United States Court of Appeals
for the Third Circuit

Mylan Pharmaceuticals Inc.,

Appellant,

v.

Warner Chilcott Public Limited Company, Warner Chilcott Company, LLC; Warner Chilcott US, LLC; Mayne Pharma Group Limited; Mayne Pharma International Pty, Ltd.,

Appellees.

Appeal from the United States District Court
For the Eastern District of Pennsylvania

Brief for Business and Policy Professors as Amici Curiae
In Support of Appellees

William F. Cavanaugh
John P. Figura
George A. LoBiondo
Clinton W. Morrison
Patterson Belknap Webb & Tyler LLP
1133 Avenue of the Americas
New York, New York 10036
(212) 336-2000
Attorneys for Amici Curiae Business and Policy Professors
TABLE OF CONTENTS

TABLE OF AUTHORITIES ........................................................................................................................ iii
STATEMENT OF INTEREST ......................................................................................................................... 1
PRELIMINARY STATEMENT ......................................................................................................................... 1
ARGUMENT .................................................................................................................................................. 2
   I.  Innovation Will Be Stifled, and Consumers Will Be Harmed, if this Court Recognizes Appellant’s Proposal for Limitless Innovation-Based Antitrust Liability ........................................................................ 2
       A.  The Antitrust Laws Should Be Applied to Promote Competition and Innovation, Especially in the Pharmaceutical Industry .................................................................................................................. 3
           1.  Scholarship, Expert Commentary, and Long-Settled Jurisprudence All Confirm the Primacy of Innovation ................................................................................................................................. 3
           2.  The Value of Innovation Extends to Incremental Innovation, Such as Product Improvements ................................................................................................................................. 5
           3.  It Is Particularly Important to Protect Innovation in the Pharmaceutical Industry, Which Is Heavily Regulated and Involves High Research and Development Costs .............................................................................. 8
       B.  It Would Be Inefficient and Anticompetitive to Force a Company to Continue Supporting an Older Product for Its Competitors’ Benefit ...................................................................................... 11
           1.  Discontinuation of Old Products Is Part of the Innovation Process ......................................................................................................................................................................................... 12
           2.  Requiring Companies to Keep Old Products Available Creates Inefficiencies in the Supply Chain that Ultimately Increase Healthcare Costs for Consumers ................................................................ 13
           3.  Forcing Manufacturers to Continue Producing and Distributing Their Old Products Will Stifle Their Innovation and Discourage Them from Bringing Improved Products to Consumers ......................................................................................... 14
II. Antitrust Law Should Not Impose upon businesses a Duty to Enable the Regulatory Advantages Enjoyed by Their Competitors. ................................................................. 15

A. There Is No Duty to Deal with Competitors ........................................... 15

B. Hatch-Waxman Is Not an Antitrust Statute and Was Not Intended to Restrict Innovation. ................................................................. 17

C. Antitrust Law Should Not Be Used to Protect Regulatory Advantages or the Business Models Built Upon them. ......................... 20

III. The Reasoning of Namenda Should Not Be Extended to the Facts Before this Court ................................................................. 23

CONCLUSION ........................................................................................................ 26
STATEMENT OF INTEREST

Amici curiae, listed below, are professors of management, organization, and policy from leading universities throughout the United States. Amici have written extensively in the fields of strategy, innovation, management, and competition. They write to bring to the Court’s attention certain considerations that inform the question presented by this appeal—whether the federal antitrust laws obligate a firm that has developed a new version of a product to continue producing the older version of the product in order to assist a competitor. The amici curiae joining in this brief include:

Rajshree Agarwal
Rudolph Lamone Chair and Professor in Strategy and Entrepreneurship
Director, The Ed Snider Center for Enterprise and Markets
Robert H. Smith School of Business, University of Maryland

Jay Barney
Presidential Professor of Strategic Management and Lassonde Chair of Social Entrepreneurship
The David Eccles School of Business, University of Utah

Russell Coff
UW Foundation Chairman Orr Bascom Professor of Strategic Management
Wisconsin School of Business, University of Wisconsin-Madison

1 The parties have consented to the filing of this brief. No one other than amici curiae and their counsel authored this brief or contributed money that was intended to fund preparing or submitting this brief.
Raj Echambadi  
Senior Associate Dean-MBA Programs & Strategic Innovation and  
Professor of Business Administration  
College of Business, University of Illinois at Urbana-Champaign

Charles Eesley  
Assistant Professor of Management Science and Engineering  
Stanford University

Alfonso Gambardella  
Professor of Management, Università Bocconi  
Visiting Professor (2015–16), Sloan School of Management, Massachusetts Institute of Technology

Martin Ganco  
Associate Professor of Strategic Management  
Wisconsin School of Business, University of Wisconsin-Madison

Nile Hatch  
Associate Professor of Entrepreneurship  
Marriott School of Management, Brigham Young University

Donald E. Hatfield  
Associate Professor of Strategic Management and Entrepreneurship  
Northern Virginia Center, Virginia Tech

Riitta Katila  
Professor of Management Science & Engineering and W.M. Keck Foundation Scholar  
Stanford University

Jeffrey T. Macher  
Professor of Strategy, Economics and Public Policy  
Director, Georgetown Center for Business and Public Policy  
McDonough School of Business, Georgetown University

Tammy Madsen  
Associate Professor of Management  
Leavey School of Business, Santa Clara University
PRELIMINARY STATEMENT

Appellant argues that when a brand-name pharmaceutical manufacturer introduces a new alternative for an existing drug, the antitrust laws require the manufacturer to continue selling the existing drug simply so that a generic competitor can gain the advantages of automatic substitution once the generic is approved.

Amici disagree. The adoption of Appellant’s position would discourage innovation in the pharmaceutical industry, to the ultimate detriment of consumers. It calls for courts to apply a test of innovation “sufficiency”—i.e., how much must a brand-name manufacturer innovate its product in order for the innovation to be substituted for the existing product. This is not only unworkable and beyond the province of the courts, but it also risks imposing on brand-name manufacturers the duty to continue selling older products indefinitely.

In essence, Appellant argues that brand-name drug manufacturers have a duty to assist their generic competitors in taking advantage of generic drug substitution laws, which permit or require pharmacists to dispense a generic equivalent of a brand name drug unless the physician directs otherwise. Automatic substitution provides generic manufacturers with virtually guaranteed sales and profits, as long as there continues to be a brand-name drug on the market for which the generic can be substituted. But imposing such an obligation on an innovator
goes beyond the scope of antitrust. One competitor has no duty to enable another competitor to exploit whatever regulatory advantages are available to them, contrary to the Second Circuit’s recent decision in *New York v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015) (“Namenda”). If policymakers wish to impose such a duty on drug manufacturers, they should do so through the legislative process, where the conflicting policy considerations can be debated and resolved.

Amici believe *Namenda* was wrongly decided, but even if this Court credits the Second Circuit’s flawed reasoning, it should not extend that reasoning to the facts at issue here. *Namenda* is largely based on findings that are absent here—namely, actual monopolization by a brand-name manufacturer and total exclusion of a generic before the end of the branded product’s patent life. The Court should reject Appellant’s arguments and affirm the decision of the district court.

**ARGUMENT**

**I. INNOVATION WILL BE STIFLED, AND CONSUMERS WILL BE HARMED, IF THIS COURT RECOGNIZES APPELLANT’S PROPOSAL FOR LIMITLESS INNOVATION-BASED ANTITRUST LIABILITY**

Appellant asks this Court to approve its theory of innovation-based antitrust liability. It claims that Appellees’ process of incremental improvements to one of their pharmaceutical products were exclusionary, because Appellant found itself unable to “keep pace with” these improvements.
Appellant’s attempt to instead use antitrust as a shield against innovation should be rejected. Companies should be incentivized to create newer products—especially in the pharmaceutical industry, where innovation is so critical to human welfare. Pharmaceutical companies should certainly not be forced to devote finite resources to producing and selling older products until such time as the judiciary determines is appropriate. While that may benefit one or more generic competitors, it would not ultimately benefit the competitive process and consumers who benefit from innovation. The district court correctly concluded that such a result would “stand the Sherman Act on its head.” JA.47.

A. The Antitrust Laws Should Be Applied to Promote Competition and Innovation, Especially in the Pharmaceutical Industry

1. Scholarship, Expert Commentary, and Long-Settled Jurisprudence All Confirm the Primacy of Innovation

Antitrust law exists to maximize consumer welfare. See Broadcom Corp. v. Qualcomm Inc., 501 F.3d 297, 308 (3d Cir. 2007) (“The primary goal of antitrust law is to maximize consumer welfare by promoting competition among firms.”); see also Reiter v. Sonotone Corp., 442 U.S. 330, 343 (1979) (observing that “Congress designed the Sherman Act as a ‘consumer welfare prescription’” (citing R. Bork, The Antitrust Paradox 66 (1978))). Improvements in consumer welfare are driven in large part by innovation, which “enables the development of new products, the improvement of processes, and the creation and improvement of

Accordingly, courts and scholars uniformly recognize that it is critically important to “safeguard the incentive to innovate.” *E.g., Verizon Commc’ns., Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 407 (2004).* As the D.C. Circuit noted in *United States v. Microsoft*, 147 F.3d 935, 948 (D.C. Cir. 1998), “Antitrust scholars have long recognized the undesirability of having courts oversee product design, and any dampening of technological innovation would be at cross-purposes with antitrust law.” *See also Paladin Assoc., Inc. v. Montana Power Co.*, 328 F.3d 1145, 1157 (9th Cir. 2003) (a rule that “the Sherman Act disfavors a business’s offering new products . . . would restrict an important form of non-price competition”).

These principles apply with particular force here. Appellant asks this Court to recognize a theory of innovation-based antitrust liability on the grounds that in pharmaceuticals, moving from one product to another “clearly constitutes exclusionary conduct.” Appellant. Br. at 43. But Appellant’s argument runs counter to established antitrust principles. As recently explained by then-FTC Commissioner Joshua D. Wright and D.C. Circuit Judge Douglas H. Ginsburg, “Competition law is not a suitable instrument for micromanaging product design and innovation. Imposing competition law liability upon new product
introductions requires competition agencies and courts to weigh the benefits to consumers from the innovation against any costs to consumers arising from the diminution of competition.” Comment of U.S. Federal Trade Commissioner Joshua D. Wright and Judge Douglas H. Ginsburg on the Canadian Competition Bureau’s Draft Updated Intellectual Property Enforcement Guidelines 2 (2015), available at https://www.ftc.gov/system/files/documents/public_statements/734661/150810canadacomment.pdf. This, they concluded, is an impossible task for which courts are especially ill-suited. See id. Amici agree, and respectfully submit that courts should not premise antitrust liability on innovation.

2. The Value of Innovation Extends to Incremental Innovation, Such as Product Improvements

When thinking about innovations with life-changing potential, one might tend to focus on blockbuster inventions that often make headlines. In reality, however, the “cumulative effect of numerous minor incremental innovations can sometimes be more transforming and have more economic impact than a few radical innovations or ‘technological breakthroughs.’” Nat’l Research Council, Prospectus for National Knowledge Assessment, National Academy Press (1996), available at http://www.nap.edu/openbook.php?record_id=9528&page=10. While incremental innovations may superficially seem relatively inconsequential, in fact they “play an important role . . . . Of all new products developed, incremental changes are much more frequent than radical innovations.” Nina
Veflen Olsen, *Incremental Product Development* 13, 15 (2006). Similarly, “even small changes in product design[] can generate significant consumer benefits, and … such changes are consistent with the normal competitive process. . . . [W]hat appear[s] to be a minor product improvement can generate a significant gain in consumer welfare.” Wright & Ginsburg at 2–3; *see also* Nat’l Research Council at 10 (noting that “radical innovations seldom stand alone, and realization of their economic or societal benefits usually requires many incremental improvements and the development of ancillary technologies”). Moreover, radical and incremental innovation are inextricably linked, because “a seemingly minor technological improvement today can lead to much greater advances in the future.” *Allied Orthopedic Appliances Inc. v. Tyco Health Care Group LP*, 592 F.3d 991, 1000 (9th Cir. 2010).

This close relationship makes it impossible to inhibit incremental innovation, by imposing additional obligations on the innovator, without discouraging radical innovation. Courts therefore have been unwilling to impose undue burdens upon the pace of a company’s innovation. As the Ninth Circuit has explained, “To weigh the benefits of an improved product design against the resulting injuries to competitors is not just unwise, it is unadministrable. There are no criteria that courts can use to calculate the ‘right’ amount of innovation, which would maximize social gains and minimize competitive injury.” *Allied Orthopedic*
Appliances, 592 F.3d at 1000; see also Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 286 (2d Cir. 1979) (concluding that, as between original Kodak film product and updated version, “no one can determine with any reasonable assurance whether one product is ‘superior’ to another”); Wright & Ginsburg at 2 (“Not only are agencies and courts ill-equipped to make such determinations, but it is also unclear whether the balancing contemplated by a rule prohibiting anticompetitive product switching can be done at all.”).

Courts also understand that they are ill-equipped to weigh the benefits of one product over another. See, e.g., Walgreen Co. v. AstraZeneca Pharm. L.P., 534 F. Supp. 2d 146, 151 (D.D.C. 2008) (“Courts and juries are not tasked with determining which product among several is superior. Those determinations are left to the marketplace.”); ILC Peripherals Leasing Corp. v. IBM Corp., 458 F. Supp. 423, 439 (N.D. Cal. 1978) (“Where there is a difference of opinion as to the advantages of two alternatives which can both be defended from an engineering standpoint, the court will not allow itself to be enmeshed in a technical inquiry into the justifiability of product innovations.” (citation and internal quotation marks omitted)). This approach is consistent with the Supreme Court’s admonition that antitrust courts should not “act as central planners.” Trinko, 540 U.S. at 408.
3. **It Is Particularly Important to Protect Innovation in the Pharmaceutical Industry, Which Is Heavily Regulated and Involves High Research and Development Costs**


As a result, branded pharmaceutical companies spend a much larger portion of their revenues on R&D than firms in most other industries. *See* The *Oxford Handbook of the Economics of the Biopharmaceutical Industry*, 2 (2012). Ultimately, only about one in 10,000 experimental compounds meet safety and efficacy benchmarks and are ultimately approved by the FDA. Martin S. Lipsky & Lisa K. Sharp, *From Idea to Market: The Drug Approval Process*, 14 J. Am. Board Fam. Med. 362, 364 (2001). This is one reason why branded pharmaceutical firms have “relatively slim returns given [their] level of risk.” Schilling at 202–03 (examining years 2009–13 and concluding that in four out of five years, branded firms’ returns were exceeded by the S&P 500 index). *See generally Pfizer’s Lipitor: The Blockbuster Drug that Almost Wasn’t*, Dec. 30, 2011, Associated
Press, available at http://www.huffingtonpost.com/2011/12/30/pfizers-lipitor-the-block_n_1176252.html (noting that it was difficult to foresee whether Lipitor would be successful when there were already four other drugs in the same class and where doctors were already “quite satisfied with the medicines we have”).

Research and development costs are not limited to the discovery and development of new molecules. Innovations often take the form of improvements to existing pharmaceutical products. Ernest R. Berndt et al., The Impact of Incremental Innovation in Biopharmaceuticals, Pharmacoconomics 24 Supp. 2d 69, 72 (2006). While Appellant and certain amici suggest that incremental product improvements have no purpose except to artificially extend patent life, the reality is that “innovation that takes the form of improved formulations, delivery methods and dosing protocols may also generate substantial benefits associated with improved patient compliance, greater efficacy as a result of improved pharmacokinetics, reduced adverse effects or the ability to effectively treat new patient populations.” Id. at 71; see also Wright & Ginsburg at 2 (noting that “new drug formulations may involve changes that appear small but are of significant benefit to consumers or are critical stepping-stones to potentially life-saving inventions”).

The benefits from these incremental innovations are not hypothetical: A 2006 study found that over 60 percent of drugs necessary for combating
prevalent diseases derived from incremental innovations. J. Cohen et al., *The role of Follow-on Drugs and Indications on the WHO Essential Drug List*, 31 J. Clinical Pharmacy & Therapeutics 585, 590 (2006). Indeed, these benefits can be seen in the record of this case. For example, the 2005 Doryx tablet launch led to the FDA later approving a 200mg Doryx tablet, which included a new dosing regimen to treat chlamydia. JA.9467.

The statutory framework governing the pharmaceutical industry recognizes the exorbitant cost burden on innovators by balancing the key values of innovation and competition. *See Teva Pharm. Indus. v. Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005) (explaining that “Congress sought to strike a balance between incentives, on the one hand, for innovation, and on the other, for quickly getting lower-cost generic drugs to market.”); *accord Tri-Bio Labs., Inc. v. United States*, 836 F.2d 135, 139 (3d Cir. 1987). As the district court correctly determined, this framework permits an innovating pharmaceutical company to discontinue a product upon introducing a newer, improved version of that product. JA. 39–44. Had the policymakers sought to impose an obligation to continue production of an existing drug until a generic version was approved and available, they could have done so. They did not. The district court’s refusal to step into the role of policymaker preserves the current framework, which encourages necessary incentives for innovator companies to invest the substantial sums necessary to
develop new medicines against long odds, while still preserving for generic manufacturers the opportunity to gain market share by offering lower-priced alternatives to branded products.

B. It Would Be Inefficient and Anticompetitive to Force a Company to Continue Supporting an Older Product for Its Competitors’ Benefit

The antitrust laws exist to protect “competition, not competitors.” Leegin Creative Leather Prods. v. PSKS, Inc., 551 U.S. 877, 906 (2007); accord Broadcom, 501 F.3d at 308 (“Conduct that merely harms competitors, however, while not harming the competitive process itself, is not anticompetitive.”). As the district court concluded, Appellant’s failure to “keep pace with” Appellees’ product updates simply does not constitute “harm to the competitive process itself,” and therefore cannot be transformed into an antitrust violation. JA.39 (concluding that Appellant was a “‘victim’ of its own business strategy, not Defendants’ ‘predatory’ conduct”). By contrast, Appellant’s reading of the antitrust laws would force Appellees to subsidize their competitors by continuing to manufacture older products indefinitely—or at least until a judge decides that the generic competitor’s needs have been met. Not only would this result “stand the Sherman Act on its head,” JA.47, it would actually harm innovation—and, by extension, consumers. See Lee Branstetter et al., Starving (or Fattening) the Golden Goose: Generic Entry and the Incentives for Early-Stage Pharmaceutical
Innovation 22, 32–33 (working paper, Dec. 8 2015). See generally Broadcom, 501 F.3d at 308 (antitrust law should “maximize consumer welfare”).

1. **Discontinuation of Old Products Is Part of the Innovation Process**

To be consistently innovative, companies must focus their resources on developing, manufacturing, and marketing new products—not spending money to support older products. Companies can incur tens of millions of dollars attributable to “inventory obsolescence,” *i.e.*, keeping discontinued products in stock.\(^2\) Second, constraints in a company’s manufacturing capacity, marketing, and other functions make it extremely difficult to adequately support a new product while simultaneously continuing an older one. This is why, for example, car manufacturers focus their resources on manufacturing and marketing their latest models. It would make little business sense to do otherwise. And it would not benefit consumers to compel companies to divert valuable resources away from newer products. Even in a highly regulated industry like pharmaceuticals, a

\(^2\) For example, a study of the medical device industry found that Guidant had to take a $28.8 million write-down when it overlapped production of its older and newer generation of cardiac rhythm management products. Medtronic had to make a similar write down of $29 million due to inventory obsolescence in its vascular and cardiac surgery lines. Arthur V. Hill & William J. Sawaya, *Production Planning for Medical Devices with an Uncertain Regulatory Approval Date*, IIE TRANSACTIONS 36, 307 (2004).
company should not be forced to make and support a product it has chosen to discontinue.

2. **Requiring Companies to Keep Old Products Available Creates Inefficiencies in the Supply Chain that Ultimately Increase Healthcare Costs for Consumers**

If Appellant’s suggestions are followed, and innovating firms are forced to continue selling both older and updated versions of their products simultaneously, the costs would not be borne by the innovators alone. In addition to putting unjustifiable strain on these companies, having both versions in the market would increase the inventory carrying costs and supply chain complexity for distributors and pharmacists. Multiple drugs would have to be shipped and stocked, increasing the capital tied up in logistics, inventory, and warehousing costs, and would have to be separately tracked to ensure that expiration dates are monitored and any regulatory issues are handled. In short, requiring Appellees to keep old products available would create inefficiencies in the supply chain. This, in turn, would significantly increase the cost of healthcare, which costs would eventually be passed to consumers. *See* Thomas Ebel, *Building New Strengths in the Healthcare Supply Chain: Pharmaceuticals and Medical Products Operations*, McKinsey & Company (Jan. 2013). Such a result would be inimical to antitrust’s goals. *See, e.g.*, *Brooke Grp. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 222 (1993) (low prices benefit consumers).
3. **Forcing Manufacturers to Continue Producing and Distributing Their Old Products Will Stifle Their Innovation and Discourage Them from Bringing Improved Products to Consumers**

If the antitrust laws are interpreted to require companies to keep older products on the market, companies will necessarily have fewer resources to develop new products or updated versions of existing products. Put simply, it would be irrational or even impossible for a company to fully support both old and new products. Thus, in a regime where the company is required to continue to support the old product—or where its reward for introducing updated products to market is the promise of burdensome antitrust litigation—it may rationally delay development of the newer product. *See* Joanna Shepherd, *Deterring Innovation: NY v. Actavis and the Duty to Subsidize Competitors’ Market Entry*, Minn. J.L. Sci. & Tech. at 28–30 (forthcoming), available at [http://ssrn.com/abstract=2669470](http://ssrn.com/abstract=2669470).

Amici respectfully assert that this Court should not support such an unfortunate outcome. Pharmaceutical innovation has yielded medical treatments that have dramatically improved health conditions around the world. *See* Branstetter et al. at 8. As the district court correctly recognized, applying an arbitrary test of innovation “sufficiency” would stifle innovation and discourage manufacturers from bringing improved products to customers. *See* JA. 43–44; *see also* Wright & Ginsburg at 4 (“[T]o engage in ex post valuation of a product design
change and weigh it against the reduction in competition and the resulting anticompetitive effects can only reduce the incentive to innovate or distort those incentives towards blockbuster innovations rather than reformulations that may result in incremental but significant consumer benefits.”). A policy that incentivizes firms to slow their innovation will lead to less discovery, slower medical and technological advancement, and lower economic welfare.

II. ANTITRUST LAW SHOULD NOT IMPOSE UPON BUSINESSES A DUTY TO ENABLE THE REGULATORY ADVANTAGES ENJOYED BY THEIR COMPETITORS.

Appellant’s proposed remedy—obligating brand-name manufacturers to innovate only if they commit to keeping older products on the market—amounts to a new antitrust duty upon manufacturers. In a departure from the well-established rule that a business—even a monopolist—has no duty to deal with its competitors, Appellant asks this Court to impose upon brand-name drug manufacturers a duty to subsidize its generic competitors by making it easier to exploit the regulatory advantages available to them. This duty goes far beyond the reach of what antitrust law requires, or should require.

A. There Is No Duty to Deal with Competitors

It is well established in antitrust that even a monopolist has “no duty to aid competitors.” Trinko, 540 U.S. at 411; see, e.g., Pac. Bell Tel. Co. v. LinkLine Commc’ns., Inc., 555 U.S. 438, 448 (2009); United States v. Colgate &
Co., 250 U.S. 300, 307 (1919). Antitrust law recognizes that businesses should not be coerced into taking measures which harm themselves and enrich their rivals absent a truly compelling justification. While the Sherman Act may be a powerful statute, “it 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 415–16.

The no-duty-to-deal rule exists for good reason; when a court rules that a private business must deal with a competitor, that court disrupts rather than safeguards market forces. Further, the court issuing such an order in spite of the general no-duty-to-deal rule risks unnecessarily entangling itself in the daily inner workings of a company. See Trinko, 540 U.S. at 415 (“No court should impose a duty to deal that it cannot explain or adequately and reasonably supervise. The problem should be deemed irremedia[ble] by antitrust law when compulsory access requires the court to assume the day-to-day controls characteristic of a regulatory agency.”).

The present case must be viewed against this backdrop. The order sought by Appellant contravenes the no-duty-to-deal rule of Trinko and would affirmatively require a private company to produce a legacy drug for the explicit purposes of aiding that company’s generic competitors. This Court should adhere
to the principles of *Trinko* and decline Appellant’s invitation to disregard well-settled Supreme Court precedent.

**B. Hatch-Waxman Is Not an Antitrust Statute and Was Not Intended to Restrict Innovation.**

Appellant would have this Court conclude that the generic substitution market represents one of those “few … exceptions” in which a firm has a “duty to aid competitors.” *Trinko*, 540 U.S. at 408. They argue that a brand-name drug manufacturer proposing to introduce a new product must continue to market an older version of its product so as not to interfere with a generic competitor’s ability to take advantage of generic substitution laws. In essence, Appellant argues that antitrust law includes a duty that firms make it easier for their competitors to take advantage of whatever regulatory benefits are available to them.

This duty takes antitrust law in a direction it should not go. Nothing in the Hatch-Waxman Act (“Hatch-Waxman” or “the Act”)—or any state law concerning generic drugs—compels brand-name drug makers to assist generics in their efforts to maximize their profits by taking full advantage of generic substitution laws. Appellant did not bring a claim under Hatch-Waxman, and it does not argue that Appellees somehow violated the Act.

Instead, Appellant protests that the district court’s opinion “contradicts the purposes of the Hatch-Waxman Act.” App. Br. at 3 (emphasis added). Similarly, amici supporting Appellant argue that “antitrust law is an
appropriate means to protect Hatch-Waxman’s carefully protected statutory scheme—designed to promote generic competition—from predatory regulatory gaming behavior that can produce serious anticompetitive harm and raise drug prices ….” IP Amicus Br. at 1. The Second Circuit’s opinion in Namenda reflects similar reasoning. The panel in that case reasoned that “what Defendants call ‘free riding’ – generic substitution by pharmacists … is authorized by law; is the explicit goal of state substitution laws; and furthers the goals of the Hatch-Waxman Act by promoting drug competition.” Namenda, 787 F.3d at 658. See also id. at 658 (“[E]fforts to manipulate aspects of the Hatch-Waxman incentive structure to exclude competition could state an antitrust claim[.]”)

Courts should be wary of such reasoning. Antitrust law is not “an appropriate means to protect” Hatch-Waxman’s statutory scheme, IP Amicus Br. at 1, for Hatch-Waxman is not an antitrust statute. The Act had two key provisions. First, it allowed brand-name drug manufacturers “to extend their exclusivity period beyond the standard 20-year patent term.” Namenda, 787 F.3d at 644. Second, it created the Abbreviated New Drug Approval (“ANDA”) process, under which manufacturers could obtain FDA authorization for generic drugs merely by showing that the generic was bioequivalent to an existing, authorized drug. Id. This process allowed generics to rely on studies already submitted by brand-name
manufacturers instead of requiring the generics to invest the time and money to conduct their own research and clinical testing. *Id.*

Hatch-Waxman’s legislative history does not indicate that the purpose of the Act was to require brand-name manufacturers to continue selling a product until a generic is approved and available for automatic substitution. As reflected by its key provisions, the Act’s purposes were to incentivize innovation by brand-name drug manufacturers and to lower drug prices for consumers by encouraging generics to challenge pharmaceutical patents. *Id.* Representative Henry Waxman, a sponsor of the legislation, said the Act reflected a “fundamental balance … that assures consumers of more low-cost generic drugs when a valid patent expires and the drug industry of sufficient incentive to develop innovative pharmaceutical therapies.” 130 Cong. Rec. 24425 (Sept. 6, 1984) (statement of Rep. Waxman).

Although Hatch-Waxman increased generic competition, it was not intended to do so by limiting innovation. As stated by FTC Commissioner Julie Brill, “Hatch-Waxman did not only foster generic competition. Congress also recognized the important role played by branded drug innovation in the pharmaceutical marketplace, and the legislation contained provisions aimed at maintaining incentives for this innovation.” Julie Brill, Comm’r, Fed. Trade Comm’n, “Antitrust and Innovation: Rebalancing the Scale,” Remarks at Meeting of International Bar Association (Sept. 14, 2013) (available at https://www.ftc.gov/)
Indeed, Hatch-Waxman has nothing to do with the regulatory process which Appellant seeks to utilize to maximize its profits. *See Namenda*, 787 F.3d at 655–56. Generic substitution requirements are creatures of state laws that “permit or require pharmacists to dispense a therapeutically equivalent, lower-cost generic drug in place of a brand drug absent express direction from the prescribing physician that the prescription must be dispensed as written.” *Id.* at 645.

Generic drug manufacturers utilize these state substitution laws to largely avoid the competitive process of marketing their products. While brand-name manufacturers must invest in research, development, and marketing in order to succeed, generic manufacturers instead merely take advantage of the free boost provided by state-supported generic substitution—what the district court accurately described as a “regulatory bonus.” JA.41. As a result of this bonus, the costs associated with bringing a generic drug to market are less than one percent of the analogous costs for brand drugs. *See* Shepherd at 3–4 ($2.6 billion estimated cost to bring brand drug to market verses $1–2 million cost for generics).

**C. Antitrust Law Should Not Be Used to Protect Regulatory Advantages or the Business Models Built Upon them.**

The “regulatory bonus” conferred by state substitution laws has delivered to generics a luxury rarely available in a free market situation: virtually
guaranteed sales, with little to no promotional expense. The panel in *Namenda*, for example, reasoned that “additional expenditures by generics on marketing would be impractical and ineffective because a generic manufacturer promoting a product would have *no way to ensure that a pharmacist would substitute its product*, rather than one made by one of its generic competitors.” *Namenda*, 787 F.3d at 656 (emphasis added).

This business model—namely, using substitution to keep costs low and sales high—has proven enormously profitable for generic manufacturers. They are largely invisible to the public because they do not advertise, but they have nevertheless transformed themselves into Goliaths of the pharmaceutical world. Generic products accounted for 80% of prescriptions filled in 2011, *see* JA.606–07, a figure that is “expected to continue to grow over the next few years.” U.S. Gov’t Accountability Office, GAO-12-371R, *Drug Pricing: Research on Savings from Generic Drug Use* 1 (2012), [http://www.gao.gov/assets/590/588064.pdf](http://www.gao.gov/assets/590/588064.pdf).

vulnerable and deserve extraordinary protection from courts in the form of new antitrust duties placed upon their competitors.

There is nothing fixed and immutable about their business model. That is the point of a free market system in which no competitor is assured of market success. If product replacement by brand-name manufacturers challenges the generic-substitution model, generics can respond by adapting their business model—by, for example, promoting their products. Nothing prevents them from doing so. But it would be bad policy to put courts in the business of monitoring innovation simply because generics prefer their current business model and the regulatory advantages upon which it is based.

This is the principal flaw in the Second Circuit’s reasoning in *Namenda*. Even if the court found the facts of that case troublesome, *see infra* Part III, the court erred in concluding that the antitrust laws require the protection of a regulatory bonus that “ensured” sales of generic drugs. *Namenda*, 787 F.3d at 656. While the Second Circuit observed that “[a]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue,” *id.* at 658, it overlooked that those circumstances are shaped entirely by generic manufacturers’ elective choice to base their businesses on a regulatory advantage that their brand-name competitors do not enjoy.
Antitrust laws exist not to further the perceived purposes of drugs laws, *contra* IP Amicus Br. at 1, or to protect firms’ regulatory advantages or their preferred business models. Rather, antitrust aims to further bona fide competition among firms. *See Broadcom*, 501 F.3d at 308. If lawmakers determine that state substitution laws and Hatch-Waxman should be expanded to restrain innovation and to guarantee the opportunity for generic free-riding, lawmakers may use the legislative process to resolve whether that is the proper course. It is not for the courts to achieve that end.

III. THE REASONING OF NAMENDA SHOULD NOT BE EXTENDED TO THE FACTS BEFORE THIS COURT

Even if this Court credited some of the reasoning in *Namenda*—and it should not, as discussed above—it should not extend *Namenda*’s logic to the inapposite facts of this case. In *Namenda*, the Second Circuit concluded that the brand-name manufacturer monopolized a market and effectively prevented a generic competitor from even entering that market. Here, Appellees control a mere product, not a market, and chose to pull the old version of their drug from the marketplace only after marketing it alongside a generic competitor for years.

In *Namenda*, the defendant attempted to replace a patented drug, Namenda IR, with an extended-release version, Namenda XR, and cease production of Namenda IR before any generic version of Namenda IR came to market. *See* 787 F.3d at 647–48. Had the company succeeded, there would have
been no brand version of Namenda IR for which generic drugs could be substituted under state substitution laws. The generic version of Namenda IR would not have been available until after Namenda XR had come to market. Under those circumstances, the Second Circuit reasoned that consumers would have been “coerced” into using the newer version of the drug. See id. at 655 (“By removing Namenda IR from the market prior to genetic IR entry, Defendants sought to deprive consumers of that choice.”).

In the present case, however, generic versions of Doryx have already come to market and have proven highly successful. Doryx capsules have been available without patent protection since 1985, a generic version of the capsule came to market in 2006, and since 2010, Mylan has sold generic versions of 75 and 100 mg Doryx tablets. See JA.38. Thus, the motivating principle behind the Second Circuit’s Namenda decision—concerns over consumer coercion in the face of a product replacement where a generic for the legacy version of a drug was not yet available—is simply not implicated in this case.

The Namenda panel itself explicitly recognized this distinction, explaining that the district court’s decision here was based upon “no evidence of coercion.” Namenda, 787 F.3d at 652 n.23. The panel observed that “because generics had already entered the market at the time of defendants’ product reformulation, ‘doctors remained free to prescribe generic Doryx; pharmacists
remained free to substitute generics when medically appropriate; and patients remained free to ask their doctors and pharmacists for generic versions of the drug.”” Id.

Moreover, this case illustrates why the Namenda panel’s concerns regarding the financial strain placed upon generic companies tasked with marketing and advertising their own products were misplaced. That panel speculated that it would be “impractical and uneconomical for generic manufacturers to market their products to doctors or pharmacists because . . . marketing costs [would] severely impact generic manufacturers’ ability to offer the lower prices upon which they compete.” Namenda, 787 F.3d at 656 n.30.

Even if this speculation was correct under the circumstances in Namenda, it should not be applied here. As the district court found, “Mylan’s generic 150 mg Doryx tablet generated a gross profit of $146 million over three years—without Mylan spending a cent on ‘extraordinary tactics,’ such as promoting its product to doctors and the public.” Id. at JA.39 (quoting W.C. S.J. at App. 7). Although Mylan manufactures generic drugs, it is a sophisticated, extremely profitable company capable of behaving like a rational market actor when it chooses to do so. See id. (noting that during its 180-day exclusivity period for 75 and 100 mg Doryx tablets, “Mylan significantly raised the price of generic Doryx”). The Namenda panel’s concerns regarding resource-strapped generic
manufacturers simply are not implicated here. Far more apt is the district court’s assessment of Mylan’s ability to contribute some of its substantial profits towards advertising and promoting its own products. JA.39.

CONCLUSION

For the reasons stated above, the decision of the district court should be affirmed.

December 21, 2015

PATTERSON BELKNAP WEBB & TYLER LLP

William F. Cavanaugh
John P. Figura
George A. LoBiondo
Clinton W. Morrison
1133 Avenue of the Americas
New York, New York 10036
(212) 336-2000
wfcavanaugh@pbwt.com
jfigura@pbwt.com
globiondo@pbwt.com
cmorrison@pbwt.com

Attorneys for Amici Curiae Business and Policy Professors
CERTIFICATE OF COMPLIANCE

I, William F. Cavanaugh, hereby certify that:

1. I am a member of the bar of this court;

2. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B), as modified for amici by Fed. R. App. P. 29(d), because this brief contains XYZ words, excluding the parts of this brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii);

3. The brief complies with the typeface limitation of Fed. R. App. P. 32(a)(5) and the style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word for Windows in 14 point Times New Roman font;

4. Pursuant to the Third Circuit Local Appellate Rule 31.1(c), the electronic version of this brief transmitted to the Clerk via the CM/ECF system is identical to the text version of the hard copies that were dispatched today to Federal Express for delivery to the Clerk within three days. This document was scanned using [INSERT VIRUS PROTECTION for PBWT] with virus definitions updated December 21, 2015. No viruses were detected.

December 21, 2015

William F. Cavanaugh
CERTIFICATE OF SERVICE

I hereby certify that on [INSERT DATE], I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Third Circuit using the appellate CM/ECF system. To the best of my knowledge, all parties to this appeal are represented by counsel who are registered CM/ECF users and will be served electronically by the appellate CM/ECF system.

December 21, 2015

William F. Cavanaugh