14-4624

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

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

v.

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

On Appeal from the United States District Court for the Southern District of New York, No. 1:14-cv-07473, Before the Honorable Robert W. Sweet

BRIEF FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS AMICUS CURIAE IN SUPPORT OF APPELLANTS

DAVID W. OGDEN
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Ave., NW
Washington, DC 20006
(202) 663-6000

MARK A. FORD
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000

Attorneys for the Pharmaceutical Research and Manufacturers of America as Amicus Curiae in Support of Appellants

January 15, 2015

CORPORATE DISCLOSURE STATEMENT

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a membership organization. PhRMA has no parent corporation, and no publicly traded company owns 10% or more of its stock. PhRMA's membership, however, includes companies that have issued stock or debt securities to the public. A list of PhRMA's members is available at http://www.phrma.org/about/member-companies.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES AND RULES

OTHER AUTHORITIES

INTEREST OF *AMICUS CURIAE*[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing leading research-based pharmaceutical and biotechnology companies. PhRMA's members[2] are the primary source of the many new drugs and biologics introduced each year. PhRMA members invest billions of dollars in discovering and developing new medicines, including $51 billion in 2013 alone. *See* PhRMA, *2014 Biopharmaceutical Research Industry Profile* 27 (2014), *available at* http://www.phrma.org/sites/default/files/pdf/2014_PhRMA_PROFILE.pdf ("*2014 Industry Profile*"). PhRMA frequently files *amicus* briefs in cases raising matters of significance to its members.[3]

PhRMA has a strong interest in this case as product improvements such as the one involved here are a common and vital means of innovation and competition in the pharmaceutical industry. PhRMA members invest billions researching, developing and marketing new versions of existing medicines, and that investment

---

[1] Pursuant to Federal Rule of Appellate Procedure 29 and Local Rule 29.1, PhRMA states that no party or party's counsel authored this brief in whole or in part. PhRMA further states that no party, party's counsel, or any other person other than PhRMA, its members, or its counsel contributed money that was intended to fund preparing or submitting this brief.

[2] Defendant Actavis plc is a member of PhRMA. A complete list of PhRMA members is available at http://www.phrma.org/about/member-companies.

[3] All parties have consented to the filing of this brief. See Federal Rule of Appellate Procedure Rule 29(a).

results in products that improve and extend the lives of patients. The district court's preliminary injunction—forcing the innovator of a new, improved product to continue to manufacture, sell and support a legacy product solely for the benefit of generic rivals—is unprecedented. The order not only undermines incentives to innovate, but it also proceeds from a misapplication of fundamental antitrust principles. For these reasons, the preliminary injunction should be overturned.

SUMMARY OF ARGUMENT

Under the auspices of the antitrust laws, the district court issued a preliminary injunction that imposes an unprecedented duty on the innovator of a new, improved pharmaceutical to continue to manufacture, sell and support an older version of that drug.[4] The court invoked Section 2 of the Sherman Act, 15 U.S.C. § 2, to require the innovator to support such sales—at significant cost and with an adverse effect on the marketing of the innovator's new product—simply to facilitate its generic competitors' ability to take advantage of automatic generic

[4] As detailed below, the district court's preliminary injunction requires Defendants-Appellants Actavis, plc and Forest Laboratories, LLC (together, "Forest") to continue making, selling and supporting the immediate release version of Namenda ("Namenda IR"). Forest has stated that it planned to discontinue full-scale distribution of Namenda IR after it launched a new, extended release version ("Namenda XR"), while maintaining limited distribution of Namenda IR through a specialty pharmacy, Foundation Care, for patients and prescribers who believe that use of Namenda IR is medically necessary.

substitution under mechanisms established by state law.[5] No principle of antitrust law supports this outcome.

To the contrary, courts have repeatedly made clear that Section 2 must be carefully applied so as not to dampen competition. Even monopolists are allowed and indeed encouraged to compete vigorously on the merits, especially by means of innovation and product improvement. This principle is critically important in the biopharmaceutical marketplace where innovation is the lifeblood of competition and yields dramatic benefits to consumers in the form of new drugs and treatment methods. Requiring a pharmaceutical company that has developed a new, successor product to continue manufacturing, distributing and supporting a prior version of the product—to the company's own detriment—deters innovation and is antithetical to the purpose of the antitrust laws.

To ensure that the antitrust laws are not employed to shield competitors *from* competition, Section 2's prohibition is narrow and extends only to ***exclusionary*** conduct—acts that foreclose competition or render rivals unable to compete effectively. The challenged conduct does neither. It is undisputed that Forest's

---

[5] The district court also held that the Attorney General "demonstrated a substantial question exists as to the legality" of Forest's limited distribution agreement with Foundation Care under Section 1 of the Sherman Act, 15 U.S.C. § 1, and under New York's Donnelly Act, N.Y. Gen. Bus. Law § 340. SA-127-128. Those determinations, however, were expressly based on the court's erroneous holding that Forest's limited distribution plan violated Section 2. *See* SA-124, SA-127.

plans for its Namenda (memantine) franchise will not block or delay entry by generic competitors. Nor will Forest's business plans prevent patients or their doctors or other market actors from choosing on the merits (including price) among branded and generic memantine offerings. Accordingly, if generic companies and other market actors wish to increase generic sales by encouraging the use of generic versions of Namenda IR over branded Namenda XR, they may do so. Forest has done nothing to render generic companies and other firms incapable of undertaking marketing and promotional efforts to that end. Therefore, because Forest's conduct is not exclusionary, the fundamental prerequisite for a Section 2 monopolization claim—and thus for the district court's unprecedented injunction—is lacking.

Although the district court found that discontinuing full-scale distribution of Forest's legacy product would likely slow the adoption of generic versions of Namenda IR when those products become available, that cannot form the basis of an antitrust injunction. Section 2 does not require a company—even if a monopolist—to facilitate the growth of its rivals. Nor does Section 2 condemn a monopolist's conduct merely because some other course might have been more helpful to its competitors. Despite these core antitrust principles, the district court justified its antitrust injunction as necessary to further the goals of New York's generic drug substitution laws. But those laws are not designed to promote

competition as the antitrust laws are; instead, they make it unnecessary for one class of manufacturers (generics) to engage in the normal incidents of effective competition, such as acquiring market share through marketing, promotion, service and product quality. And even on their terms, New York's substitution laws do not impose any duty on a company to continue to make, sell and support a superseded product. By purporting to find such a duty in the federal antitrust laws, the district court violated the Supreme Court's mandate that the antitrust laws not be applied to advance different goals of other statutory regimes.

Accordingly, PhRMA respectfully submits that this Court should reverse the district court's preliminary injunction order.

BACKGROUND

The average innovator drug requires 10 to 15 years to develop and costs in excess of $2.5 billion when factoring in the unavoidable reality that many investments do not result in marketable products. *See 2014 Industry Profile* at 45; Tufts Center for the Study of Drug Development & Tufts School of Medicine, *Briefing: Cost of Developing a New Drug* 5, 18 (Nov. 18, 2014), *available at* http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf ("*Tufts CSDD Briefing*"). Indeed, the nature of scientific research and development is that the likelihood of commercial success for any individual new initiative is small. Tens of thousands of compounds may be

screened early in development, but only one ultimately may receive approval. *2014 Industry Profile* at 45. Most compounds never reach the clinical trial phase of development and, of those that do, less than 12% are approved by the Food and Drug Administration ("FDA"). *2014 Industry Profile* at 45-47; *Tufts CSDD Briefing* at 17. After FDA approval, the average effective exclusivity period for new drugs is only 12.9 years. Grabowski, Henry, et al., *Recent Trends in Brand-Name and Generic Drug Competition*, 17 J. Med. Econ. 207, 211 (2014) ("Grabowski, et al., *Recent Trends*"). Ultimately, even out of every 10 new drugs that reach the market, only 2 earn revenues that match or exceed research and development costs. Vernon, John A, Joseph H. Golec, & Joseph A. DiMasi, *Drug Development Costs When Financial Risk is Measured Using the Fama-French Three-Factor Model*, 19 Health Econ. 1002, 1004 (2010).

One important and beneficial way pharmaceutical companies innovate is by improving existing products. If approved by FDA, product improvements can enjoy a period of regulatory exclusivity and, in some cases, patent exclusivity. Some of the most important medical advances involve improvements to existing medicines, such as improved delivery systems or dosage forms, or expanded uses of approved products. *2014 Industry Profile* at 48. In 2012 alone, PhRMA members spent an estimated $6.7 billion on Phase IV clinical trials involving research on already-approved products. *Id.* at 71. When successful, this research

has resulted in the launch of product compositions, formulations, and/or applications that improve or extend the lives of patients. For example, progress in the battle against HIV and AIDS followed this path and depended on constant learning about the optimal use of HIV drugs following FDA approval, including the development of a one-pill-once-a-day treatment in 2006. *See id.* at 8-9. Given the investments that innovators make to improve existing products, innovators also devote manufacturing, distribution, marketing and sales resources to successfully launch the new product.

While innovator companies are responsible for the discovery of therapeutic breakthroughs, generic versions of innovator drugs today comprise the substantial majority of prescription sales in the United States. In 2013, 86% of prescriptions dispensed were generics, up from 49% in 2000. *Id.* at *ii*. Unlike their branded counterparts, generic companies need not and typically do not undertake the costly and time consuming effort of discovering safe and effective treatments, and they can obtain FDA approval without investing in expensive clinical studies. *See* FDA, *Abbreviated New Drug Application (ANDA): Generics*, *available at* http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/.

In addition, most states—including New York—have enacted laws allowing or even requiring pharmacists to fill branded-drug prescriptions with available generics that meet the FDA's bioequivalence requirements (so-called "AB-rated" generic drugs). *See* Nat'l Ass'n of Boards of Pharmacy, *Survey of Pharmacy Law* 64-67 (2012).[6] Accordingly, notwithstanding the fact that a doctor may have prescribed a particular branded drug for the patient, the pharmacist can be required under state law to sell that patient the AB-rated generic version. These "generic substitution" laws thus allow generic entrants to capitalize on the commercial success the innovator achieved through years of expensive innovation and promotion. In fact, largely as a result of these laws, the rate at which generics capture sales in the market has increased significantly over the last decade. According to one study, generics entering the market in 2011-2012 supplanted on average 84% of the branded drug's sales within a year. Grabowski, et al., *Recent Trends*, 17 J. Med. Econ. 207-214 (2014). Where generic substitution is automatic, generic manufacturers attain those sales without having to invest in any meaningful marketing or promotional effort. *See* SA-78-80.

Whether substitution is automatic or not, of course, generic manufacturers are always free to promote their products. Importantly for purposes of this case,

---

[6] As discussed in the Brief for Defendants-Appellants, at 11-13, generic substitution laws vary from state to state, and some states do not limit substitution to AB-rated generics.

the ability of generic manufacturers to promote their products is unaffected by any improvement in the branded drug. To be sure, most states do not permit pharmacists to substitute *automatically* a generic version of a legacy product when a customer is prescribed the improved branded version, but nothing in such circumstances prevents a generic manufacturer, or third-party payors like insurance companies or state health agencies, from promoting generic options to doctors, pharmacies, and formularies. In fact, many insurers engage in "counter-detailing," directly encouraging physicians to prescribe generic versions, even if they are not AB-rated as equivalent to an improved product. *See* Malkin, Jesse, et al., *The Changing Face of Pharmacy Benefit Design*, 23 Health Affairs 194, 198 (2004). For example, one insurer actively encouraged physicians to switch patients from a branded statin (a class of drugs used to lower cholesterol) to a generic version of a different statin. *See* Fuhrmans, Vanessa, *Doctors Paid to Prescribe Generics Pills*, The Wall St. J. (Jan. 24, 2008). This practice is increasingly common: one survey found that 80% of physicians had been asked by an insurer to switch a patient's prescription from a branded drug to a generic version of a different branded drug. PhRMA, *The Facts About Pharmaceutical Marketing & Promotion* 4 (July 2008), *available at* http://www.phrma.org/sites/default/files/pdf/marketing_and_promotion_facts_071108_final.pdf. That is but one of the many forms of competition that are unaffected by the alleged conduct at issue here.

This case arises from an innovator's attempt to support the launch of a new, improved product. The development and marketing of a once-a-day, extended release Namenda XR was an unquestioned improvement over the prior twice-a-day, immediate release formulation. SA-35, ¶ 45 (describing Forest's 8-year R&D investment "for an improved version of Namenda"). As the record evidence demonstrates, once-a-day dosing provides significant therapeutic advantages. *See e.g.,* SA-36, ¶ 47 (citing studies demonstrating that "extended-release agents are associated with improved tolerability, greater patient adherence to treatment, reduced total treatment costs, and better long-term clinical outcomes"). The benefits of once-daily dosing are not merely a matter of patient convenience; to the contrary, they are especially important for Namenda's target patient population, those suffering from Alzheimer's disease. These patients often experience "sundowning," the "tendency for some patients with Alzheimer's disease to become more confused, anxious, paranoid, [and] restless later in the day." *Id.* Once-daily dosing of Namenda—which typically can be accomplished in early hours—thus improves the lives of patients and eases the burdens on caregivers. *Id.*

Importantly, there is no allegation in this case that any aspect of Forest's Namenda XR launch plan will delay or block market entry of a generic version of Forest's legacy product, Namenda IR. Whether or not Forest continues to support full-scale distribution of Namenda IR as required by the district court, generic

versions of Namenda IR are expected to launch on July 11, 2015. SA-33, ¶ 41. Five generic manufacturers are poised to launch on that date, with an additional seven manufacturers expected to launch as early as October 11, 2015. *Id.* Nor is there any allegation that Forest has done anything to impede any efforts by the generic manufacturers to promote their generic versions of Namenda IR as lower-cost alternatives to Namenda XR.

The essential purpose of the Attorney General's complaint was to maintain Namenda IR's sales level so that generic versions of Namenda IR could capture more sales through automatic substitution when those products become available later this year. *See* Am. Compl., No. 1:14-cv-07473-RWS, ECF No. 70 at 3 (S.D.N.Y. Dec. 10, 2014). To accomplish this, the Attorney General sought to compel Forest to continue to support full scale distribution of Namenda IR, in competition with Forest's own improved Namenda XR, until generic versions of Namenda IR enter the market. The district court's preliminary injunction goes even further: it requires Forest to "make Namenda IR (immediate-release) tablets available on the same terms and conditions applicable since July 21, 2013 (the date Namenda XR entered the market)," and to continue supplying the market on those terms "until thirty days after July 11, 2015 (the date when generic memantine will first be available)." *See* SA-137-138, ¶¶ 2, 4.

ARGUMENT

The Sherman Act is the "Magna Carta of free enterprise"; it guarantees "each and every business … the freedom to compete—to assert with vigor, imagination, devotion, and ingenuity whatever economic muscle it can muster." *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 610 (1972). The district court turned this principle on its head in a misguided attempt to conscript federal antitrust law in service of state generic substitution laws, laws that themselves *undermine competition* by allowing generics to free-ride on the innovator's research, development, and marketing efforts. The district court violated the most important tenet of Section 2 jurisprudence: it has prohibited "vigorous competition" and supplanted the "rule of the marketplace" despite the absence of any element of unlawful monopolization. *See Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 767-768 (1984). The district court's unprecedented injunction deters, rather than incentivizes, innovation and competition, and should be reversed.

I. THE PRELIMINARY INJUNCTION DAMPENS THE VERY COMPETITION AND INNOVATION THE ANTITRUST LAWS ARE INTENDED TO FOSTER

Section 2 of the Sherman Act incentivizes innovation and efficiency by encouraging vigorous competition. Even "a monopolist is permitted, and indeed encouraged, by § 2 to compete aggressively on the merits[;] any success that it may achieve through 'the process of invention and innovation' is clearly tolerated by

the antitrust laws." *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 281 (2d Cir. 1979); *see also Virgin Atlantic Airways, Ltd. v. British Airways plc*, 257 F.3d 256, 259 (2d Cir. 2001) ("Foremost among [the concepts underlying antitrust law] is the notion that competition fosters consumer welfare … what the antitrust laws are designed to protect is competitive conduct, not individual competitors.").

Accordingly, courts applying the antitrust laws must be mindful not to chill or undermine competition. *Spectrum Sports, Inc. v. McQuillan*, 506 U.S 447, 458-459 (1993) ("[T]his Court and other courts have been careful to avoid constructions of § 2 which might chill competition, rather than foster it."); *cf Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 226 (1993) (liability for aggressive pricing is especially risky because it would "chill the very conduct the antitrust laws are designed to protect"). Forcing a successful firm to act for the benefit of its competitors does just that. *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407-408 (2004) ("Compelling such firms to share the sources of their advantage is in some tension with the underlying purpose of antitrust law, since it may lessen the incentive for the monopolist, the rival, or both to invest in those economically beneficial facilities."). As this Court stressed nearly 70 years ago, "[t]he successful competitor, having been urged to compete, must not be turned upon when he wins." *United States v. Aluminum Co. of Am.*, 148 F.2d 416, 430 (2d Cir. 1945).

Observing these principles is especially important when addressing claims arising from product innovation. *Berkey Photo*, 603 F.2d at 281. Firms must be allowed to reap the commercial benefits flowing from their innovation, including traditional first-mover advantages. *Id.* "If a firm that has engaged in the risks and expenses of research and development were required in all circumstances to share with its rivals the benefits of those endeavors, [the incentive to innovate] would very likely be vitiated." *Id.*; IIIB Areeda, Phillip E. & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 775, at 284 (3d ed. 2008) ("Any judicial rule for condemning possibly anticompetitive innovation under the antitrust laws must be formulated so as not to discourage the great majority of innovations that are competitive.").

Moreover, where, as here, the challenged conduct involves patent rights, courts should be particularly reluctant to employ injunctive relief to disrupt the exploitation of those patent rights in a manner which upsets the "complementary balance" between patent and antitrust law. *Atari Games Corp. v. Nintendo of Am., Inc.*, 897 F.2d 1572, 1576-1577 (Fed. Cir. 1990) (overturning a preliminary injunction precluding assertion of patent rights and declaring that "[a] preliminary injunction takes on special significance when the injunction involves patent rights and antitrust allegations"); *see also Massachusetts v. Microsoft Corp.*, 373 F.3d 1199, 1219 (D.C. Cir. 2004) (rejecting proposed antitrust order requiring broad

disclosure of Microsoft technology to rivals, holding that "[t]he effect upon Microsoft's incentive to innovate would be substantial"). Indeed, this Court has made clear that "conduct permissible under the patent laws cannot trigger liability under the antitrust laws." *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981)

Finally, courts must not condemn competition through innovation merely because the innovator's intent is to maximize profits and gain market share from rivals. Aggressive pursuit of commercial success "is not only not unlawful, it is an important element of the free-market system … it induces risk taking that produces innovation and economic growth." *Trinko*, 540 U.S. at 407. In fact, seeking to maximize market share at the expense of rivals is "what the antitrust laws aim to promote, not to discourage." *Buffalo Courier-Express, Inc. v. Buffalo Evening News, Inc.*, 601 F.2d 48, 55 (2d Cir. 1979) (Friendly, J.); *see also* IIIB Areeda ¶ 775, at 284-285 (analyzing an innovator's intent "is the worst way of handling claims that innovation violates the antitrust laws. … Innovation *always* entails taking business away from rivals; if it did not do so, it would not be profitable").

The district court's order violates each of these principles. Its unprecedented injunction requires an innovator to undermine the success of its own new, indisputably improved product (and to bear substantial unwanted and unnecessary costs) by continuing to manufacture, sell and support a prior version solely for the

benefit of its competitors. Moreover, by requiring Forest to continue sales of a patented product (Namenda IR), the injunction undercuts a fundamental right conferred by the Patent Act: the right to dictate use *and non-use* of a patented invention. *See In re Independent Serv. Organizations Antitrust Litig.*, 203 F.3d 1322, 1328 (Fed. Cir. 2000) (holding that refusal to sell a patented part fell within the scope of the patent grant).[7] And, finally, the decision in large part was improperly driven by documents and testimony showing (unsurprisingly) that the goal of Forest's launch strategy was to maximize the commercial success of its new product, including against expected generic versions of Namenda IR. *See, e.g.,* SA-49 (citing an internal Forest document explaining that "the core of [Forest's] brand strategy with XR is to convert [its] existing IR business to Namenda XR as fast as [it] can and also gain new starts on Namenda XR").

Instead, the district court should have focused on the actual *effect* Forest's planned action would have on *competition*. As the next section demonstrates, this case does not involve any injury to competition cognizable under the Sherman Act, and the district court's unprecedented imposition on the freedom to innovate and compete is accordingly unjustified.[8]

---

[7] A patentee's right not to use or sell a patented invention is discussed more fully in the Brief of Defendants-Appellants, at 34-37.

[8] Moreover, the preliminary injunction seeks to manage the market in a way that "is beyond the practical ability of a judicial tribunal to control without courting

II. THE DISTRICT COURT ERRED BY CONDEMNING INNOVATIVE CONDUCT THAT LACKED ANY EXCLUSIONARY EFFECT

In order to avoid "dampen[ing] the competitive zeal of a single aggressive competitor," Section 2 of the Sherman Act has been narrowly construed to prohibit only "exclusionary conduct." *Spectrum Sports*, 506 U.S. at 456; *Trinko*, 540 U.S. at 415-416. The "exclusionary conduct" element of a Section 2 claim requires—as a threshold matter—the use of "monopoly power 'to foreclose competition, to gain a competitive advantage, or to destroy a competitor." *Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 482-483 (1992) (quoting *United States v. Griffith*, 334 U.S. 100, 107 (1948)). The Supreme Court explained that it is not enough to label conduct "unfair" or find that it provided a monopolist some advantages over rivals: "[Section] 2 makes the conduct of a single firm unlawful only when it actually monopolizes or dangerously threatens to do so." *Spectrum Sports*, 506 U.S. at 459. Accordingly, the challenged conduct must, at a minimum,

---

intolerable risks of chilling legitimate" pro-competitive conduct. *See Brooke Group*, 509 U.S. at 223. The injunction not only compels Forest to supply the market with Namenda IR until after generic entry, but also fixes the terms of sale for that patented drug at July 2013 levels, thus requiring Forest to make, sell and support a patented product but rendering it unable to adapt to changes in competitive conditions, such as entry of generics. This perfectly illustrates the institutional concerns the Supreme Court raised about the dangers of these types of antitrust injunctions. *Trinko*, 540 U.S. at 407-408 (courts should avoid entering orders compelling sales for prudential reasons because it "requires antitrust courts to act as central planners, identifying the proper price, quantity, and other terms of dealing—a role for which they are ill suited.").

impair the ability of rivals to compete effectively. *See Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 605 (1985).

The district court failed to examine properly whether Forest's conduct was exclusionary within the meaning of Section 2. Instead, the court mistakenly concluded that Forest's approach was exclusionary simply because generic versions of Forest's legacy product might not gain the same market share via state substitution laws as they would have gained if Forest had employed a "soft[er]" approach. *See, e.g.*, SA-29, SA-130. Conduct is not exclusionary, however, merely because some other imagined course of conduct might have permitted rivals to achieve greater success, or because the conduct at issue forces rivals to compete rather than free-ride. *See, e.g., Trinko*, 540 U.S. at 415-416; *Berkey Photo*, 603 F.2d at 282.

A. Forest's Approach Does Not Foreclose Competition Within The Meaning Of Section 2

Courts have found Section 2 violations only where the conduct at issue *blocks* competition by creating barriers, thus rendering rivals *unable* to compete in a way that would threaten the alleged monopoly. III Areeda ¶ 651d, at 116 ("Exclusionary behavior must be conduct that prevents actual or potential rivals from competing or that impairs their opportunities to do so effectively."). Such conduct typically involves foreclosing access to essential inputs, *see, e.g.*, *Lorain Journal Co. v. United States*, 342 U.S. 143, 153 (1951) (dominant local paper

refused to sell advertising to persons that patronized a rival radio station); *Aspen*, 472 U.S. at 594 (alleged monopolist's refusal to continue joint ski ticket program with competitor deterred skiers from using rival resort, and rendered rival unable to compete effectively against alleged monopolist), or closing off markets or distribution channels to rivals, *United States v. Denstply Int'l, Inc.*, 399 F.3d 181, 191 (3d Cir. 2005) (cited at SA-118) (monopolist's exclusive dealing arrangements blocked competitors' access to essential means of product distribution); *LePage's Inc. v. 3M*, 324 F.3d 141, 159-160 (3d Cir. 2003) (cited at SA-118) (bundled rebates and exclusive dealing "cut LePage's off from key retail pipelines").

The alleged conduct here does not create any of these types of barriers to effective competition. It does not threaten to block or delay any generic approval or market launch; foreclose or limit the generics' means of distribution; prevent generics from promoting their products to patients or physicians; block patients or physicians from choosing the generics' products over branded alternatives; or prohibit formularies or HMOs from favoring or incentivizing the use of generic versions of Namenda IR over branded Namenda XR. SA-33, SA-77-82.

Accordingly, this is not a case like *Dentsply* or *LePage's*, where exclusionary acts prevented rivals from accessing essential means of competition that they were otherwise ready, willing and able to purchase; rather, the underlying concern here is merely that generic competitors will not be able to gain the benefit

of state automatic substitution laws but instead will need to promote their products if they wish to gain sales.[9] While generic manufacturers will not in all states[10] be able to free-ride off prescriptions for Forest's new, improved product (Namenda XR) through automatic substitution with their generic version of the legacy product (Namenda IR), they (and other market participants interested in promoting generic drugs) are free to convince physicians, pharmacies, and formularies that a generic version of the legacy drug should be prescribed instead of the new branded product. *Id.* at SA-78-82. Likewise, patients and their doctors can always choose the generic version of the legacy product if they believe the new product's improvement is not worth the price difference.

Similarly, this is not a case in which product or design changes effectively render rival products incompatible or useless. *See, e.g.*, *United States v. Microsoft Corp.*, 253 F.3d 34, 64-66 (D.C. Cir. 2001) (cited at SA-113) (imposing liability on

---

[9] It is no answer to observe, as did the court below, that "[e]xclusionary behavior need not result in 'total foreclosure' of competition." SA-118 (citing *Denstply* and *LePage's*). As the cases the district court cited make clear, the challenged conduct must still erect barriers to effective competition before courts may condemn it as exclusionary within the meaning of Section 2. *Dentsply* and *LePage's*, for example, involved monopolists closing off essential means of distribution and retail outlets for sale, respectively. *See supra* 19. Here, there is no allegation that generic competitors will not have access to *the very same* wholesalers and retailers (and physicians, pharmacies, and formularies) as Forest does.

[10] As detailed further in the Brief of Defendants-Appellants, at 11-13, some states may allow pharmacists unilaterally to fill prescriptions for Namenda XR with generic versions of Namenda IR.

Microsoft for commingling Windows with Explorer thereby preventing/deterring OEMs and customers from loading competing browser Netscape onto dominant, Windows-based operating systems); IIIB Areeda ¶ 776, at 285-287 (explaining that while innovation rarely should result in antitrust liability, "strategic creation of incompatibility" may warrant exception in "rare case[s]").[11] To the contrary, generic versions of Namenda IR will be valuable and profitable FDA-approved drugs, bioequivalent to a drug that enjoyed huge commercial success and was prescribed millions of times, an alternative that doctors and patients will be entirely able to use and thus free to select.

Because the conduct did not impair *competition* within the meaning of Section 2, it does not matter if Forest's intent was to maximize its market position vis-à-vis generic competitors. *See Olympia Equip. Leasing Co. v. Western Union Tel. Co.*, 797 F.2d 370, 379 (7th Cir. 1986) (Posner, J.) ("We add, what has

---

[11] The district court cited dictum in *Berkey Photo,* where this Court observed that antitrust liability *might* have applied if Kodak had discontinued its prior line of film upon the introduction of its next generation film. *Berkey Photo*, 603 F.2d at 287 n.39. Importantly, however, this Court did not explain under what circumstances such a discontinuation would run afoul of the antitrust laws. Regardless, that hypothetical product withdrawal is easily distinguishable from this case because withdrawing Kodak's legacy film products would have had precisely the exclusionary effect lacking in this case. Kodak was the dominant supplier of film at the time, and it designed its new film so that it was compatible only with Kodak's new camera. *Id.* Thus, if Kodak had discontinued its legacy film product, rival camera companies would have been *unable* to compete because there would have been no compatible film on the market for cameras they were trying to sell. *Id.* at 269-270.

become an antitrust commonplace, that if conduct is not objectively anticompetitive the fact that it was motivated by hostility to competitors … is irrelevant.").

B. The Antitrust Laws Do Not Require Forest To Sacrifice Its New Product's Commercial Success Merely To Benefit Generic Competitors

Instead of analyzing the effect on *competition*, the court below erroneously framed the issue as whether some "soft[er]" approach by Forest in connection with its Namenda XR launch could result in greater sales of generic drugs via New York's automatic substitution laws. *See, e.g.*, SA-48, SA-81. Even if that were the case, however, it would not render Forest's approach exclusionary within the meaning of Section 2, and certainly provides no grounds for an unprecedented order forcing an innovator to undergo unnecessary costs and to undermine the commercial success of its new, patented product.

The Sherman Act "does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition." *Trinko*, 540 U.S. at 415-416. As this Court and others have long stressed, Section 2 does not impose any duty affirmatively to facilitate the growth of competitors. *Twin Labs., Inc. v. Weider Health & Fitness*, 900 F.2d 566, 568 (2d Cir. 1990) ("Antitrust law … does not require one competitor to give another a break just because failing to do so offends notions of fair play.");

Olympia Equip., 797 F.2d at 379 ("Consumers would be worse off if a firm with monopoly power had a duty to extend positive assistance to new entrants….").

The district court placed undue emphasis on the premises that "[g]eneric products are *typically* not marketed to physicians or patients" and that "[g]eneric manufacturers do not *generally* market to health plans." SA-78-79, ¶¶ 128-130 (emphases added). Importantly, there was no evidence that generic companies are somehow *unable* to undertake such marketing efforts—they plainly can. Generics may understandably prefer not to spend money on marketing, but that preference is not a commercial imperative, and certainly not a right protected by the antitrust laws. *See, e.g.*, *Johnson v. University Health Servs., Inc.*, 161 F.3d 1334, 1338 (11th Cir. 1998) (holding that antitrust law protects only against "interference with the *freedom* to compete," and finding that plaintiff "had every opportunity to enter and be fully competitive … she simply chose not to do so.") (emphasis added). Section 2 does not grant any competitor, even a new entrant, freedom from the burdens of competition. *Berkey Photo*, 603 F.2d at 282 (using the antitrust laws to facilitate free-riding by competitors "encourag[es] the sluggishness the Sherman Act was designed to prevent").

Olympia Equipment is particularly instructive here. In that case, a competing telex terminal vendor (Olympia) saw its sales fall to zero after Western Union instructed its sales force to stop providing subscribers a list of competing

vendors—a practice that previously enabled Olympia to make substantial sales without any sales or marketing investment of its own. 797 F.2d at 372-373, 377. In rejecting Olympia's Section 2 claims, Judge Posner, writing for the Seventh Circuit, made clear 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 372-375. The court stressed that "nothing prevented" Olympia or any other vendor "from acquainting the customers with their existence." *Id.* at 377. Finally, in language equally applicable to this matter, the court concluded that "Olympia had no right under antitrust law to take a free ride on its competitor's sales force." *Id.* at 377-378 (labeling such free-riding as "the antithesis of competition").

Generic drug manufacturers, like the plaintiff in *Olympia Equipment*, are perfectly capable of undertaking their own marketing efforts, rather than simply relying on the opportunity created by state substitution laws. Indeed, even without any promotional effort by the generics, payors in the pharmaceutical industry regularly and actively encourage doctors and patients to switch from branded drugs to generic versions of different branded drugs. *See supra* p. 8 (discussing counter-detailing strategies). Accordingly, the purported "anticompetitive effect" on which

the district court relied—a mere diminution in the ability to free-ride—cannot support a Section 2 violation or justify such an extraordinary injunction.[12]

III. THE POLICIES UNDERLYING STATE SUBSTITUTION LAWS DO NOT JUSTIFY THE DISTRICT COURT'S UNPRECEDENTED DISTORTION OF FEDERAL ANTITRUST DOCTRINE

The lower court's unprecedented antitrust injunction can find no refuge in the goals of state substitution laws. SA-118 (stating that the alleged conduct "thwart[ed] state substitution laws"). As the Supreme Court has emphasized, the mere fact that other statutes are intended to aid certain competitors does not mean they are appropriately enforced by means of a federal antitrust claim. *Trinko*, 540 U.S. at 406 (concluding that even though "Congress [in the Telecommunications Act of 1996] created these duties [to assist competitors,]" those duties could not be enforced under the antitrust laws, whose focus is on free competition).

State substitution laws are driven by goals and policies different from, and in many ways in tension with, the procompetitive goals underlying federal antitrust law. The district court correctly observed that "state substitution laws aim to encourage generic drug sales," (SA-24), but it failed to recognize that they

---

[12] It does not matter that sales through automatic substitution are the most "cost-efficient" for the generics. SA-78 (quoting generic executive as stating that "generic products … most efficiently will achieve sales through AB-rated substitution …"). Free-riding off Western Union's sales effort was similarly the most cost-efficient way for Olympia to earn sales, but a rival's ability to free ride is not the type of "efficiency" that the antitrust laws promote or protect for the reasons Judge Posner explained.

accomplish this aim not by freeing generic manufacturers to compete but instead by *insulating* generic companies *from* competition by allowing or mandating that prescriptions written for a branded drug be filled with a generic. Thus, while state substitution laws do favor one category of competitors—generic manufacturers—by enhancing their ability to free-ride off the efforts and expenditures of branded companies, thereby conferring huge benefits that would not exist in the arena of free competition, these statutes should not be mistaken as procompetitive under standard antitrust principles.

The federal antitrust laws favor competition in general, not any particular competitor or class of competitors. *See Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977) ("The antitrust laws … were enacted for 'the protection of competition not competitors'" (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962))). As then-Judge Breyer explained the distinction, while economic regulators seek to achieve certain market outcomes directly, antitrust seeks to achieve the goals of efficiency and innovation "indirectly by promoting and preserving a process that tends to bring them about." *Town of Concord v. Boston Edison Co.*, 915 F.2d 17, 22 (1st Cir. 1990) (Breyer, J.)

A Federal Trade Commission report from the mid-1980s makes clear that state substitution laws were developed to create certain *market outcomes* rather than to promote the *competitive process*:

> The aim of the drug product selection laws was to reduce the prices consumers pay at retail for their prescription drugs by *shifting some market share* from higher-price leading brands to lower-price versions of the drug, and this aim was accomplished.

FTC Staff Report, Bureau of Economics, *Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws* 8 (1985), *available at* http://www.ftc.gov/sites/default/files/documents/reports/generic-substitution-prescription-drug-prices-economic-effects-state-drug-product-selection-laws/massonsteiner.pdf (emphasis added).

Thus, even if a regime under which generic manufacturers must actively compete against new branded products were somehow inconsistent with the spirit of state substitution laws, it is perfectly consistent with federal antitrust laws. An antitrust injunction in service of state substitution laws, therefore, is improper because the Supreme Court directs that the federal antitrust laws should not be applied to advance different goals of other statutory regimes—even other *federal* statutory regimes. *Trinko*, 540 U.S. at 415 ("The 1996 Act is, in an important respect, much more ambitious than the antitrust laws. It attempts 'to eliminate … monopolies ….' Section 2 of the Sherman Act, by contrast, seeks merely to prevent unlawful monopolization. It would be a serious mistake to conflate the two goals."); *Pacific Bell Tel. Co. v. linkLine Commc'ns., Inc.*, 555 U.S. 438, 450 (2009) (while duty to deal with rivals may arise under applicable FCC regulations,

Sherman Act created no such duty). The same certainly applies to the state substitution laws invoked by the district court here. As Judge Friendly warned, "[c]ourts must be on guard against efforts of plaintiffs to use the antitrust laws to insulate [competitors] from the impact of competition." *Buffalo Courier-Express*, 601 F.2d at 55. It would be perverse, then, to conscript federal antitrust law in service of state policies designed to do just that: insulate generic manufacturers from the impact of competition. Any attempt to use antitrust law to advance this purpose invariably would result in distortion of core antitrust principles, as the decision below has shown.

Imposition of antitrust remedies here is even more misguided than it would have been in *Trinko* because the injunction here goes far beyond anything New York law itself requires. In *Trinko*, the antitrust claim arose from a purported direct violation of a duty imposed by the Telecommunications Act of 1996. Here, New York's substitution laws may "aim to encourage generic drug sales" (SA-24), but they do not impose any duties *at all* on drug manufacturers; instead, they merely regulate the conduct of pharmacists. While the district court concluded that Forest's plans are somehow inconsistent with the *purposes* of New York's substitution laws, *see* SA-28, "[n]o legislation pursues its purposes at all costs." *Rodriguez v. United States*, 480 U.S. 522, 525-526 (1987). "[I]t frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers

the statute's primary objective must be the law." *Id.* at 526. There can simply be no justification, then, for an *antitrust* injunction that *expands* a state law's exception to competition. [13]

CONCLUSION

The district court's preliminary injunction order should be reversed.

Respectfully submitted,

/s/ Mark A. Ford

MARK A. FORD
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000

DAVID W. OGDEN
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Ave., NW
Washington, DC 20006
(202) 663-6000

Attorneys for the Pharmaceutical Research and Manufacturers of America as Amicus Curiae in Support of Appellants

January 15, 2015

[13] The district court adds that Forest's planned limited distribution of Namenda IR also "violates the spirit of the Hatch-Waxman Act." SA-135. But, as the district court acknowledges, Hatch-Waxman addresses the *availability* of generics, not the *selection* between branded and generic options once generics are on the market. SA-134-135. Nevertheless, even if generic substitution did fall within the "spirit" of Hatch-Waxman, the antitrust laws should not be conscripted to advance that policy for the same reasons discussed herein.

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), the undersigned hereby certifies that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B).

1. Exclusive of the exempted portions of the brief, as provided in Fed. R. App. P. 32(a)(7)(B), the brief contains 6,810 words.

2. The brief has been prepared in proportionally spaced typeface using Microsoft Word 2010 in 14 point Times New Roman font. As permitted by Fed. R. App. P. 32(a)(7)(C), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

/s/ Mark A. Ford
MARK A. FORD
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000

January 15, 2015

CERTIFICATE OF SERVICE

I hereby certify that, on this 15th day of January, 2015 I filed the foregoing Brief for the Pharmaceutical Research and Manufacturers of America as Amicus Curiae in Support of Appellants with the Clerk of the United States Court of Appeals for the Second Circuit via the CM/ECF system, which will send notice of such filing to all registered CM/ECF users.

/s/ Mark A. Ford
MARK A. FORD
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000