No. 15-2236

IN THE
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.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

BRIEF *AMICUS CURIAE* OF THE NATIONAL ASSOCIATION OF MANUFACTURERS IN SUPPORT OF APPELLEES

Linda E. Kelly
Quentin Riegel
MANUFACTURERS' CENTER FOR LEGAL ACTION
733 10th Street, NW
Suite 700
Washington, DC 20001
202.637.3000

Thomas R. McCarthy
William S. Consovoy
J. Michael Connolly
CONSOVOY MCCARTHY PARK PLLC
3033 Wilson Blvd.
Suite 700
Arlington, VA 22201
703.243.9423
will@consovoymccarthy.com

Attorneys for Amicus Curiae

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INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae the National Association of Manufacturers ("NAM") is the largest manufacturing association in the United States. Its membership comprises small and large manufacturers in every industrial sector and in all fifty States. The manufacturing industry employs over twelve million men and women, contributes roughly $2.1 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for two-thirds of all private-sector research and development. The NAM's mission is to enhance the competitiveness of manufacturers and to improve American living standards by shaping a legislative and regulatory environment conducive to economic growth. Indeed, the NAM is the leading advocate for laws and policies that help American manufacturers compete in the global economy and create jobs throughout the United States. To that end, the NAM regularly participates as *amicus curiae* in cases of particular importance to the manufacturing industry. *See, e.g.*, *Tyson Foods, Inc. v. Bouaphakeo*, No. 14-1146 (S. Ct. 2015); *UPMC Presbyterian Shadyside v. NLRB*, No. 14-4523 (3d Cir. 2015); *Trinity Wall Street v. Wal-Mart Stores, Inc.*, No. 14-4764 (3d Cir. 2015).

[1] All parties have consented to the filing of this amicus brief. No party's counsel authored this brief in whole or part, and no party, party's counsel, or other person—other than amicus curiae, its members, or its counsel—contributed money that was intended to fund the preparation or submission of this brief.

This litigation raises issues of direct concern to the NAM and the American industry as a whole. American manufacturers are among the most dynamic and innovative in the world. The NAM's members develop technologies that create jobs and stimulate our economy. America's economic future depends on our continued ability to innovate and commercialize new products and processes. Legal rules that disrupt the incentives for future innovation-directed research and development thus will harm manufacturers and consumers, as well as the American economy.

The theory of antitrust liability advanced by Appellant Mylan would impose a duty upon Appellees to market older drug formulations—in order to help Mylan take advantage of state generic-substitution laws—unless Appellees can demonstrate that their older drug formulations are "sufficiently" innovative. If accepted, this theory would create a rule that is unadministrable in practice, counter to basic principles of antitrust law, and a hindrance to innovation. Although the focus of this case is the pharmaceutical industry, the rule advanced by Appellants is not limited to that industry and could apply equally to all industrial sectors that depend on strong intellectual property rights.

INTRODUCTION AND SUMMARY OF ARGUMENT

In 1985, Defendant-Appellee Mayne Pharmaceuticals introduced to the market in capsule form a delayed-release version of doxycycline hyclate—one

among a class of mild antibiotics known as oral tetracyclines that are used primarily for treating acne. Mayne branded this drug with the name Doryx. This capsule form of Doryx was never patented, a circumstance that has allowed other drug manufacturers to enter the market and compete with Mayne's Doryx capsules. Competitors did so, bringing to market generic versions of Doryx and various other oral tetracyclines that are equally effective in treating acne. Brief of Appellees at 2, 8, 10, 63, 88.

Over time, Mayne developed new and improved versions of Doryx in response to competitive market forces and observed difficulties with the administration of Doryx. By 2005, Mayne and Defendant-Appellee Warner Chilcott ("Warner") brought to market an FDA-approved Doryx tablet that it had spent six years developing. The Doryx tablet demonstrated a marked improvement in product stability over the Doryx capsule, and it significantly reduced the risks of esophageal injury associated with capsules. Unsurprisingly, Mayne obtained patent protection for the Doryx tablet as a result of these innovations. Mayne continued to develop new FDA-approved formulations of its Doryx tablet, introducing scoring to provide flexibility in dosage options and to reduce the price per dose.

During this time, Plaintiff-Appellant Mylan engaged in "start-and-stop efforts to develop generic forms of Doryx." Brief of Appellees at 18. Although Mylan never developed a generic form of Doryx capsules, it did bring to market a

generic Doryx tablet, obtaining 180 days of first-filer Hatch-Waxman exclusivity that yielded Mylan substantial profits. As Mayne continued to develop new formulations of Doryx, Mylan attempted to keep up with these changes, hoping to benefit from state laws that allow or, in some cases, require pharmacies to substitute a branded drug with its bioequivalent generic counterpart. At times, Mylan benefited from Mayne's and Warner's product switching. Indeed, after Mayne and Warner ceased selling 75 and 100 mg Doryx tablets in 2011 (in favor of tablets with larger dosages), Mylan became "the exclusive seller of 75 and 100 mg tablets—branded or generic—for two and a half years." During that time, "Mylan raised [its] tablet prices to levels that were higher than Defendants' last reported prices for [branded] Doryx." Joint Appendix ("JA") 23; *see also* Brief of Appellees at 21.

Notwithstanding widespread entry and competition in the market for acne-fighting drugs and the profits Mylan was able to reap by producing unbranded Doryx, Mylan brought this antitrust lawsuit against Mayne and Warner. Mylan alleged that Mayne and Warner illegally thwarted competition in the sale of generic drugs by so-called "product hopping"—*i.e.*, "making changes to [Doryx] that ostensibly provided no significant improvements but prevented pharmacists from automatically filling Doryx prescriptions with generic equivalents." JA 17. Mylan specifically attacked four "product hops": (1) Mayne's and Warner's "2005

change from 75 and 100 mg capsules to 75 and 100 mg tablets"; (2) "2008 introduction of a single-scored 150 mg tablet"; (3) "2009 addition of a single score to 75 and 100 mg tablets"; and (4) "2011 change from single to dual score on the 150 mg tablet." JA 24. As Appellees put it, "Mylan asked the district court to impose a special duty requiring Warner to sell only unpatented Doryx capsules to help Mylan make more sales, … argu[ing] that the benefits of the new versions of Doryx tablets were not 'meaningful' enough to permit their sale in the U.S." Brief of Appellees at 1.

Although the district court properly rejected Mylan's claims, Mylan attempts to relitigate them on appeal. Under Mylan's proposed theory of liability, Appellees must market older drug formulations—in order to help Mylan take advantage of state generic-substitution laws—unless Appellees can demonstrate that the older drug formulations are "sufficiently innovative." JA 43. In other words, all four versions of Mayne's patented Doryx tablets would be unlawful, *see* JA 169-77, ¶¶ 52-56, 60-72, and Appellees would be forced to "sell unpatented Doryx capsules until Mylan can launch a competing version," Brief of Appellees at 88; *id.* at 89 ("Mylan's rule would require Warner to sell only trade-secret-protected Doryx capsules instead of patented tablets.").

Appellees rightly explain that Mylan's claims must fail because Mylan failed to demonstrate that Appellees possessed market power and because "no

patent or other conduct prevented or hindered Mylan's ability to compete in generic Doryx capsule or tablet sales at any time from the 1985 launch of unpatented Doryx capsules through the alleged 'product-hops' at issue here." Brief of Appellees at 26.

The NAM respectfully submits this brief to highlight the vital importance of intellectual property rights to American manufacturers and the significance of incremental changes in driving innovation. The NAM further explains that requiring judicial supervision of manufacturers' business judgments regarding when and how to innovate would create an unadministrable rule that runs counter to antitrust law and would deter innovation.

ARGUMENT

I. STRONG INTELLECTUAL PROPERTY RIGHTS ENABLE THE INNOVATION THAT DRIVES OUR ECONOMY AND ARE VITALLY IMPORTANT TO AMERICAN MANUFACTURERS.

Like Appellees, most American manufacturers hold patents, trade secrets, and other intellectual property rights. Indeed, "[t]he entire U.S. economy relies on some form of IP because virtually every industry either produces or uses it." Economics and Statistics Administration, *Intellectual Property and the U.S. Economy: Industries in Focus* vi (2012), *available at* http://www.uspto.gov/sites/default/files/news/publications/IP_Report_March_2012.pdf ("*Intellectual Property and the U.S. Economy*"). Innovation is the primary driver of economic

growth and national competitiveness in the global economy. *See* National Economic Council, Council of Economic Advisers, and Office of Science and Technology Policy, *A Strategy for American Innovation: Securing our Economic Growth and Prosperity* (2001), *available at* http://www.whitehouse.gov/innovation/strategy ("*Strategy for American Innovation*").

IP-intensive industries, in particular, drive our economy. In 2010, the seventy-five industries classified as IP-intensive accounted for 27.1 million jobs—or nearly 19% of all employment in the economy. *Intellectual Property and the U.S. Economy* at 45. Moreover, "every two jobs in an IP-intensive industry support an additional job somewhere else in the economy," which means that nearly 28% of all jobs "were directly or indirectly attributable to the most IP-intensive industries." *Id.* at vii. And the average wages for these jobs are approximately 42 percent higher than weekly wages in other (non-IP-intensive) private industries. *Id.*

IP-intensive industries likewise are the chief engine of production. In 2010, they accounted for over $5 trillion in value added, or 35 percent of U.S. gross domestic product (GDP). *Id*. And they accounted for over three-quarters of a trillion dollars or over 60 percent of all U.S. merchandise exports. *Id.* at viii.

Critical to this creative activity is a robust intellectual property regime. American manufacturers constantly must make business judgments regarding whether and to what extent they should invest capital in the development of new

and improved products that may be offered alongside or as replacements to existing products. But the investments necessary to innovate and to develop IP often are substantial. Holders of capital will make the necessary investments only if they have "assurance that they will benefit from and recover the costs of the creation of intellectual property." *Id.* at 1.

Our intellectual property system is intended to promote innovation, *see, e.g.*, U.S. Const., art I, §8, cl. 8, and thus affords protections for intellectual property that provide the financial incentive for American manufacturers to undertake the research and development costs necessary to foster innovation. Without those protections, "the creators of intellectual property would tend to lose the economic fruits of their own work, thereby undermining the incentives to undertake the investments necessary to develop the IP in the first place." *Id.* at v; *see also Strategy for American Innovation* at 11.

II. INCREMENTAL INNOVATION IS THE PREDOMINANT MECHANISM FOR IMPROVING PRODUCTS IN THE MANUFACTURING AND HIGH-TECHNOLOGY INDUSTRIES.

Most innovation does not arise from pioneering breakthroughs but from incremental steps. "[R]epeated incremental improvement is the predominant mechanism of innovation and product development within most manufacturing and high-technology industries." Albert Wertheimer et al., *Too Many Drugs? The Clinical and Economic Value of Incremental Innovations*, 14 Investing in Health:

The Social & Economic Benefits of Health Care Innovation 77, 78 (2001). When a company brings a pioneering invention to market, it often will quickly offer new, improved versions of the product, as it seeks to build and to develop its previously unknown advances. *See, e.g.*, Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* at 6 (2003) (noting that "computer hardware and software contain an incredibly large number of incremental innovations"). "Once a company has a product up and running it tends to have built up considerable amounts of human capital and competencies so [it] may as well devote time to making it better or reducing costs." *Incremental Innovation vs. Radical Innovation*, Incremental Innovation (2012), *available at* http://goo.gl/cCASO0.

Indeed, one report predicts that $5 trillion of growth during this decade will be based not on revolutionary breakthroughs, but on the premise of "everything the same, but nicer." *See The Great Eight: Trillion-Dollar Growth Trends to 2020*, Bain & Company 8 (2011), *available at* http://www.bain.com/Images/BAIN_BRIEF_8MacroTrends.pdf. "Innovation will increasingly come in new forms beyond novel technologies like iPads and Twitter." *Id*. Businesses are expected to invest more heavily in "soft innovations," which will offer customers "premium products and services as substitutes for common consumer purchases, better products commanding higher prices, and a greater variety of niche

products." *Id*.

Google's release of Gmail is a good example of successful incremental innovation. When Gmail launched, it offered one unique advantage over its competitors: its user interface was simple and user friendly. Over time, Google released more features that made Gmail better, faster, and easier to use. Years later, Gmail was taken out of "beta" and finally listed as being "complete," even though Google still continually improves upon the product. Google has used this same formula to bring other new products, such as its Maps service and Chrome browser, to market. *See Incremental Innovation*, *supra*; *see also* Devendra Sahal, Patterns of Technological Innovation 37 (1981) (examining the history of the "aluminum production, electricity generation, and synthetic fiber industries" and concluding that "progress frequently takes the form of several minor innovations"). These products show that "innovations, including even small changes in product design, can generate significant consumer benefits, and that such changes are consistent with the normal competitive process." Joshua D. Wright & Judge Douglas H. Ginsburg, *Comment Regarding the Canadian Competition Bureau's Intellectual Property Enforcement Guidelines* 2 (Aug. 10, 2015).

The pharmaceutical industry is no exception. "[M]ost innovation in the pharmaceutical industry is incremental, creating new products that expand therapeutic classes, increase available dosing options, remedy physiological

interactions of known medicines or improve other properties of existing medicines." Joanna Shepherd, *Deterring Innovation: NY v. Actavis and the Duty to Subsidize Competitors' Market Entry*, Minnesota Journal of Law, Science & Technology 28 (forthcoming). "The vast majority of clinically important drugs developed over the last 50 years have resulted from an evolutionary process, involving multiple, small, successive improvements within a pharmacological class." Dr. Albert Wertheimer, et al., *The Value of Incremental Pharmaceutical Innovation for Older Americans*, Temple University 3 (2001).

According to FDA data, two-thirds of new drug approvals are for incremental innovations. *See* The National Institute for Health Care Management Research and Educational Foundation, *Changing Patterns of Pharmaceutical Innovation* 3 (2002). And these changes are often improvements to essential drugs. For example, 63 percent of the drugs on the World Health Organization's Essential Drug Lists are so-called "follow-on" drugs. J. Cohen & K. Kaitin, *Follow-On Drugs and Indications: The Importance of Incremental Innovation to Medical Practice*, 15 Am. J. Therapeutics 89-91 (2008).

Mylan's criticism of "product hopping" thus misses the point. "[N]ew 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." Wright & Ginsburg, *supra*, at 2. And these "incremental pharmaceutical

improvements" have led to (1) "[f]ewer side effects"; (2) [i]mproved drug safety and effectiveness"; (3) "[g]reater ease of use, facilitating compliance with prescribed therapeutic regimens"; and (4) "[p]roduct alternatives that permit treatments to be better tailored to the individual patient's needs." Wertheimer, *The Value of Incremental Pharmaceutical Innovation for Older Americans*, *supra*, at 3. For example, an individual with HIV once needed to take a complex "cocktail" of drugs that was difficult to administer and prone to error. Cohen & Kaitin, *supra*, at 90. But incremental improvements to this cocktail have now simplified the dosage to a single pill. *Id*.

Thus, many changes to drugs that may appear minor are actually critical to the patient's overall health. For example, "[l]ow patient adherence is a major barrier to realizing the benefits of medications that have been shown to do more good than harm in clinical trials …. Many patients stop taking their medication in the first months following initiation, often without informing their provider, with further attrition over time. In addition, many patients who continue their medication do not consistently take it as prescribed." Robbie Nieuwlaat et al., *Interventions for Enhancing Medication Adherence*, Cochrane Database of Systematic Reviews (2014). Thus, innovations in drugs enable physicians to tailor treatments to patient needs, to provide backups if other drugs are unavailable, and to offer alternatives based on both price and quality. Wertheimer, *Too Many*

Drugs?, *supra*, at 78-79. In addition, alternative dosing and delivery mechanisms can help patients take their medications more easily and consistently. *Id*. For example, patient compliance with directions regarding medication is "higher with once than multiple daily dosing regimens." Matthew Falagas et al., *Compliance with Once-Daily Versus Twice or Thrice-Daily Administration of Antibiotic Regimens: A Meta-Analysis of Randomized Controlled Trials*, PLoS One (Jan. 5, 2015).

At bottom, the future medicines that will save lives in this country and around the world are likely to arise not from technological breakthroughs, but from "[t]he cumulative effect of numerous minor incremental innovations." Nat'l Research Council, *Prospectus for National Knowledge Assessment*, National Academy Press (1996). Those who doubt the significance of "incremental innovation and follow-on improvements to existing therapies … need to look more deeply at the reality of what subsequent innovation provides.… Pharmaceutical innovation is an inherently dynamic process; one innovation builds on another and improvements draw from a long history of earlier technological advances." Dr. Kristina Lybecker, *The Case for Incremental Innovation: The Importance of Protecting Follow-on Pharmaceutical Discoveries*, IPWatchdog (June 23, 2014), *available at* http://goo.gl/gxyzWl. To diminish incremental innovation is thus to diminish technological progress.

III. JUDICIAL SUPERINTENDENCE OF MANUFACTURERS' JUDGMENTS ABOUT WHEN AND HOW TO INNOVATE WILL CREATE AN UNADMINISTRABLE TEST THAT RUNS COUNTER TO ANTITRUST LAW, IS DESTRUCTIVE OF PATENT RIGHTS, AND STIFLES THE INCENTIVE TO INNOVATE.

Mylan advocates a new rule of antitrust law that would impose a duty upon Appellees to market older drug formulations—in order to help Mylan take advantage of state generic-substitution laws—unless Appellees can demonstrate that such older drug formulations are "sufficiently" innovative. The district court properly rejected Mylan's proposed test, which would be unadministrable, contrary to antitrust law, destructive of patent rights, and a hindrance to innovation.

Determining whether a new or reformulated product is sufficiently innovative is a task that courts are "ill-equipped" to handle. Wright & Ginsburg, *supra*, at 2. Indeed, the federal courts have long understood that such a task would be fruitless because there would be no criteria to guide judicial decisionmaking. *See Allied Orthopedic Appliances v. Tyco Health Care Group*, 592 F.3d 991, 1000 (9th Cir. 2010) ("There are no criteria that courts can use to calculate the 'right' amount of innovation, which would maximize social gains and minimize competitive injury."). A judge can no better decide whether one product is superior to another—much less whether a certain incremental innovation is procompetitive—than any individual consumer. Indeed, a judge would be left with precisely the same tools possessed by any other consumer—his or her own

personal preferences. He or she thus would be making a *consumer* decision, not a *judicial* one. Judges should not be picking winners and losers in the marketplace. Indeed, courts and "antitrust scholars have long recognized the undesirability of having courts oversee product design." *United States v. Microsoft Corp.*, 147 F.3d 935, 948 (D.C. Cir. 1998). Antitrust law properly leaves these decisions to the market, in part because individual consumer decisions are a matter of personal "taste," *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 287 (2d Cir. 1979) ("[N]o [individual] can determine with any reasonable assurance whether one product is 'superior.'"), whereas the market has the virtue of strength in numbers, *id.* ("[W]hether one product is "superior" to another … can only be inferred from the reaction of the market."). To subordinate these market decisions to the preferences of individual judges would be "unadministrable" and "unwise." *Allied Orthopedic Appliances*, 592 F.3d at 1000.

Perhaps more importantly, Mylan's proposed test flatly contradicts a fundamental principle of antitrust law by requiring manufacturers to aid their competitors. As the district court recognized, the end goal of Mylan's test is to impose on Appellees a "duty to facilitate Mylan's business plan [of taking advantage of generic substitution laws] by keeping older versions of branded Doryx on the market." JA 41. But this entire enterprise runs counter to the basic principle that the Sherman Act protects *competition*, not *competitors*. *See Verizon*

Commc'ns v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 411 (2004) ("There is no duty to aid competitors."); *see also Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 338 (1990); *Brunswick Corp. v. Pueblo Bowl O-Mat, Inc.*, 429 U.S. 477, 484, 488-89 (1977).

On top of that, Mylan's theory would make it unlawful for Mayne to market its patented Doryx tablets. Indeed, Mylan is quite clear about this. *See* JA 169-77, ¶¶ 52-56, 60-72. Though antitrust law places some limits on how a patent holder may exploit his or her patent, no case supports the idea that a patent holder may be barred entirely from practicing his or her patent in order to aid a rival.

In short, judicial superintendence of manufacturers' business judgments will, at a minimum, inject uncertainty into a manufacturer's decision to invest in innovation. This will hinder manufacturers' and patent holders' ability to recoup their investments and deter beneficial innovation. *See* JA 44 ("Mylan's theory also risks slowing or even stopping pharmaceutical innovation."). Manufacturers will leave investment capital to sit on the sidelines rather than undertake the risk and uncertainty of costly litigation necessary to bring a new or reformulated product to market. *See* JA 24 ("The prospect of costly and uncertain litigation every time a company reformulates a brand-name drug would likely increase costs and discourage manufacturers from seeking to improve existing drugs."). This "dampening of technological innovation would be at cross-purposes with antitrust

law," *Berkey Photo*, 603 F.2d at 287, and threaten to halt the innovation that is the engine of our dynamic economy.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Dated: December 21, 2015

/s/ William S. Consovoy
Thomas R. McCarthy
William S. Consovoy
CONSOVOY MCCARTHY PARK PLLC
3033 Wilson Blvd.
Suite 700
Arlington, VA 22201
703.243.9423
will@consovoymccarthy.com

Linda E. Kelly
Quentin Riegel
MANUFACTURERS' CENTER FOR LEGAL ACTION
733 10th Street, NW
Suite 700
Washington, DC 20001
202.637.3000

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2. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 3,582 words excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

3. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman.

4. The electronic version of this brief was prepared in portable document format; it is identical to the paper version of the brief filed with the Court. This document was scanned using McAfee VirusScan software, and no virus was detected.

/s/ William S. Consovoy

Counsel for Amicus Curiae

CERTIFICATE OF SERVICE

I hereby certify that, on December 21, 2015, this pleading was served on all counsel of record via the Electronic Case Filing system for the United States Court of Appeals for the Third Circuit.

/s/ William S. Consovoy

Counsel for Amicus Curiae