Therapeutic Interchange Programs*, 28:08 U.S. Pharmacist (Aug. 15, 2003).

States with mandatory substitution laws achieve an 80-90% generic conversion rate through compulsion. Brand sales in those states generally occur when doctors specify "Dispense as Written" on the prescription. Vivian, *Generic-Substitution Laws*, *supra*, at 1-2. Elsewhere, generics rely on market intermediaries to achieve the same conversion rates. Pharmacies make more money on generics, and have enormous incentives to substitute them. JA-289-90 (Kolassa); Dep't of Health and Human Servs. Office of Inspector General, *Medicaid Pharmacy—Actual Acquisition Cost of Generic Prescription Drug Products*, at 5-6 (Mar. 2002), http://1.usa.gov/1Arzh3m. Pharmacists often call physicians to urge switching to a non-AB rated generic drug. *See* JA-951 (Kolassa). One successful call means that physicians will likely switch other patients to the generic. *Id.*

Health care plans and insurers—third-party payors—have similar incentives to promote generics. SA-19-20. Payors use their enormous financial leverage to negotiate pricing with manufacturers. SA-60-62. Because generics increase the payors' profit margins, payors employ powerful tools to steer physicians and patients toward generics. *See* SA-25; JA-290-95 (Kolassa); JA-270 (Devlin). Payors pressure pharmacies and physicians to switch patients from brands to generics that treat the same conditions, even if the generics have different dosages.

JA287-88, JA-303-08 (Kolassa); JA-525-26 (Kohrman). Some generic manufacturers also advertise. JA-299-300 (Kolassa); JA-863-65 (Harper).

B. Factual Background

Forest (now owned by Actavis) manufactures drugs that treat many debilitating conditions, including depression (Celexa® and Lexapro®); hypertension (Bystolic®); cystic fibrosis (Zenpep®); chronic obstructive pulmonary disease (Tudorza® and Daliresp®); and irritable bowel syndrome (Linzess®). Forest, *Our Products* (2015), http://www.frx.com/Products. Actavis is also a major generic manufacturer. JA-805; JA-848 (Saunders).

Forest makes two memantine-based products approved to treat moderate to severe dementia of the Alzheimer's type: Namenda® IR and Namenda XR®. SA-12, SA-30. Alzheimer's afflicts five million Americans. SA-13. In 2014, 469,000 new patients were diagnosed. Alzheimer's Association, *Alzheimer's Disease Facts & Figures*, at 19 (2014), http://bit.ly/1ihNu7U. Science has yet to find a cure.

Caregivers face tremendous challenges in caring for Alzheimer's patients. JA-317 (Reisberg). Many patients resist medications and consider them an affront to their dignity. JA-319, JA-323 (Rovner); JA-593-94 (Reisberg). Further, many patients "sundown"—their conditions decline significantly and their mental impairment and distress worsens once the sun sets. JA-279 (Jacobs); JA-254 (Kohrman); JA-328 (Rovner). Most patients abandon treatment within a year,

partly because of the burden of complex pill-taking schedules. JA-324 (Rovner).

1. Forest's Three Generations of Alzheimer's Treatments

a. Twice-A-Day Namenda IR

In January 2004, Forest introduced Namenda IR tablets, the first FDA-approved dementia treatment based on memantine, an NMDA receptor antagonist. *Id.* IR indisputably was a breakthrough, one that has helped Alzheimer's patients communicate with their families and perform daily tasks for longer periods. *E.g.*, JA-327 (Rovner), JA-316 (Reisberg). The German company Merz exclusively licensed IR to Forest in 2000 and Forest worked to develop and obtain FDA approval of IR for the U.S. market. SA-30.

In 2004, Forest introduced twice-daily tablet Namenda IR. In 2005, Forest introduced a twice-daily oral liquid version of IR for patients who have trouble swallowing. SA-32. But IR was a twice-daily drug in a market dominated by once-daily therapies; all other Alzheimer's drugs are once-daily, because that is the most convenient dosage for patients and caregivers. JA-200 (Meury); JA-937 (Kohrman); JA-408 (Solomon).

b. Once-Daily Namenda XR

Forest thus sought to develop XR, a once-a-day extended release capsule, which took years and about [redacted]. JA-381 (Meury). (Overall, Forest invested [redacted] to develop, license, and obtain FDA approval for Namenda products, including XR. *Id.*). The FDA approved XR in June 2010; Forest launched it in June 2013. *Id.*; SA-7, SA-37.

New York does not question XR's clinical benefits. Its witness Dr. Lah testified that with XR available, IR is no longer medically necessary or needed in the marketplace. JA-811, JA-815 (Lah). XR's once-daily dosage significantly benefits patients and caregivers. By "reduc[ing] the frequency of medication administration," XR "can improve medication adherence, enhance patient self-efficacy, and reduce behavior problems, caregiver burdens, and healthcare costs." JA-319 (Rovner); *see* JA-937-38 (Kohrman); JA-933-34 (Reisberg). As the district court acknowledged, XR especially helps patients who resist pills, or who "sundown" and resist them at night. SA-35-36. By reducing patients' and caregivers' pill burden, XR increases the odds that patients continue treatment. JA-324 (Rovner). That may also delay the need for expensive long-term professional care. JA-319, JA-323 (Rovner); JA-817 (Lah). The FDA also approved XR as administrable in applesauce, which is especially helpful for elderly patients. Namenda XR Package Insert at 1, 2, http://bit.ly/1HN7lI6.

Thus, "for many patients there is likely a preference for once-daily versus twice-daily Namenda." JA-881, JA-885 (Berndt); *accord* JA-817 (Lah).

c. Namzaric's Fixed Dose Combination

Forest recently developed Namzaric™, a "fixed dose combination [FDC] of Namenda XR with an acetylcholinesterase inhibitor," which eliminates yet another daily pill. JA-301 (Kolassa). The FDA approved Namzaric on December 23, 2014. Actavis Press Release, http://bit.ly/141qffk.

2. Forest's Decision to Increase XR Production and Distribution and Limit IR Distribution

About 500,000 patients take IR tablets; some 240,000 patients take XR. *See* JA-359 (Cremieux). Fewer patients take IR oral solution. SA-32, SA-75. As of June 2014, over 21,000 patients per month were switching to XR. JA-904 (Kane); JA-359 (Cremieux); JA-196 (Namenda Longitudinal Patient Tracker). XR and IR typically cost patients the same amount, and XR costs wholesalers less than IR. JA-382 (Meury). New York's competition expert, Dr. Berndt, confirms that these cost savings benefit consumers. JA-887 (Berndt).

Forest's IR patent and regulatory exclusivities end on October 11, 2015. Pursuant to agreements, five generic manufacturers may start selling generic IR tablets sooner—on July 11, 2015. JA-401 (Solomon). Another seven generic manufacturers may start selling IR on October 11, 2015. *Id.* Thus, in July, New

York pharmacists must switch patients from branded IR to generic IR without consulting patients or doctors. Pharmacists in permissive substitution states can choose to switch patients, and third-party payors will heavily pressure them to do so. SA-25; Vivian, *Generic-Substitution Laws*, *supra*, at 3-5. Within months, 80-90% of IR prescriptions will switch to generics. *See* SA-27.

Because XR supplants the market need for IR, leaving IR on the market only maximizes generics' free-riding on state substitution laws. To maximize returns on its substantial investment in XR, Forest by February 2014 decided to shift from IR tablets to XR and encourage physicians to transition patients to XR before 2015. Forest relied on substantial evidence that switching is safe and beneficial for patients. The FDA found switching safe, and instructions for switching appear in XR's labeling. JA-17-26 (FDA Review); Namenda XR Package Insert, *supra*, at 1, 2. Clinical studies and five expert witnesses confirm "there is no risk in switching patients from Namenda IR to Namenda XR." JA-319, JA-330 (Rovner); *see* JA-279-80 (Jacobs), JA-316 (Reisberg); JA-255 (Kohrman); JA-258, JA-264-65 (Ferris).

New York pointed to no instance of medical harm from switching, despite substantial and relevant empirical experiences. In June 2014, Forest's XR manufacturing process was unexpectedly disrupted. SA-63-64. Patients who had switched to XR briefly switched back to IR tablets. These switches—IR to XR to

IR—took place smoothly. JA-937-38 (Kohrman); JA-316 (Reisberg); JA-255 (Kohrman).

In transitioning to XR, Forest considered discontinuing IR tablets entirely or instead limiting distribution channels. Both approaches are common in the industry. JA-285-87 (Kolassa) (discussing six examples). Forest first planned to discontinue IR. Forest notified the FDA in February 2014 that it was discontinuing IR; it also informed patients, caregivers, physicians, pharmacies, third-party payors, and the public. JA-158-61 (Forest Press Release, Feb. 14, 2014, http://bit.ly/P61KWW).

The XR production disruption delayed the transition, and Forest announced in June 2014 that IR tablets would be available into the fall. JA-189-90 (Forest Press Release, June 10, 2014, http://bit.ly/1Bz6Uzc). Forest also announced in November 2014 that instead of discontinuing IR entirely, it would make IR available to patients whose doctors deemed IR medically necessary. Forest entered into an agreement with mail-order pharmacy Foundation Care to take over distributing IR to those patients as of January 2015. JA-563-64 (Actavis Press Release, Nov. 5, 2014, http://bit.ly/1KlNJgD). There is "no cap" on how many prescriptions Foundation Care can fill, but Forest expects a small number due to the lack of need. JA-845 (Saunders); JA-904 (Kane).

Five to six generic manufacturers are expected to enter the market in July 2015. JA-886 (Berndt); JA-401 (Solomon). Forest's decision to withdraw IR from general distribution has stopped none of them. After generic IR comes on the market in July 2015, existing XR patients, their caregivers, and physicians will choose between XR's benefits and the possible cost savings of generic IR tablets. Patients who start taking memantine after July will likewise choose between XR and generic IR tablets (or IR oral solution).

Once generic manufacturers introduce generic IR, they have many options for converting XR prescriptions to generic IR. They can advertise to persuade patients, caregivers, and doctors that possible cost savings outweigh XR's once-a-day benefits. JA-505-06 (Clark); JA-864-65 (Harper). They can rely on pharmacies and payors to pressure physicians to prescribe generic IR. JA-289-90 (Kolassa). Generic manufacturer Mylan estimates that these tactics will convert up to [redacted] of XR prescriptions to generic IR. JA-870-71, JA-874 (Berndt). Meanwhile, generic manufacturers filed Paragraph IV certifications challenging Forest's XR patents, and seek to introduce generic XR immediately. SA-3. Litigation over the XR patents is pending. *E.g.*, *Forest Labs., Inc. v. Teva Pharm. USA, Inc.*, No. 14-cv-121 (D. Del.).

SUMMARY OF ARGUMENT

The district court entered a sweeping injunction forcing Forest to drop everything and start producing an outdated drug. It should be reversed.

Until the decision below, the standard for obtaining this kind of injunction was supposed to be high. The injunction ordered Forest to change course and restart production of its old drug. New York needed to be clearly right on the merits and make a strong showing of irreparable harm. New York did neither.

Until the decision below, a strong showing of irreparable harm required harms that are both legally cognizable and not compensable with money damages. Worse, the court traduced the company for putting at risk those afflicted with Alzheimer's, yet ignored the FDA and empirical and expert evidence establishing that switching patients from IR to XR is safe. And the court discounted the injunction's irreparable harm to Forest.

Until the decision below, patent law immunized companies from antitrust liability if they simply exercised core patent rights to decide how to price, produce, and distribute patented products. The district court cast that century-old rule aside without even acknowledging it.

Until the decision below, companies had no duty to affirmatively aid competitors by keeping an older product on the market that competes with the

company's new product. The court's rule is unworkable, untenable, and impossible to square with antitrust law as it currently exists.

Until the decision below, injunctions had to be precise and narrowly tailored. Critical questions remain about how Forest can provide IR tablets on terms and conditions prevailing over a 17-month period when those terms and conditions fluctuated. The court also failed to justify the injunction's nationwide scope or why it should apply to patients who start Namenda now.

STANDARD OF REVIEW

"A preliminary injunction is an extraordinary remedy never awarded as of right." *Salinger v. Colting*, 607 F.3d 68, 79 (2d Cir. 2010). This Court "review[s] the district court's entry of [a] preliminary injunction for abuse of discretion, which will be found if the district court applies legal standards incorrectly or relies upon clearly erroneous findings of fact, or proceed[s] on the basis of an erroneous view of the applicable law." *Corning Inc. v. PicVue Elecs., Ltd.*, 365 F.3d 156, 157 (2d Cir. 2004) (internal quotations omitted).

ARGUMENT

I. The District Court Applied the Wrong Legal Standard for Relief

The district court's injunction cannot stand under any standard, even the one the court applied. But the court erred at the outset by requiring New York to show merely a likelihood of success on the merits and a "substantial chance" of

irreparable harm, the test for prohibitory preliminary relief. SA-102, SA-131. A "heightened" standard applies when the relief sought is either (1) "mandatory" or (2) "will provide … substantially all the relief sought." *Tom Doherty Assocs., Inc. v. Saban Entm't, Inc.*, 60 F.3d 27, 34-35 (2d Cir. 1995) (internal quotations omitted). When either condition is met, the plaintiff must make "a clear showing" that its claims would succeed, *id.* at 34, and a "strong" showing of irreparable harm, *Doe v. New York Univ.*, 666 F.2d 761, 773 (2d Cir. 1981). The heightened standard applies here because both conditions are met.

The injunction is mandatory. The district court held otherwise because the injunction supposedly "maintain[s] the status quo." SA-100. But "[t]he distinction between mandatory and prohibitory injunctions … cannot be drawn simply by reference to whether or not the *status quo* is to be maintained or upset." *Abdul Wali v. Coughlin*, 754 F.2d 1015, 1025 (2d Cir. 1985). What matters is "whether [Forest] is being ordered to perform an act." *Id.* *Any* injunction "order[ing] an affirmative act or mandat[ing] a specified course of conduct" is "mandatory." *Louis Vuitton Malletier v. Dooney & Bourke, Inc.*, 454 F.3d 108, 114 (2d Cir. 2006). If even "one provision … is arguably mandatory," or "arguably alters the status quo" by requiring a defendant to "do[] more than is required" absent the injunction, the "heightened standard" applies. *Tom Doherty*, 60 F.3d at 35.

The injunction's plain language is mandatory. Forest "shall … make Namenda IR … available." SA-137. Forest "shall inform healthcare providers, pharmacists, patients, caregivers, and health plans" of its court-compelled future conduct. SA-137-38. These orders command "positive act[s]." *Tom Doherty*, 60 F.3d at 34. And they upset the "status quo," even if that is considered to be "continu[ing] [Forest's] current Namenda IR sales and distribution activities." SA-100. Forest had stopped making IR batches and has been implementing plans to limit distribution for months. JA-994 (Stewart). Now the injunction forces Forest to dramatically alter its plans. This Court considered "mandatory" an injunction that would have made a company keep supplying a single patient a drug. *See Cacchillo v. Insmed, Inc.*, 638 F.3d 401, 406 (2d Cir. 2011). This infinitely broader injunction is also mandatory.

Second, the injunction "render[s] a trial on the merits … meaningless." *Tom Doherty*, 60 F.3d at 35. The injunction compels Forest to keep selling IR, not until an as-yet-unscheduled trial, but until "[30] days after July 11, 2015," when generics enter. SA-138. That order would look no different had the court entered a permanent injunction. And there would be no damages to collect, as the injunction will prevent any supposed damages. The injunction has surely given New York "substantially all the relief sought." *Tom Doherty*, 60 F.3d at 34.

II. New York Failed to Show Irreparable Harm

The district court profoundly erred in finding that New York established "irreparable harm[,] … the single most important prerequisite for the issuance of a preliminary injunction." *Faiveley Transp. Malmo AB v. Wabtec Corp.*, 559 F.3d 110, 118 (2d Cir. 2009) (internal quotations omitted). The court found that Forest's conduct would harm competition and increase prices once generics enter the market in July 2015. SA-95, SA-131. But even if this harm materialized, it is quintessentially *reparable* harm: it is compensable and readily quantifiable. The court also found irreparable harm on the ground that transitioning patients from IR to XR risks health consequences. SA-55-56, SA-131. But non-economic harms are not grounds for an antitrust injunction. Moreover, the court's finding of risk to Alzheimer's patients is not just unsupported; it is at war with the FDA's judgment, the record, and extensive empirical experience confirming that switching to XR is safe, beneficial, and relieves patients and caregivers' pill burdens. That error is fatal, because "[i]n the absence of evidentiary support of irreparable harm, there [is] no basis for the entry of a preliminary injunction." *Faiveley*, 559 F.3d at 120. New York failed to show a substantial risk of irreparable harm—let alone the strong showing of irreparable harm required to obtain the mandatory injunction here. *Doe*, 666 F.2d at 773.

A. There Is No Irreparable Harm to Competition

The district court's finding of irreparable injury to "competition in the memantine market," SA-131, proves the impropriety of injunctive relief, not its necessity. Even if Forest's conduct were anticompetitive—which it is not, *infra* pp. 40-55—the district court found that any resulting harm to competition is *monetary*, because "[c]onsumers would bear approximately [redacted] in additional co-payment costs and [redacted] in third party payor costs." SA-95; *see* SA-132.

By definition, quantifiable financial harm is not irreparable harm. "[I]t has always been true that irreparable injury means injury for which a monetary award cannot be adequate compensation and that where money damages [are] adequate compensation a preliminary injunction will not issue." *Jackson Dairy, Inc. v. H.P. Hood & Sons, Inc.*, 596 F.2d 70, 72 (2d Cir. 1979). There can be no irreparable injury, and no injunction, when "there is an adequate remedy at law, such as an award of money damages," *Faiveley*, 559 F.3d at 118, or when the court can "'wait[] until the end of trial to resolve the harm,'" *Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 114 (2d Cir. 2005). This rule is particularly applicable here, because a "triple-damage antitrust case" would provide "a very liberal rule for the proving of damages." *Jack Kahn Music Co., Inc. v. Baldwin Piano & Organ Co.*, 604 F.2d 755, 763 (2d Cir. 1979). Preliminary injunctions are reserved for

exceptional cases. *Salinger*, 607 F.3d at 79. The district court's ruling would open the floodgates to injunctive relief as a matter of course to any plaintiff claiming predicted monetary harm, and should be reversed.

B. Medical Harm Is Non-Cognizable and Nonexistent

The district court's other basis for finding irreparable harm—medical risk to patients—is neither legally cognizable nor remotely supported by the record. The court found that for some vulnerable patients, "the benefits of the change to Namenda XR are outweighed by the risks of changing the medical routine." SA-55; *see* SA-131.

But courts cannot find irreparable harm warranting an antitrust injunction based on harm that antitrust law does not recognize. *Cargill Inc. v. Monfort of Colo., Inc.*, 479 U.S. 104, 109, 112 (1986). Medical risk is a grave charge against a pharmaceutical company—which is why Forest sought FDA approval and did clinical studies on the safety of switching from IR to XR, and introduced at trial expert opinion. Medical risk, however, is no basis for an antitrust injunction; antitrust law only remedies economic harms, and this antitrust lawsuit is not the appropriate vehicle for New York to raise health claims. *Infra* pp. 48-49.

In any event, not a shred of evidence supports the court's conclusion. New York did not bother to introduce a single medical expert. The court relied on a fact witness, Dr. Lah, who asserted that "[a]ny small change in medication raises the

risk of an adverse effect." SA-55-56, SA-92. New York made no effort to qualify Lah as an expert. Lah offered no basis for this assertion, knew of no examples of harm, and had not even reviewed the FDA label. JA-237-38, JA-241 (Lah). He further admitted that he "ha[s] no foundation or basis on which to conclude that … an individual patient will have greater adverse effects going to XR from IR. It's a potential concern, *not a known concern*." JA-243 (Lah) (emphasis added). The court also cited Dr. Berndt's speculation that switching might be medically disruptive, SA-56, but Berndt is an economics PhD with zero basis for opining about medical risks.

In contrast to this speculation, there is the FDA: XR's FDA-approved label confirms that switching is safe and simple. Namenda XR Package Insert, *supra*, at 2. And there is widespread experience: Some 250,000 patients have already switched from IR to XR; New York identified no harm to any of them. And during XR supply shortages in summer 2014, patients who had switched from IR to XR had to switch from XR back to IR, then back to XR. JA-933 (Reisberg); JA-937-38 (Kohrman). New York identified no harm to these patients either. On top of that, Forest introduced *five* Alzheimer's experts; all confirm switching is safe. *Supra* p. 19.

There is more: the court's other findings confirm that patients, caregivers, and physicians have *no need* for Namenda IR because XR is an improvement. The

court credited testimony that reducing the pill burden produces an "exponential difference" for Alzheimer's patients and caregivers and that "[m]any controlled clinical trials have also shown that 'extended-release agents are associated with improved tolerability, greater patient adherence to treatment, reduced total treatment costs, and better long-term clinical outcomes.'" SA-35-36. Dr. Lah testified that there was no "market need" for IR once XR came on the market. JA-815 (Lah). That only confirms that patients are *not* at risk from switching; otherwise, IR would still be needed.

There is no medical risk from switching—but even if there were, distribution through Foundation Care eliminates it. If there are any patients for whom switching presents a medical risk, they will never have to switch; their physicians can sign a one-page form confirming IR's medical necessity. Uncontroverted evidence shows doctors would not hesitate to do so. JA-934 (Reisberg); JA-938-39 (Kohrman). And there is no cap on how much Namenda IR Foundation Care can supply. JA-845 (Saunders); JA-904 (Kane). All the district court said on this point was that doctors who saw *no medical need for IR whatsoever* would be

reluctant to sign Foundation Care's form. SA-69. But that just proves Forest's point.[4]

The court's reasoning that "'[a]ny small change in medication'" might hurt certain patients also proves too much. SA-92 (quoting Lah). As New York's Dr. Berndt agreed, "a lot of Alzheimer's patients . . . are going to have a change in their routine when they get the generic memantine." JA-882 (Berndt). Those generic versions could deliver memantine at a rate and extent that is anywhere between 80-125% of the memantine delivered by Namenda IR. *Supra* pp. 10-12. Generic IR will enter the market without the rigorous clinical safety and efficacy tests that Forest did for Namenda IR. *Id.* Patients could receive drugs from different generic manufacturers with every refill, without choosing this. In short, every refill, patients and caregivers could see drugs with different shapes, sizes, colors, taste, and preservatives that potentially deliver different memantine absorption rates. *Id.* This injunction ensures that cost concerns trump everything else—patient choice, caregiver convenience, and continuity in medication.[5]

[4] The court stated that only 2.4% of patients would be able to obtain the drug under the "'medical necessity' standard." SA-70. Again, no evidence suggests reluctance by doctors worried about medical harm from a change in dosage. Moreover, the 2.4% figure is not a limit on IR's availability for medically needy patients. It is a prediction reflecting the low number of patients who want to stay on IR. SA-67, 70.

[5] Of course state substitution laws allow physicians to write "Dispense as Written" on the prescription so that patients for whom switching could be potentially risky need not switch. But if (as the district court implausibly found) physicians are

Finally, the injunction will delay the launch of Forest's newest fixed-dose-combination innovation, Namzaric, which means two fewer pills for IR patients to take. Those patients, and their caregivers, will lose months of experiencing a beneficial therapy because the court is ordering Forest to instead produce outdated IR tablets. *Infra* pp. 35-40. Even if the district court's finding of irreparable medical harm were correct, the outcome the court ordered is indefensible.

C. The Court Ignored Irreparable Harm to Forest

In any event, the district court erred in holding that the balance of harms favors New York rather than Forest, which suffers demonstrable and significant irreparable harm from the injunction. SA-132-33; *see Random House, Inc. v. Rosetta Books LLC*, 283 F.3d 490, 492 (2d Cir. 2002). Patent law gives Forest an unqualified right to control how it makes, distributes, and sells IR. *Infra* pp. 34-38. The injunction obliterates that right to benefit Forest's future competitors. This infringement upon "the fundamental nature of patents" is alone irreparable harm. *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1149 (Fed. Cir. 2011).

Just complying with the injunction irreparably harms Forest. Until the injunction, Forest no longer made IR. The FDA certified only one Forest plant in Dublin, Ireland to make Namzaric, XR, or IR. The same employees make each

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reluctant to sign a form indicating that Namenda IR is necessary, these same physicians would presumably be reluctant to stop generic substitution with a similar certification.

drug, and the same employees and equipment test them; making IR thus trades off against making XR and developing Namzaric. Obtaining FDA approval for a different factory would take years. JA-994-95 (Stewart). Until the injunction, that factory's Namenda production was exclusively dedicated to XR, and was to begin producing Namzaric, for which XR is a key ingredient. The injunction compels Forest to radically change course and quickly produce IR. Because XR production relies on the same operators and chemists, Forest must alter XR production drastically, which also delays Namzaric's launch. *Id.*; JA-979 (Meury). The district court's finding that Forest would face no "hardship" complying with the injunction is inexplicable. SA-133.

Moreover, Forest's business plan is at a critical stage. The injunction compels Forest to abandon the distribution strategy Forest has been pursuing for months, and will force layoffs and retrenchments. New York's economist testified that Forest will lose [redacted] if Forest cannot transition patients to Namenda XR. JA-877 (Berndt). Forest cannot recover that sum from the State should Forest later prevail. *United States v. New York*, 708 F.2d 92, 93 (2d Cir. 1983) (per curiam). And loss of good will, personnel layoffs, and abandonment of research devoted to developing other uses for a drug are irreparable harms. *Sanofi-Synthelabo v. Apotex Inc.*, 488 F. Supp. 2d 317, 342 (S.D.N.Y. 2006), *aff'd*, 470 F.3d 1368, 1382-83 (Fed. Cir. 2006).

III. New York's Antitrust Claims Fail As a Matter of Law

A. Forest's Patent Rights Foreclose Antitrust Liability

1. Because Forest has merely exercised rights afforded by the Patent Act, its conduct does not violate antitrust law. It has been clear for a century that antitrust liability cannot be premised on the exercise of rights granted by the Patent Act. "The patent laws … are in *pari materia* with the antitrust laws and modify them *pro tanto*." *Simpson v. Union Oil Co. of Cal.*, 377 U.S. 13, 24 (1964). "[A] patent is an exception to the general rule against monopolies and to the right to access to a free and open market," *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945), and a patentee's decision "to exclude others from the use of the invention … is not an offense against the Anti-Trust Act," *United States v. United Shoe Mach. Co.*, 247 U.S. 32, 57 (1918).

The Patent Act defines the scope of the patent: it grants a "patentee … or [its] assigns … the right to exclude others from making, using, offering for sale, or selling the invention." 35 U.S.C. § 154. Patent rights are "the compensation which the law grants for the exercise of invention," and "exerti[ng]" those rights "within the field covered by the patent law is not an offense against the [Sherman] Act." *United Shoe*, 247 U.S. at 57. Thus, the "threshold question" in antitrust cases involving the exercise of a valid patent is whether the conduct "exceeds the

scope of the patent grant." *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1327 (Fed. Cir. 2000) ("*ISO*").

Of course, conduct not authorized by the Patent Act (*e.g.*, tying or restrictive licensing terms) is subject to antitrust scrutiny.[6] Or if there are serious doubts about the patent's validity and parties collusively settle that litigation, patent law may yield to antitrust scrutiny. *See Actavis*, 133 S. Ct. at 2236. But if the defendant exercises core rights on a valid patent, the "inquiry is at an end." *ISO*, 203 F.3d at 1328. As this Court held, "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) (emphasis added).

2. The district court considered Forest's patent rights over Namenda IR and XR so irrelevant as to not even warrant mention, and treated this as a garden-variety antitrust case. SA-113-15. It is not. Forest's right to control or stop IR distribution falls in the heartland of its patent rights. The right not to use a patent encompasses the right not to produce, distribute, market, or sell the patented product. "The essential rights of a patentee … include[] the right to suppress the invention." *United States v. Studiengesellschaft Kohle, m.b.H*, 670 F.2d 1122,

[6] Tying arrangements can trigger antitrust liability because a patentee "may not condition the right to use his patent on the licensee's agreement to purchase, use, or sell, or not to purchase, use, or sell another article of commerce not within the scope of his patent monopoly." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 136 (1969).

1127 (D.C. Cir. 1981). It "has been settled doctrine since at least 1896" that "[a] patent owner … has no obligation either to use [the patent] or to grant its use to others." *Hartford-Empire Co. v. United States*, 323 U.S. 386, 432-33 (1945). A "court should not presume to determine how a patentee should maximize its reward for investing in innovation. … The market may well dictate that the best use of a patent is to exclude infringing products, rather than market the invention." *King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995).[7] The Patent Act, in short, gives Forest an unfettered right to make (or not make) and sell (or not sell) as much (or as little) IR as Forest chooses.

If the above precedents were not enough, Congress amended the Patent Act in 1988 to provide that "refus[ing] to … use any rights to the patent" cannot constitute "misuse or illegal extension of the patent right." 35 U.S.C. § 271(d)(4) (1988). That language insulates non-use of a patent from antitrust liability. *See ISO*, 203 F.3d at 1326. Congress knows how to create antitrust carve-outs: the very next subsection provides that certain tying agreements *could* be "misuse or illegal extension of the patent right" if the patentee has "market power in the relevant market." 35 U.S.C. § 271(d)(5). Congress's "use of explicit language" in

[7] *Special Equip. Co. v. Coe*, 324 U.S. 370, 378 (1945) (Congress "did not" "condition[] [patents] upon the use of the patented invention"); *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436, 457 (1940) (patentees have "right to refuse to sell … patented products"); *Cont'l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 429 (1908) (patentees can "use or not use [their patents], without question of motive"); *Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538, 1547 (Fed. Cir. 1995) (en banc) (similar).

Section 271(d)(5) "confirm[s]" the lack of a comparable limitation in Section 271(d)(4). *Marx v. Gen. Revenue Corp.*, 133 S. Ct. 1166, 1177 (2013). And the legislative history demonstrates that Congress intended Section 271(d)(4) to codify this Court's holding in *SCM* that unilaterally refusing to use or license a patented product cannot violate antitrust law. 134 Cong. Rec. H10646, H10648-02 (Oct. 20, 1988) (statement by primary sponsor Rep. Kastenmeier).

Accordingly, New York's claims are barred, because antitrust law cannot proscribe "the right of the patentee to refuse to sell or license in markets within the scope of the statutory patent grant." *ISO*, 203 F.3d at 1327; *see* 2 ABA Section of Antitrust Law, *Antitrust Law Developments* 1107 (7th ed. 2012) ("[U]nilateral refusal to use … a patent … cannot form the basis for an antitrust claim.").[8]

3. New York asserts that Forest cannot use its patent rights in a way that hampers generic competitors entering the market in July 2015. But the Patent Act confers patent rights for the *entire* patent term. Patents are not designed to ensure that competitors enter the market (much less succeed) the day a patent expires. No court has ever deemed conduct within the scope of the patent a violation of the antitrust laws merely because competitors will find competition tougher later. Instead, a patent includes the right to exclude others from engaging in R&D to

[8] New York does not challenge the IR or XR patents' validity, nor does it dispute that Forest is exercising rights within the scope of those patents. Moreover, "New York has never" argued that Forest engaged in "anticompetitive use of patents." NY Concl. of Law Reply ¶ 23.

develop competing products that would infringe on the patent—even when the result is to delay and impede competitors' market entry post-patent. *Roche Prods., Inc. v. Bolar Pharma. Co., Inc.*, 733 F.2d 858, 864 (Fed. Cir. 1984).[9] Likewise, a firm with a patent monopoly may replace an older product with a newer one during the patent exclusivity period, even if doing so impedes competitors' market entry after the old patent expires. *E.g., Cal. Computer Prods., Inc. v. IBM*, 613 F.2d 727, 744 (9th Cir. 1979) (IBM "had the right to redesign its products …. It was under no duty to help [competitors reliant on its older products] survive or expand.").

New York's contrary rule has no limiting principle, and would inject courts into impossible determinations of how soon into the patent term various patent rights should be curtailed to benefit competitors later. And this rule would allow courts to make basic business decisions about how companies should allocate resources and what products to make. Since the Founding, the federal government has guaranteed patent-holders a limited but absolute right to exclude competition within the scope of the patent. 35 U.S.C. § 154; U.S. Const. art. I, §8, cl. 8. This injunction renders that promise meaningless.

B. Forest's Conduct Would Not Violate Antitrust Law Irrespective of Patents

[9] The Hatch-Waxman Act responded to *Bolar* by authorizing generic drug companies to engage in otherwise infringing research prior to patent expiration. 35 U.S.C. § 271(e)(1). Tellingly, Congress did not otherwise limit a patentee's right to affect post-patent competition through pre-expiration exercise of patent rights.

New York's suit would fail even if the Patent Act did not immunize Forest's conduct. Section 2 of the Sherman Act prohibits companies from obtaining or maintaining monopoly power through exclusionary, anticompetitive conduct. *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966); *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993). New York must show that Forest engaged in "the willful acquisition or maintenance of [monopoly] power" through exclusionary conduct, "as distinguished from … 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). New York also must show that this conduct actually had anticompetitive effect. *Cargill*, 479 U.S. at 110-11.

New York's other claims all derive from its Section 2 claim. The court tied its Section 1 ruling—that Forest likely illegally contracted with Foundation Care to distribute IR—to its Section 2 analysis. SA-125. New York's Donnelly Act claim is entirely derivative of the Section 1 claim; that Act does not prohibit unilateral conduct under Section 2. SA-127-28; *Global Reins Corp.-U.S. Branch v. Equitas Ltd.*, 18 N.Y. 3d 722, 731 (N.Y. App. Div. 2012). New York's Executive Law Section 63(12) claim provides another state remedy for the federal claims. SA-128-29. New York is not likely to prevail on these claims, and cannot show a clear entitlement to relief.

1. Forest Did Not Engage in Any Exclusionary Conduct

a. Product Switches Are Not Exclusionary Conduct

Exclusionary conduct is the *sine qua non* of a Section 2 claim. *Trinko*, 540 U.S. at 407. "The antitrust laws … were enacted for the protection of competition not competitors." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977) (internal quotations omitted). Exclusionary conduct "comprehends at the most behavior that not only (1) tends to impair the opportunities of rivals, but also (2) either does not further competition on the merits or does so in an unnecessarily restrictive way." *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 605 n.32 (1985) (internal quotations omitted).

Forest has done nothing to prevent "competition on the merits" by generics. Forest has not locked up generic suppliers or distributors through exclusive dealing contracts. Forest has not engaged in any tying arrangement. Nor has Forest refused to deal with its competitors, denying them the supply of some input or access to some facility necessary for them to compete. All Forest has done is reduce its competitors' ability to free-ride on prescriptions for an older version of Namenda. But preventing free-riding is not anticompetitive or exclusionary conduct and does not violate Section 2. *E.g.*, *Morris Commc'ns Corp. v. PGA Tour, Inc.*, 364 F.3d 1288, 1295 (11th Cir. 2004) (rejecting Section 2 claim where

conduct was intended to prevent free-riding); *Olympia Equip. Leasing Co. v. W. Union Tel. Co.*, 797 F.2d 370, 372-73, 377-78 (7th Cir. 1986) (Posner, J.) (same).

Before July 2015, Forest seeks to limit distribution of its older product so that consumers buy its newer product. That conduct cannot harm competition because, before July 2015, Forest is the only seller of memantine-based drugs. Competition between XR and IR is competition between Forest's own drugs. Such competition within the same firm raises no antitrust concern, as "implement[ing] a single, unitary firm's policies" does not "deprive[] the marketplace of the independent centers of decisionmaking that competition assumes and demands." *Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 771 (1984). Even had Forest denied consumers any access to IR—which it will not—product withdrawal is not exclusionary conduct. Refusals to supply customers (like when Coke pulled Coke Classic from the market in favor of New Coke) do not raise antitrust concerns. *E.g.*, *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1358 (Fed. Cir. 1999). And New York's economist Dr. Berndt conceded that patients who switch from IR to XR before July 2015 get a "lower priced product" that is "good for the consumers." JA-887 (Berndt). The district court confirmed this: the court found that XR substantially benefits patients and caregivers by reducing the pill burden and increasing convenience and compliance. SA-35-36.

After July 2015, Forest's conduct is not anticompetitive. If anything, there will be a surfeit of competition. Five generic manufacturers plan to enter the market in July alone and can compete vigorously. *Supra* p. 21. New York has not alleged that Forest blocked generic IR's approval. *Compare Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408, 424-28 (D. Del. 2006). Nor has Forest allegedly blocked access to the research and information needed to make generic IR. *Compare In re Suboxone Antitrust Litig.*, 2014 WL 6792663, at *3-4 (E.D. Pa. Dec. 3, 2014). Nor has Forest impeded access to product distribution channels. *Compare United States v. Microsoft Corp.*, 253 F.3d 34, 59-62 (D.C. Cir. 2001) (en banc). Quite the contrary: pharmacies have huge financial incentives to distribute generic IR. The end result: Physicians and patients can choose generic IR if they want it.[10]

[10] The district court's examples of when "[a] monopolist's decision to withdraw a product … constitutes exclusionary conduct," SA-114, reinforce that Forest's conduct is *not* exclusionary. *Glen Holly Entertainment v. Tektronix Inc.*, 352 F.3d 367, 372 (9th Cir. 2003), recognizes that "antitrust laws do not preclude any manufacturer from independently discontinuing a product line." In *Xerox Corp. v. Media Sciences International*, 511 F. Supp. 2d 372, 387-89 (S.D.N.Y. 2007), Xerox was a monopolist in both the color printer and printer ink cartridge markets; it redesigned color printers so that rivals' ink cartridges—which work only with a printer—could not be used. *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 287 n.39 (2d Cir. 1979), similarly hypothesizes that a monopolist in film and camera markets could violate antitrust law if it stopped making film that fit rivals' cameras, rendering rivals' products unusable. But the Supreme Court has never endorsed an "essential facilities" theory, *Trinko*, 540 U.S. at 410-11, and consumers do not need to take Namenda IR for generic IR to work. In *Free Freehand Corp. v. Adobe Systems Inc.*, 852 F. Supp. 2d 1171, 1181 (N.D. Cal. 2012), plaintiffs claimed that conduct lawful in isolation became unlawful in combination. The district court misquoted the decision, which states: "it is reasonable to infer that Adobe's discontinuation of FreeHand, in aggregate with Adobe's other conduct, reduced competition." *Id.* at 1183.

b. Reducing Competitors' Profits from State Substitution Laws Is Not Exclusionary Conduct

The district court concluded that antitrust law "requires [Forest] to allow generic competitors a fair opportunity to compete using state substitution laws" by keeping IR on the market and selling it at significant levels past July 2015. SA-95-96, SA-137-38; *accord* SA-80 ("[S]tate substitution laws" create "the principal means by which generics are able to compete."). According to the court, by reducing the number of IR prescriptions outstanding in July 2015, Forest will violate Section 2 by preventing generic manufacturers from solely relying on state substitution laws to award them 80-90% of sales in July 2015. SA-48, SA-111-12.

Neither the Supreme Court nor this Court has endorsed this type of analysis, which vitiates settled antitrust principles. The injunction compels Forest to continue distributing IR so that its competitors can free-ride on that product to cannibalize its sales. Forest has no such obligation. The Seventh Circuit rejected a competitor's claim that a monopolist that had previously advertised for its rivals had to keep doing so once a competitor "could not survive without access" to this advertising. *Olympia Equip.*, 797 F.2d at 372-33, 377. The court held that "a firm with lawful monopoly power has no general duty to help its competitors, whether by holding a price umbrella over their heads or by otherwise pulling its competitive punches." *Id.* at 375. A competitor "ha[s] no right under antitrust law to take a free ride on its competitors' sales force …. Advertising a competitor's products

free of charge is not a form of cooperation commonly found in competitive markets; it is the antithesis of competition." *Id.* at 377-78; *see Pac. Bell Tel. Co. v. LinkLine Commc'ns, Inc.*, 555 U.S. 438, 449-51 (2009).

New York's theory would require Forest not merely to "help its competitors" through advertising or other indirect assistance, but literally to hand over sales. The more IR Forest produces and sells between now and July 2015, the more prescriptions state law will convert into sales for generic competitors. If a business has no antitrust duty to advertise for its competitors, it certainly has no duty to maximize its competitors' market share.

And the district court's contradictory opinion illustrates the absurdity of imposing such a duty. The court deemed Forest's conduct anticompetitive, yet concluded that Forest could use different means to achieve the *same* outcome of reducing IR sales now to reduce generic IR substitution later. The court stated that "soft switches"—*e.g.*, using marketing to get consumers to change products—were "the industry practice." SA-96-97. A soft switch, the court concluded, is *lawful*, because it "maintains consumer choice before and after generic entry." SA-130. New York's economist, Dr. Berndt, testified that it would *not* be anticompetitive for Forest to increase IR's price "ten fold," which would effectively end demand for IR. JA-886 (Berndt). In other words, it is "a legitimate soft switch tactic" for

Forest to stop selling Namenda IR by eliminating demand, yet limiting IR distribution is somehow unlawful. *See id.*

This nonsensical distinction ignores basic laws of supply and demand and is inimical to antitrust law, which treats charging high prices for a product and refusing to supply it as identical. *E.g.*, *LinkLine*, 555 U.S. at 450 ("[F]or antitrust purposes, there is no reason to distinguish between price and nonprice components of a transaction."); *W.L. Gore & Assocs., Inc. v. Carlisle Corp.*, 529 F.2d 614, 623 (3d Cir. 1976) (similar). If a soft switch that prevents state substitution laws from converting Namenda IR prescriptions to generic IR is not exclusionary, *a fortiori* a so-called "hard switch" with the same effect is not either. Equally unclear is how much of a limit on distribution is too much. Would Forest violate antitrust law if only 30,000 of the 59,000 pharmacies that carry IR now would carry it in July? Could Forest announce tomorrow that it will withdraw Namenda IR from the market the day the injunction expires? Nor is it apparent why Forest must keep selling IR 30 days after generic entry, versus 15 or 45. All New York's economist, Dr. Berndt, offered was: "I'm not sure what the rationale" for requiring Forest to keep selling IR past July 2015 "would be other than punitive." JA-892 (Berndt).

The imponderables and inconsistencies do not end there. New York suggests that the problem here was timing: Forest sought to withdraw IR as it

"fac[ed] imminent" generic entry. JA-605 (Am. Compl.). So Forest presumably could have withdrawn IR one or two years before generic entry—yet that would have the same effect, if not greater, on generics. New York says that Forest's conduct is only anticompetitive if its new drug is not "better than the original," or "offer[s] little to no therapeutic advantage over the prior versions." JA-616 (Am. Compl.). So Forest presumably could withdraw IR if a sufficient consensus of scientists (or doctors? or FDA regulators?) rated XR's benefits highly enough over IR. Antitrust law cannot turn on such arbitrary and unworkable distinctions.

c. Antitrust Law Is Not a Vehicle for Enforcing the Spirit of Drug Laws

The district court found that Forest "attempt[s] to manipulate the regulatory system," SA-29, and "violat[e] the spirit of the Hatch-Waxman Act," SA-135. But even if Hatch-Waxman or state substitution laws imposed a duty on Forest to keep selling IR for generics' benefit (they do not), that would be irrelevant to New York's antitrust claims. The Supreme Court rejected a nearly identical argument in *Trinko*, finding that Verizon's duty under the Telecommunications Act to aid a competitor does "not automatically lead to the conclusion that [this duty] can be enforced by means of an antitrust claim." 540 U.S. at 406; *see In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 135 (2d Cir. 2014).

If antitrust law is unavailable to enforce actual regulatory obligations, it is not a vehicle for enforcing laws that *permit* the conduct at issue. Forest's conduct

violates neither Hatch-Waxman nor state substitution laws, and no one has suggested otherwise. (That is presumably why the district court (SA-135) invoked their "spirit.") And Congress passed Hatch-Waxman to encourage brand innovation and facilitate generic entry into the market, not to guarantee generic manufacturers total market dominance thereafter. *Supra* pp. 10-11.

Moreover, New York has a remedy that will not explode the reach of antitrust law. New York's claim stems from the fact that if patients in July 2015 are on XR rather than IR, New York's generic substitution law does not automatically convert those prescriptions into generic IR. But that is only because New York's law considers drugs of different dosages too different for pharmacists to automatically substitute them. No federal law imposes this rule. New York actually posits that drugs of different dosages—here, XR and IR—are "virtually identical." JA-606 (Am. Compl.). If so, New York can amend its law and make pharmacists substitute generic IR for Namenda XR.

At bottom, the district court's approach makes it impossible to apply the Sherman Act on a uniform, nationwide basis. If changing the effect of generic substitution laws is an antitrust violation, it exists only in states where pharmacists can automatically substitute generic IR for Namenda IR but not XR. But in up to 20 other states, there is no violation; pharmacists can substitute generic IR for XR. *Supra* p. 13. Courts, however, must interpret antitrust law in ways that guarantee

"clear rules" that require minimal judicial supervision. *LinkLine*, 555 U.S. at 452-53. The Sherman Act's meaning cannot turn on the vicissitudes of state law.

2. Forest's Conduct Will Not Have Anticompetitive Effects

The anticompetitive harms that the district court predicted do not support liability. The court found that generics do not advertise, and if they must start instead of relying on state substitution laws, they will have to raise prices. SA-78-79. But the need to advertise is proof of effective competition, not its absence. When a company "obligate[s] [its competitor] to increase its own advertising, competition [is] only enhanced," because "advertising and promotion [are] essential to vigorous market rivalry." *Covad Commc'ns Co. v. Bell Atl. Corp.*, 398 F.3d 666, 674-75 (D.C. Cir. 2005). The court's finding also is clearly erroneous; New York's own competition expert testified that generics can use general marketing effectively to generate sales, and can form joint ventures to advertise. JA-887 (Berndt).

The district court found that inducing physicians to switch patients to XR risks harming patients whose health could be jeopardized by "[a]ny small change in medication." SA-92 (quoting Lah). Even if this finding were supportable—it is not, *supra* pp. 28-32—antitrust law remedies only "injur[y] [to] business or property," *i.e.*, economic "loss or damage." 15 U.S.C. §§ 15(a), 26. The terms "'business or property' …. *exclude personal injuries suffered*." *Reiter v. Sonotone*

Corp., 442 U.S. 330, 339 (1979) (emphasis added). Concerns about "public safety" and health may be part of other statutes, but importing them into the Sherman Act "would be tantamount to a repeal of the statute" and "a frontal assault on [its] basic policy." *Nat'l Soc. of Prof'l Eng'rs v. United States*, 435 U.S. 679, 690 (1978). If New York sought to vindicate such concerns, it should have sued under another law.

The district court found that if patients are doing well on Namenda XR, physicians might not switch patients to generic IR come July 2015. SA-72, 90-91, 120-21. But the first firm in a market often enjoys an incumbency advantage by virtue of having had a lawful monopoly before new competitors enter, and new entrants always bear the burden of convincing customers to switch. The advantage of being first is precisely the type of reward for "superior skill, foresight and industry" that antitrust law encourages. *United States v. Aluminum Co. of Am.*, 148 F.2d 416, 430 (2d Cir. 1945) (Hand, J.).

Undoubtedly, trying to persuade physicians and patients to switch to generic IR—*i.e.*, *competing*—takes greater effort from generic manufacturers than relying on the coercive effect of state substitution laws. But antitrust law encourages that additional effort, which in any event entails a single phone call from pharmacists to persuade physicians to switch the patient to generic IR. *See* SA-58. And the record belies the notion that such competitive efforts are doomed to fail. Were that

so, no slew of generic manufacturers would be expected to enter the market in July and October 2015. And once they enter, the wind will be at their sails, regardless of state substitution laws: using powerful incentives and leverage, third-party payors and pharmacists will pressure physicians, patients, and caregivers to switch to generic IR. *Supra* pp. 14-15.[11]

The district court found that Forest's conduct limits patients' choices, and patients and insurance companies may ultimately pay more. SA-91, SA-131-32. But as noted, before July 2015 this harm is illusory. The loss of choice among a single firm's products is not anticompetitive (even if that firm is a monopolist), and XR costs less than IR. *Supra* p. 41. After July 2015, patients lose no choice. They can choose among generic IR, XR, Namzaric (once it launches), and IR oral solution. New York's substitution law will work as intended: unless doctors specify otherwise, pharmacists will fill Namenda IR prescriptions with generic IR. If patients and insurance companies pay more for memantine-based drugs, that is the market's choice. Claims that conduct "has the effect of reducing consumers' choices or increasing prices to consumers do[] not sufficiently allege an injury to

[11] The only contrary evidence came from New York's witness David Stitt, who is employed by a minor regional healthcare provider and concedes he does not know how his company will act in July 2015, or know about state substitution laws or conditions outside New York. JA-829, JA-831-32 (Stitt). The court erred in relying on Stitt for generalizations about the national market.

competition," because "[b]oth effects are fully consistent with a free, competitive market." *Brantley v. NBC Universal, Inc.*, 675 F.3d 1192, 1202 (9th Cir. 2012).[12]

3. Forest's Conduct Is Procompetitive

a. New York's claims independently fail because Forest's conduct is *pro*competitive. Forest's 2013 introduction of XR eliminated any market need for IR tablets. Forest then sought to maximize its return on its investment in XR. That is the kind of behavior antitrust law encourages. The Sherman Act must be interpreted in ways that "safeguard the incentive to innovate," *Trinko*, 540 U.S. at 407, and "any dampening of technological innovation would be at cross-purposes with antitrust law," *Microsoft*, 147 F.3d at 948. Launching a new product, like Forest did here, advances competition by adding a better product to the market and by paving the way for further innovation.

This is a case in point. The Patent and Trademark Office issued patents for Namenda IR and XR, and the FDA, through its arduous approval process, confirmed that both drugs are safe and therapeutically beneficial. That alone shows these products are not shams created just to thwart generics. Moreover, Forest worked to develop XR because the market demands once-daily drugs; every other Alzheimer's drug is once-daily. *See* SA-35. Extensive record evidence

[12] *Accord Meijer, Inc. v. Biovail Corp.*, 533 F.3d 857, 867 (D.C. Cir. 2008); *Doctor's Hosp. of Jefferson, Inc. v. S.E. Med. Alliance, Inc.*, 123 F.3d 301, 310 (5th Cir. 1997).

confirms that XR offers significant benefits over twice-daily IR. Once-daily dosing reduces risk of a missed dose; alleviates burdens on caregivers who manage complex pill schedules; helps patients suffering dementia who resist pills; and makes it easier for patients to stay with their families for longer. *Supra* pp. 17-18.

Unrebutted testimony from Forest's five expert medical witnesses confirms these conclusions. *Supra* pp. 19-20. New York's fact witness Dr. Lah agreed that with XR, there is no "market need" for IR tablets. JA-815 (Lah). While the district court castigated follow-on drugs that "offer little to no therapeutic advantage over the prior formulation," SA-29, the court *credited* testimony about XR's benefits. SA-35. It would have been impossible for Forest to develop Namzaric without including the XR formulation. JA-993-94 (Stewart). And empirical evidence confirms that much of the market prefers XR to IR. JA-915-16 (Meury). As Actavis's CEO explained, "[W]hat we hoped for and what we'll have to see what plays out when generic competitors enter the market in 2015 is do patients and physicians and caregivers, you know, view the innovation of XR important enough to pay for it … [P]eople will have that chance to vote with their wallets." JA-836 (Saunders); *see* JA-372-73 (Hausman).

Withdrawing an old drug while promoting a new one is also procompetitive. Preventing "free-riding" by competitors is a legitimate business purpose. *See*

Cont'l T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36, 55 (1977). And Forest's conduct is common in the pharmaceutical industry. In 2002, Allergan withdrew its older glaucoma treatment to favor a new version with a different preservative; generics entered a year later and still captured a 50% market share. JA-304-05 (Kolassa). In 2011, ISTA Pharmaceuticals stopped selling its twice-daily anti-inflammatory drug, and promoted a once-daily version. Again, generics captured significant sales after entering the market months later. Other examples abound. JA-285-88, JA-303-08 (Kolassa).

The district court also found that Forest's conduct would cost Forest short-term profits from IR sales. SA-123. But short-term costs do "not distinguish anticompetitive from procompetitive uses of innovation." Areeda & Hovenkamp, Antitrust Law, ¶ 651 (2014). The court ignored the above procompetitive justifications, and discounted the more than [redacted] in additional XR sales that Forest stood to earn.

The court also found that "[c]ontinuing to keep IR tablets available is highly unlikely to have any impact on [Forest's] incentive to innovate," because Forest previously "launched 8-9 new drugs" without limiting distribution. SA-76. But this injunction compels Forest to produce a first-generation, 10-year-old drug with no market need. And Forest must do so at the expense of selling new and improved XR or launching Namzaric because of its production constraints. The

injunction thus impedes Forest's ability to bring newer innovations to the marketplace *at this very moment*. *See* JA-982-83 (Meury), JA-993-94 (Stewart).

b. New York contends that Forest's conduct cannot be procompetitive because XR is not "truly" innovative. *E.g.*, JA-616 (Am. Compl.). Overwhelming evidence refutes that position. *Supra* pp. 19-20, 31-32. But the dangers of this position bear emphasis. Under this theory, courts—not scientists, regulators, or markets—decide when a new version of a drug is sufficiently ingenious to avoid antitrust liability. If changing dosage form halted all patient deterioration, Forest could presumably pull IR from the market with impunity. Yet any benefits short of this—including, apparently, XR's conceded benefits of convenience and patient compliance—are not innovative enough. Courts are not equipped to make these kinds of medical and scientific judgments, let alone to second-guess the judgments the PTO and FDA already made.

4. New York's Section 1 Claim Independently Fails

New York's Section 1 (and Donnelly Act) claims rest on the counterintuitive theory that Forest violated antitrust law by agreeing to distribute IR through Foundation Care, rather than pulling IR entirely. Rather than looking at the effects of this distribution agreement, the district court reasoned that Forest's conduct was

anticompetitive under Section 2; thus, any agreements that advanced this conduct violated Section 1 also. SA-125-26.

That was the wrong inquiry under Section 1, which only prohibits agreements that "unreasonabl[y] restrain … trade." *E & L Consulting, Ltd. v. Doman Indus. Ltd.*, 472 F.3d 23, 29 (2d Cir. 2006). To hold that Section 1 is violated just because of the predicted (not actual) impact Forest's change in distribution would have on the market, New York had to identify collusive conduct that is *per se* anticompetitive. *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 885-86 (2007). It did not.

Forest's agreement with Foundation Care is subject to the rule of reason, because "[a] manufacturer of course generally has the right to deal, or refuse to deal, with whomever it likes." *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 761 (1984). An "exclusive distributorship arrangement[]" thus is "presumptively legal" under Section 1. *E & L Consulting*, 472 F.3d at 30 (internal quotations omitted). Alleging that customers had less choice in suppliers, or even paid higher prices, "is not a sufficient allegation of harm to competition caused by the exclusive distributorship." *Id*. Rather, such agreements violate Section 1 only if they "will have an actual adverse effect on competition in the relevant market," which requires more than a reduction in the number of firms that distribute Forest's products. *Elecs. Commc'ns Corp. v. Toshiba Am. Consumer Prods., Inc.*, 129 F.3d

240, 244 (2d Cir. 1997). Because Forest's agreement to distribute IR solely through Foundation Care does not harm generic competition, it is of no concern to antitrust law. *E.g.*, *Cowley v. Braden Indus., Inc.*, 613 F.2d 751, 755 (9th Cir. 1980). That is especially true because there is zero evidence that Forest agreed with Foundation Care to cap IR sales. Undisputed evidence shows the contrary. JA-845 (Saunders); JA-904 (Kane).

The district court's reasoning would open the floodgates to antitrust liability. Any subsidiary agreement a Section 2 defendant entered into would trigger separate Section 1 liability. And all counterparties to these subsidiary agreements could face Section 1 liability as well.

IV. The Injunction Is Vague and Overbroad

Independent of anything else, this Court must vacate the injunction as impermissibly vague and overbroad. An injunction must "state its terms specifically" and "describe in reasonable detail … [the] acts sought to be restrained." Fed. R. Civ. P. 65(d). Any order that fails to do so "will not withstand appellate scrutiny," because of "the dangers inherent in the threat of a contempt citation for violation of an order so vague that an enjoined party may unwittingly and unintentionally transcend its bounds." *Corning*, 365 F.3d at 158. Likewise, "courts must take care to ensure that injunctive relief is not overbroad," because "a court is only empowered to grant relief no broader than necessary to cure the

effects of the harm caused by the violation." *City of New York v. Mickalis Pawn Shop, LLC*, 645 F.3d 114, 144 (2d Cir. 2011) (internal quotations omitted). The district court ignored these maxims.

1. The injunction orders Forest to "make" IR "available on the same terms and conditions applicable since July 21, 2013 (the date Namenda XR entered the market)." SA-137. Given how terms and conditions have shifted over the past 17 months, that is an unintelligible command. IR's price fluctuated both in absolute terms and relative to XR. Adding to the confusion, XR entered the market in June 2013, not July. *Supra* p. 17. The only conduct the injunction specifically prohibits is for Forest to "impose a 'medical necessity' requirement or form for the filling of prescriptions of Namenda IR." SA-138. It is simply "not possible to ascertain from the four corners of the order precisely what acts are forbidden." *Corning*, 365 F.3d at 158 (internal quotation marks omitted).

At the injunction hearing, Forest's counsel sought clarification of what the "same terms and conditions" means. JA-1017. No clarification came. The court responded, "Let's stop right there. … You have been negotiating with distributors over this entire period. If you do it consistent with what you have been doing, I don't see why it isn't consistent … but I am not going to give you any absolution absent the facts." *Id.* The court elaborated: "I am not unaware of the difficulties that this creates for the parties," but "I am not going to interpret the language any

more than you all. You will have to see what you think it means. I think I know what it means, but we will see." *Id.* Forest's counsel followed up: "[O]ne question we have … is whether [the order] freezes the price exactly at the price as of that date." *Id.* The court replied: "[Y]ou will have to make your own conclusion," and added, "I am not going to change the words. Good luck." *Id.*

Understanding what an injunction means should not require luck. The injunction must "state its terms specifically." Fed. R. Civ. P. 65(d). But this injunction's ambiguity places "the entire conduct of [Forest's] business under the jeopardy of punishment for contempt for violating the injunction." *Sanders v. Air Line Pilots Assoc., Int'l*, 473 F.2d 244, 248 (2d Cir. 1972). The Supreme Court has vacated injunctions that vaguely enjoined defendants from "enforc[ing] 'the[ir] present [] scheme.'" *Schmidt v. Lessard*, 414 U.S. 473, 476-77 (1974). This Court has similarly vacated injunctions that compel defendants to take "appropriate prophylactic measures" without specifying particular conduct. *Mickalis Pawn*, 645 F.3d at 144. Ordering Forest to conform its conduct to undefined, shifting conditions over a 17-month period likewise deprives Forest of "explicit notice of precisely what conduct is outlawed." *Schmidt*, 414 U.S. at 476. On pain of contempt, Forest must apply to the court to approve decisions concerning IR going

forward—exactly the kind of economic micromanagement that the Supreme Court rejects in antitrust cases. *E.g.*, *LinkLine*, 555 U.S. at 452-54.

2. The nationwide injunction (*see* SA-137-38) is also fatally overbroad. Under New York's theory, there is no antitrust harm in the up to 20 states whose generic substitution laws allow pharmacists to automatically substitute generic IR for Namenda XR. In those states, generics can still capture 80-90% of sales, averting all alleged antitrust harms. *Supra* pp. 15-16. This alone was an abuse of discretion. *E.g.*, *Emergency One, Inc. v. Am. Fire Eagle Engine Co., Inc.*, 332 F.3d 264, 274 (4th Cir. 2003) (vacating "nationwide injunction" absent "factual basis" for finding nationwide violation). Nor is this defect easily remedied. On remand, the court would have to parse states' varying generic substitution laws to determine which states allow this type of substitution. Some states, for instance, leave substitutability up to pharmacists' professional judgments. *E.g.*, Minn. Stat. Ann. § 151.21. Determining what that means, and whether generic IR can be substituted for Namenda XR, is a state-by-state task. This is why state laws should not control what the Sherman Act means.

The injunction is also overbroad because it forces Forest to offer IR tablets to *new* patients until 30 days after generic entry on July 11. SA-137-38. The district court's reasoning did not remotely justify this. Patients whose doctors decide to prescribe them a memantine-based drug after generic entry start from

scratch. They have no prescriptions for state substitution laws to convert into generic IR prescriptions. Yet the injunction compels Forest to offer new patients an old prescription drug. And the complexity of distinguishing between new and existing patients would require additional fact-finding. This is why courts should not seize control and supervision of day-to-day business operations.

CONCLUSION

The district court's injunction breaks dangerous new ground. No court before has nullified a manufacturer's valid patent rights and commandeered its factory to aid future competitors. No federal agency has this power. Even the FDA, with its extraordinary control over the pharmaceutical industry, cannot "require a company to manufacture a drug, maintain a certain level of inventory … or reverse a business decision to cease manufacturing." FDA, *Strategic Plan for Preventing and Mitigating Drug Shortages*, at 6 (Oct. 2013), http://1.usa.gov/1xEUBAC. Allowing courts to assume these powers is unprecedented, dangerous, and unwarranted. The decision and injunction below should be reversed.

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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
cmoore@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

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/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 Final Form 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 Final Form 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 20, 2015

/s/ Lisa S. Blatt
Lisa S. Blatt