No. 14-4624

IN THE
United States Court of Appeals
FOR THE SECOND CIRCUIT

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

Plaintiffs-Appellees,

v.

ACTAVIS PLC FOREST LABORATORIES, LLC,

Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTHERN DISTRICT OF NEW YORK

BRIEF OF BUSINESS AND POLICY PROFESSORS AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS-APPELLANTS

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**Application for admission to the U.S. Court of Appeals for the Second Circuit pending*

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STATEMENT OF INTEREST[1]

Amici curiae are professors of management, organization, and policy from leading universities throughout the United States. (A list of the amici curiae is attached as Appendix A.) Amici have written extensively in the fields of strategy, innovation, management, and competition. They write to bring to the Court's attention certain policy considerations that inform the question presented by this appeal – whether to apply the federal antitrust laws to require a pharmaceutical firm that has developed a newer version of a drug to continue producing an older version of a drug purely as a means to facilitate generic competition.

SUMMARY OF ARGUMENT

This appeal challenges an injunction entered by the district court that requires Forest Laboratories (Forest) to continue to manufacture and distribute Namenda IR, a drug to treat Alzheimer's Disease that must be taken twice a day. Absent the injunction, Forest will discontinue Namenda IR because it has introduced a new product, Namenda XR, which offers significant advantages over the old product, notably that it must only be taken once a day.

The district court concluded that an injunction was necessary to promote competition and consumer welfare. Based on their experience studying the

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[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.

behavior of manufacturing companies, as well as a vast body of scholarly literature, the amici believes that the injunction will have the opposite effect. To the contrary, it is inefficient and anti-competitive to force a company to continue to support a product that it has replaced and for which the government's witness agrees there is no "market need."[2]

As a threshold matter, the court's approach is ill-suited to the question of whether to permit product discontinuations because it ignores or undervalues important drivers of innovation, both generally and in the pharmaceutical industry in particular. The need to protect innovation is heightened in the pharmaceutical industry, which is heavily regulated and involves high research and development costs. The statutory framework governing competition in the pharmaceutical industry balances two key values – innovation and competition. Amici believe that this balance tips strongly in favor of permitting an innovator, or brand-name, company to discontinue a product upon introducing a newer, improved version of that product. This approach preserves necessary incentives for innovator companies to invest the substantial sums necessary to develop new medicines against what are often long odds, while still preserving adequate opportunities for

[2] Lah Hr'g. 85:14-23, available at Pace Decl. Ex. 1, attached to Def.- Appellants' Motion to Stay at the Second Circuit, Dec. 18, 2014, Dkt. No. 41-2.

generic manufacturers to gain market share and offer lower-priced alternatives to branded products.

Even if this Court upholds the approach applied by the district court and considers whether procompetitive justifications for removing Namenda IR from the market outweigh any anticompetitive effect, the Court should recognize the procompetitive advantages of innovation that were overlooked by the district court. Requiring Forest to keep Namenda IR on the market would be unnecessary and inefficient, and would have little effect beyond subsidizing Forest's generic competitors.

ARGUMENT

I. The District Court's Analysis Requires Courts To Make Judgments About Manufacturing Decisions For Which They Are Ill-Equipped.

In evaluating Forest Laboratories' decision to discontinue Namenda IR, the district court applied the "rule of reason" under the antitrust laws, which entails weighing the anticompetitive effects of the defendant's conduct against any procompetitive justifications. *See FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2236 (2013) ("An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason.").

From the amici's standpoint as scholars in the field of manufacturing strategy and innovation, the rule of reason is an inappropriate approach to assess decisions to discontinue products upon the introduction of newer versions of those products. The district court applied the rule of reason to require Forest to continue manufacturing a product it has replaced with an improved product. This approach directly implicates a concern identified by the Supreme Court—that antitrust laws not be construed in such a way that courts act as "central planners, identifying the proper price, quantity, and other terms of dealing—role for which they are ill-suited." *Verizon Comm'n, Inc. v. Trinko*, 540 U.S. 398, 408 (2004).

As discussed in the following section, a closer look at the district court's analysis underscores the unsuitability of the rule of reason here because that analysis ignores important considerations about innovation, both generally and in the pharmaceutical industry specifically, and the interrelationship between innovation and the discontinuation of older products.

II. The District Court Ignores Important Considerations About the Nature of Innovation.

A. Discontinuation of Old Versions is Part of the Process of Innovation.

To successfully innovate, firms need to refocus their manufacturing, marketing and sales efforts and other resources on new products and discontinue their predecessors. For example, Apple usually discontinues its old iPhone models simultaneously or shortly after releasing a newer model; when it does overlap models they overlap only for a year, and the old model is significantly discounted so that Apple can tap a more price conscious segment that would not purchase the new model.[3] Within a year or two of discontinuing production of a model, it will also cease to provide software support for the discontinued model. To do otherwise would be an extremely costly diversion of resources. In the automobile industry,

[3] Brian X. Chen, *Apple Unveils Faster iPhone, and a Cheaper One, Too*, N.Y. TIMES, Sept. 10, 2013, http://www.nytimes.com/2013/09/11/technology/appleshows-off-2-new-iphones-one-a-lower-cost-model.html?pagewanted=all&_r=0; Chris Burns, *iPhone 5 Discontinued: Where Did They All Go?* Slashgear, Sept. 12, 2013.

automobile manufacturers replace inventory of old models with newer models every few years and focus all marketing towards the newer product. And for good reason – it is usually the new model that everyone wants, making the old model obsolete to most consumers, and rendering it a waste of a manufacturer's resources to continue manufacturing and promoting the older version.[4] Efficiency concerns dictate that a company should not be forced to manufacture or market a product it no longer wants to sell and provide the legitimate justification for terminating the old product.

The process of replacing an older product with a new product is known as a "product rollover." The product rollover strategy employed significantly influences the success of a new product introduction.[5] Billington, Lee and Tang argue that "In an ideal product rollover, the old product is sold out at the planned introduction of the new product, and the new product is readily available."[6] Studies by both Koca, Souza and Druehl,[7] and Levinthal and Purohit[8] show that a "single roll" rollover

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[4] Charles Darveight, *Automotive Industry Gotchas*, Autoevolution, Dec. 23, 2010. http://www.autoevolution.com/news/automotive-industry-gotchas-how-to-buy-agood-new-car-without-getting-screwed-by-marketing-tricks-28762.html.

[5] Eylem Koca, et al., *Managing Product Rollovers*. 41 DECISION SCI., 403, 423 (2010).

[6] Corey Billington, Hau L. Lee & Christopher S. Tang, *Successful Strategies for Product Rollovers*, SLOAN MGMT. REV. 23, 30 (Spring1998).

[7] Koca, *supra* n. 5.

[8] Daniel A. Levinthal & Devarat Purohit, *Durable Goods and Product Obsolescence*, 8 MARKETING SCI. 35 (1989).

strategy (when the old product is discontinued as soon as the new product is available) is almost always the most effective rollover strategy for introducing and building demand for innovations. Single roll is especially preferred when the advantage of the new product is clear to the market and there is no need to continue supplying the old product, as reflected in surveys of doctors and caregivers in this case. For example, the record here shows that surveys of doctors were undertaken, with 99% of doctors preferring the new once-daily version of Namenda over twice-daily Namenda, and that just 2.4% of patients were expected to have any continuing medical need for Namenda IR.[9]

A "dual roll" strategy (when the old product is maintained on the market for some time after the new product is introduced)—which Forest undertook by keeping Namenda IR on the market for a period of time that is lengthened by the district court's decision—can facilitate a transition between products, but also has numerous disadvantages. First, manufacturing, marketing, distributing, and otherwise supporting two products is more expensive than performing those activities for one product. When the new product will serve the same market as the old product, there is ordinarily no additional gain to offset this cost. One or both products will sell in lower volumes than it otherwise would, potentially reducing

[9] Pace Decl. Ex. 7, Decl. of William Meury dated Oct. 21, 2014, Ex. B at 506; Pace Decl. Ex. 17, Decl. of William Kane dated Dec. 12, 2014, ¶ 11.

economies of scale. As noted in the strategy and economics research, a broader product line typically results in higher per-unit production costs,[10] added design costs, and additional inventory costs.[11]

These principles apply with particular force here. For example, Forest's managers noted that maintaining both products increases the burden of managing regulatory filings and requests, and handling returns.[12] Moreover, the costs will not be borne by Forest alone. Having both products in the market will increase the inventory carrying costs and supply chain complexity for distributors and pharmacists. Both drugs would have to be stocked, increasing the capital tied up in inventory and warehousing costs. Both drugs would also have to be tracked to ensure that expiration dates are monitored and any regulatory issues are handled. In short, routinely requiring companies to keep old products available would create

[10] William J. Baumol, John C. Panzar & Robert D. Willig, *Contestable Markets and the Theory of Industry Structure* (1982); Barry L. Bayus & William P. Pusis, Jr., *Product Proliferation: An Empirical Analysis of Product Line Determinants and Market Outcomes,* 18 MARKETING SCI. 137, 153 (1999).
[11] Kelvin Lancaster, *Variety, Equity and Efficiency* (1979); Kelvin Lancaster, *The Economics of Product Variety: A Survey*, 9 MARKETING SCI. 189, 206 (1990); K. Sridhar Moorthy, *Market Segmentation, Self-Selection, and Product Line Design,* 3 MARKETING SCI. 288, 307 (1984).
[12] Pace Decl. Ex. 18, Meury Decl. dated Dec. 12, 2014, Dkt. No. 41-6.

massive inefficiencies in the supply chain, significantly increasing the cost of healthcare.[13]

Another reason companies discontinue older versions of new products is to eliminate confusion in the marketplace that results from having both products on the market simultaneously.[14] As applied to the two versions of Namenda, this confusion could result in patients experiencing more uncertainty about the advantages of the new product (slowing adoption), and could lead to more accidents with respect to dosing. Confusion between similar looking products or similar sounding brand names implicates consumer protection concerns because consumers can suffer physical harm when they inadvertently buy a different product from the one they intended.[15] There is a potential for real medical harm to confusion in the administration of medication by nursing facilities, with pill errors "occurring at a rate of nearly 1 of every 5 doses."[16]

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[13] Thomas Ebel, Building *New Strengths In the Healthcare Supply Chain: Pharmaceuticals and Medical Products Operations*, McKinsey & Company (January 2013).

[14] Vincent-Wayne Mitchell & Vassilious Papavassiliou, *Marketing Causes and Implications of Consumer Confusion*, 8 J. PROD. & BRAND MGMT., 319, 342 (1999).

[15] Anthony L. Fletcher & David J. Kera, *The 40th Year of Administration of the Lanham Trademark Act of 1946*, 77 The Trademark Reporter, 445, 672 (1987).

[16] Kenneth N. Barker, et al., *Medication Errors Observed in 36 Health Care Facilities*, Archives Internal Med. 1897, 1903 (Sept. 2002); *See also* Polivka West Declaration (Pace Ex. 19), ¶ 10 ("Penalties for errors can be substantial, and errors are unfortunately a relatively common occurrence with an estimated 20% of (cont.)

There are situations when keeping older products on the market is a valuable strategy because it enables greater market segmentation by price, or because it helps to ensure customers who have made investments in complementary products (such as applications for smartphones or videogames for video game consoles) are not stranded. However, the district court made no such finding here, and, in fact, neither of these contingencies applies in the case of Namenda IR and Namenda XR. According to the company's documents, Namenda XR is offered at a discounted price relative to Namenda IR[17] (obviating the use of Namenda IR for serving more price sensitive customers), and there are no complementary technologies that tie a patient to Namenda IR. Namenda XR contains the same active ingredient, just in an extended release, once-per-day capsule. The government's witness (Dr. Lah) agrees there is no "market need".[18] In addition, Forest has recently obtained FDA approval of Namzaric, a fixed-dose combination product that complements, and can only be used with, Namenda XR.

There are substantial benefits to permitting Forest to engage in unbridled manufacture and promotion of Namenda XR given its significant advantages to the

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medication errors occurring in long-term care facilities. These errors adversely affect patient outcomes, and place the facility at risk of sanctions from the CMS as well as potential malpractice lawsuits.").

[17] Pace Decl. Ex. 18, Meury Decl. dated Dec. 12, 2014, Dkt. No. 41-6.

[18] Lah Hr'g 85:14-23, available at Pace Decl. Ex. 1, attached to Def.-Appellants' Motion to Stay at the Second Circuit, Dec. 18, 2014, Dkt. No. 41-2.

patient and caregivers.[19] First, because XR is in capsule form, it can be opened and sprinkled over applesauce (or, presumably, other soft/liquid foods). This is a particularly important innovation because people with late-stage Alzheimer's often have trouble chewing and swallowing, and will refuse many kinds of foods or medicines.[20] Second, since XR is only taken once a day, it reduces the "pill burden" for the patient. This is especially important for Alzheimer's patients because it can be difficult to achieve medication compliance in patients with dementia. As the district court acknowledged, compliance is particularly burdensome in the evenings when many patients become agitated or confused.[21] A once-a-day formula that allows for a single dose in the morning alleviates this burden. Third, since the medication is taken once a day, it can now be combined with Aricept (an acetylcholinesterase inhibitor that is taken once a day), enabling

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[19] *See* Pace Decl. Ex. 7, Decl. of William Meury dated Oct. 21, 2014, Ex. B at 506, Dkt. No. 41-4 (finding 99% of physicians anticipate patients and caregivers would prefer Once-daily Namenda XR); Pace Decl. Ex. 17, Decl. of William Kane dated Dec. 12, 2014, ¶ 1, Dkt. No. 41-6 (explaining that Forest expects only 2.4% of patients will have a medical need for Namenda IR).

[20] *Medication Safety and Alzheimer's*, Alzheimer's Association, www.alz.org/care/dementia-medication-drug-safety.asp.

[21] Point 47 in opinion dkt 80 (*citing* Rovner Dep. 245:8-14; Kohrman Hr'g 740:3-9; Polivka-West Dep. 120:10-121:6. As Dr. Lah testified, "sundowning may lead to agitation" which "may make it more difficult to get the patient the medication they need." Lah Hr'g 98:18-99:2; Lah Dep. 173:16-18; *see also* Rovner Dep. 247:21-248:2 (reporting that half of his sundowning patients have trouble taking medication at night); Rovner Decl. (PX358) 41-42; Ferris Decl. (PX276) 41; Hausman Hr'g 714:13-15 (acknowledging caregiver burden and difficulties associated with getting patients to take a drug in the afternoon)).

the patient to receive the benefit of both types of medications in a once-per-day dose. It would be highly undesirable to apply the antitrust laws to deter development and use of these new therapies.

In sum, it is more efficient and procompetitive for Forest Laboratories to discontinue the production and marketing of Namenda IR and focus its efforts instead on Namenda XR. Selling both products simultaneously is an unnecessary diversion of scarce resources, will make it harder for the company to recoup its development expense, and could slow diffusion of the new product and thus prevent customers from reaping the value of its benefits. Forcing a pharmaceutical company to make investments in a product it wishes to discontinue is inefficient, and anti-competitive. It handicaps the firm's ability to compete and survive, and to develop products that better serve customers' needs.

B. Forcing Companies to Continue to Produce, Distribute, and Market Their Old Products Will Cause Firms to Invest Less in Innovation.

A policy that requires firms to keep old products on the market is likely to cause firms to delay development of new products. These firms may not have enough resources (e.g., manufacturing capacity, advertising budget, sales personnel) to simultaneously support both old and new product lines and thus may

be forced to wait until they are released from their resource commitments to old products in order to support the production and promotion of the new products.[22]

Forest's case exemplifies this problem because the FDA certified only one factory to manufacture Namenda products. *See* Defs.' Br. 32-33., Jan. 8, 2015, Dkt. No. 108-1. The district court's injunction would force Forest to use this one FDA-approved factory, which is now exclusively dedicated to producing XR and will also be used to produce Namzaric, to manufacture IR as well. Furthermore, as mentioned previously, having both products on the market simultaneously means that one or both products will sell in lower volumes than either would otherwise, potentially causing diseconomies from inadequate scale. In many instances, it is irrational, or even *impossible*, for the firm to fully support both old and new products. Thus, in a regime where the firm is required to continue to support the old product, the firm may rationally delay development of the new product.

That is a troubling outcome because innovation is one of the most powerful drivers of increased human welfare available to us. Innovation in the pharmaceutical industry has yielded medical treatments that have dramatically improved health conditions around the world. A policy that incentivizes firms to

[22] Charles W. L. Hill & Frank T. Rothaermel, *The Performance of Incumbent Firms in the Face of Radical Technological Innovation*, 28 ACAD. OF MGMT. REV. 257, 274 (2003); William Walker, *Entrapment in Large Technology Systems: Institutional Commitment and Power Relations*, 29 RES. POL'Y 833, 846 (2000).

slow their innovation will lead to less discovery, slower medical and technological progress, and lower economic welfare.

III. Protecting Innovation Is Critically Important in the Pharmaceutical Industry

A. Pharmaceutical Research and Development Costs Are Prohibitive, Underscoring The Need For Incentives to Innovate.

Consumers benefit both from efforts to develop new products—dynamic efficiency—and from improved access to lower priced versions of existing products—static efficiency.[23] Though both types of efficiencies confer benefit, dynamic efficiencies attributable to innovation in healthcare and pharmaceuticals in particular are a major cause of improved standards of living over the last century.[24] Economic studies of particular drug classes demonstrate that societal

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[23] *See* William J. Kolasky, *The Merger Guidelines and the Integration of Efficiencies Into Antitrust Review of Horizontal Mergers,* 71 ANTITRUST L.J. 207, 247-48 (2003) ("The dynamic efficiency principle, most closely associated with Austrian economist Joseph Schumpeter, suggests that the short run costs associated with allocative and productive inefficiencies stemming from market power can more than be offset by benefits from encouraging dynamic efficiencies through 'creative destruction.'") Static efficiency concerns the optimal use of current resources (*e.g.*, drugs already developed) to maximize short-run welfare, while dynamic efficiency balances static efficiency with incentives to develop new resources (*e.g.*, new drug development) over the long run.

[24] Fiona Scott Morton & Margaret Kyle, *Markets for Pharmaceutical Products*, *in* 2 HANDBOOK OF HEALTH ECONOMICS (2000); *see also* Kolasky, 71 ANTITRUST L.J. at 247-48 . ("Dynamic efficiency arises from market processes that encourage innovation to lower costs and develop new and improved products. Whereas allocative and productive efficiency can be viewed as static criteria--holding society's technological knowhow constant--a more dynamic view of efficiency examines the conditions under which technological know-how and the set of (cont.)

returns from pharmaceutical development are not only large, but often far outpace the cost of innovation.[25]

Though the benefit derived from dynamic efficiencies attributable to pharmaceutical development is large and important, promoting innovation in this industry is a particular challenge because research and development costs are abnormally high. Most studies indicate that it costs at least $1.5 billion and a decade of research to bring a new FDA-approved pharmaceutical product to market.[26] As a result, branded pharmaceutical companies spend a much larger

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feasible products optimally can be expanded over time through means such as learning by doing, research and development, and entrepreneurial creativity."); Frank R. Lichtenberg, *Sources of the U.S. Longevity Increase, 1960–2001*, 44 Q. REV. ECON. & FIN. 369, 369 (2004); Frank R. Lichtenberg, *The Impact of New Drugs on US Longevity and Medical Expenditure, 1990–2003: Evidence from Longitudinal, Disease-Level Data*, 97 AM. ECON. REV. 438, 442 (2007); Pierre-Yves Crémieux et al., *Pharmaceutical Spending and Health Outcomes in the United States*, *in* INVESTING IN HEALTH: THE SOCIAL AND ECONOMIC BENEFITS OF HEALTH CARE INNOVATION 59, 68 (2001).

[25] *See, e.g.*, Tomas Philipson & Anupam B. Jena, *Who Benefits from New Medical Technologies? Estimates of Consumer and Producer Surpluses for HIV/AIDS Drugs*, 9 F. FOR HEALTH ECON. & POL'Y, issue 2, art. 3, at 1–2 (2006) ($1 spent on HIV/AIDS drugs benefits society by approximately $18); *See also* David C. Grabowski et al., *The Large Social Value Resulting From Use Of Statins Warrants Steps To Improve Adherence and Broaden Treatment*, 31 HEALTH AFF. 2276, 2280 (2012) (statins provide value at four times their cost); Frank R. Lichtenberg, *Are the Benefits of Newer Drugs Worth Their Cost? Evidence from the 1996 MEPS*, 20 HEALTH AFF. 241, 241–245 (2001) (substituting new drugs for older drugs leads to significant improvements in patient health).

[26] *See* Joseph A. DiMasi & Henry G. Grabowski, *The Costs of Biopharmaceutical R&D: Is Biotech Different?*, 28 MANAGERIAL & DECISION ECON. 469, 469 (2007).

portion of their revenues on R&D than firms in most other industries. [27] That only a few initially promising experimental compounds—about one in 10,000[28]—meet safety and efficacy benchmarks and are ultimately approved by the FDA drives a substantial portion of that cost. And the cost is only expected to rise. One expert has noted that every nine years, each billion dollars spent on research results in half as many new drugs as in the previous nine year period.[29]

Innovator companies are often only able to recoup their high-risk investments in pharmaceutical products because of the patent protection their successful inventions receive.[30] One study concluded that about 65% of

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[27] *The Oxford Handbook of the Economics of the Biopharmaceutical Industry*, 2 (2012) ("The US research-based pharmaceutical industry invests about 15 percent of its sales in research and development (R&D), compared with about 4 percent for US industry in general.").

[28] Martin S. Lipsky & Lisa K. Sharp, *From Idea to Market: The Drug Approval Process*, 14 J. AM. BOARD FAM. MED. 362, 364 (2001).

[29] Jack W. Scannell et al., *Diagnosing the Decline in Pharmaceutical R&D Efficiency*, 11 Nature Reviews Drug Discovery 191, 191–92 (2012).

[30] *See* Henry Grabowski. *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. OF INT'L. ECON. L., 849, 860 (2002); Henry G. Grabowski & John M. Vernon, *Effective Patent Life in Pharmaceuticals*, 19 INT'L J. TECH. MGMT. 98, 99 (2000) (pharmaceutical industry particularly sensitive to patent incentives); Bronwyn H. Hall & Dietmar Harhoff, *Recent Research on the Economics of Patents*, 4 ANN. REV. ECON. 541, 548 (2012) (describing a survey that found that patents effectively increase innovation primarily in the pharmaceutical industry); Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 545–56 (2008) (describing the pharmaceutical industry's unique dependence on patent protection to spur research and development investment).

pharmaceutical inventions would not have been introduced into the market absent patent protection.[31]

Reduction in patent value through measures such as forced continuation of old products could effectively reduce incentives to innovate. *See* Jonathan Orszag & Robert Willig, A Preliminary Economic Analysis of FTC Chairman Leibowitz's June 23rd Speech, 4 (2009) ("The prospect of facing patent challenges and more frequent protracted litigation to defend patents may also discourage investments in innovation to develop new drugs in the first place.").[32] Importantly, these decreases in dynamic efficiency (innovation) could more than offset the supposed short-term consumer gains from access to generic drugs. Indeed, one economic study analyzed the effects of eliminating drug patents and found that the reduced flow of new therapies would cause consumer losses *three times* the short-term gains from immediate generic competition on all drugs.[33]

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[31] Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI. 173, 175 tbl.1, 175–76 n.8 (1986); *see also* Ernst R. Berndt and Ian M. Cockburn, *The Hidden Cost Of Low Prices: Limited Access To New Drugs In India*, 33 Health Affairs, 1568, 1573 (2014) (attributing the "low and slow" diffusion of new drugs in India to weak patent protection).

[32] *Available at* http://www.compasslexecon.com/highlights/Documents/Orszag-Willig%20Statement%C20Re%C20FTC%C20Reverse%C20Payment%C20Settlement%Ştudy.pdf.

[33] James W. Hughes et al., *Napsterizing Pharmaceuticals: Access, Innovation, and Welfare*, at 3, 15–16 (Nat'l Bureau of Econ. Research, Working Paper No. 9229, 2011).

B. Competition between Branded Pharmaceutical Companies is Intense and Results in Multi-Dimensional Product Improvement, Whereas Preferential Treatment for Generics Shifts Focus to Price Competition, and May Undermine Innovation.

Competition among branded pharmaceutical companies is vigorous and takes place across multiple dimensions, *e.g.*, improved efficacy, reduced side effects, increased reliability and safety, greater ease of use, better value, etc. Generics, on the other hand, introduce only one form of competition – price competition. They do not invest in developing better products or in educating the market. Furthermore, by piggy-backing on the development work and testing of the branded pharmaceutical company's efforts, generics can cherry-pick from already-proven drugs, and skip most of the FDA-testing process, thereby reaping a huge cost advantage. Whereas branded pharmaceutical companies spend more than $1.3 billion to develop a new drug, the overall cost of developing a generic drug is estimated at a few million dollars.[34] By advantaging generic manufacturers further, the district court's injunction elevates price competition over other forms of

[34]Henry G. Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries*, 8 GEO. PUB. POL'Y Rev. 7 (2003). In 2003, the FDA undertook a more detailed evaluation and estimated that, at that time, it cost a generic firm between $300,000 and $1 million to prepare and submit an ANDA. Requirements for Submission of In Vivo Bioequivalence Data; Proposed Rule, 68 Fed. Reg. 61640 (Oct. 29, 2003).

competition, which could slow the development of a better treatment or cure for Alzheimer's.[35]

C. Pharmaceutical Firms Must Invest in Broad Portfolios of Drug Development Projects, and Cannot Waste Resources Supporting Obsolete Products.

Innovator firms must carefully allocate cash among R&D investments, manufacturing, and marketing, with an eye to both short-run cash flow and long-term survival.[36] Most firms face serious constraints in capital and other resources, forcing them to choose between multiple valuable projects. These choices have to be guided by the firm's short and long-term objectives, the firm's human and capital resources, and a balance between short and long-term cash flow needs. [37] A firm that has strong cash flows can focus on more significant long-term growth by allocating higher percentages of its R&D budget to major breakthrough projects,

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[35] Hughes, *supra* n. 34 at 33 ("Specifically, the model yields the result that for every dollar in consumer benefit realized from providing greater access to the current stock, future consumers would be harmed at a rate of three dollars in present value from reduced future innovation.").

[36] Bansi Nagji & Geoff Tuff, *Managing Your Innovation Portfolio*. HARVARD BUS. REV. (2012); Melissa A. Schilling & Charles W. L. Hill, *Managing the New Product Development Process: Strategic Imperative,* 12 Academy of Mgmt. Exec. 67, 81 (1998); Robert G. Cooper, Scott J. Edgett & Elko J. Kleinschmidt, *New Product Portfolio Management: Practices and Performance*, 16 J. PROD. INNOVATION MGMT. 333, 351 (1999).

[37] Melissa A. Schilling, *Strategic Management of Technological Innovation* (2008).

while a firm that is cash strapped and needs to generate more short-term profit may allocate a higher percentage to incremental projects.[38]

In balancing their R&D portfolios, firms must also consider their long-term strategic momentum.[39] For instance, a firm that invests heavily in incremental projects that may be immediately commercialized with little risk may appear to have good returns on its R&D investment in the short run, but then be unable to compete when the market shifts to a newer technology. On the other hand, a firm that invests heavily in advanced R&D or breakthrough projects may be on the leading edge of technology, but run into cash flow problems from a lack of revenues generated from recently commercialized incremental projects. As once noted by Jack Welch, former CEO of General Electric, "You can't grow long term if you can't eat short term. Anyone can manage short. Anyone can manage long. Balancing those two things is what management is."[40]

Any resources used to support the continued manufacture and distribution of Namenda IR could otherwise be used to develop new products in the high risk, low margin pharmaceutical industry. These new developments, and the continued

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[38] Clayton M. Christensen, *Using Aggregate Project Planning to Link Strategy, Innovation, and the Resource Allocation Process,* Harvard Business School Background Note 301-041(2000).
[39] Nagji & Tuff, *supra* n. 36; Schilling, *supra* n. 37.
[40] J. A. Byrne, *How Jack Welch Runs GE*, BusinessWeek, June 8, 1998, at 90.

financial efficiency of Forest Laboratories, bear the promise of increased consumer welfare through increased pharmaceutical innovation.

D. The District Court's Approach Threatens To Deter Innovation In The Field Of Alzheimer's Disease.

Alzheimer's is a devastating, fatal disease that affects an estimated 5.2 million Americans.[41] The decision notes that "[i]n 2012, generic drugs saved the health system $217 billion."[42] This number, however, is very small in comparison to the $1.5 trillion per year that analysts predict Alzheimer's will cost the U.S. by 2050 if a more effective treatment is not developed.[43] A cure for Alzheimer's would yield *greater savings than all generics* combined. This requires innovation beyond the availability of generic alternatives to existing products

Alzheimer's is a disease that can be even harder on the families and caregivers of the patient than on the patient themselves. The direct costs to the nation of Alzheimer's in 2014 are estimated to total $214 billion. Adding in the informal costs (the costs of family members and friends providing unpaid care to

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[41] *2014 Alzheimer's Disease Facts and Figures*, 10 Alzheimer's & Dementia, e47, e92 (2014).

[42] Opinion 27, ¶ 33 (citing "Generic Drug Savings in the U.S.," published by the Generic Pharmaceutical Association, PX8, available at http://www.gphaonline.org/media/cms/2013_Savings_Study_12.19.2013_FINAL.pdf).

[43] Julie Zissimopoulos, Eileen Crimmins & Patricia St. Clair, *The Value of Delaying Alzheimer's Disease Onset*, F. HEALTH ECON. & P. (Nov. 2014).

those with dementia) doubles those figures.[44] The bulk of Alzheimer's costs are not due to the cost of drugs or doctor's visits; the vast majority of the costs (75.84%) are due to the cost of nursing home care, plus formal and informal home care.[45] The drugs currently available for Alzheimer's (cholinesterase inhibitors and memantine) offer only incremental improvements in symptoms—they do not stop the progression of the disease.[46] In other words, there remains a substantial need for companies to invest in developing better treatments. As noted by Senator Susan Collins, chair of the Senate Special Committee on Aging, "[i]f you contrast our Alzheimer's funding to the other major diseases, or compare the spending on research to the cost of care, we're not spending nearly enough to find ways to deal with this problem."[47]

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[44] *Id.*

[45] Michael Hurd, et al., *Monetary Costs of Dementia in the United States*, 368 N. ENGL., J. OF MED., 1326, 1334 (2013).

[46] Amos D. Korczyn, *Why Have We Failed to Cure Alzheimer's Disease?* 29 J. OF ALZHEIMER'S DISEASE, 275, 282 (2012); Harish Kavirajan & Lon S. Schneider. *Efficacy and Adverse Effects of Cholinesterase Inhibitors and Memantine in Vascular Dementia: A Meta-analysis of Randomized Controlled Trials.* 6 THE LANCET NEUROLOGY, 782, 792 (2007); T. Nhi-Ha, et al., *Efficacy of Cholinesterase Inhibitors in the Treatment of Neuropsychiatric Symptoms and Functional Impairment in Alzheimer Disease.* 289 J. OF THE AM. MED. ASS'N 210, 216 (2003); Krista L. Lanctôt, et al., *Efficacy and Safety of Cholinesterase Inhibitors in Alzheimer's Disease: A Meta-Analysis.* 3 CLINICAL INTERVENTIONS IN AGING 211, 225 (2008).

[47] T. R. Reid, *Falling Behind on Alzheimer's Research.* AARP Bulletin, January/February 2015.

E. Requiring Branded Companies to Subsidize the Marketing and Sales Efforts of Generic Companies is Anti-Competitive.

In general, markets are more efficient and generate more economic welfare when they are transparent, and when competitive forces induce firms to innovate to offer better products and services while driving down their costs.[48]

The principal statute regulating brand and generic drug competition, known as the Hatch-Waxman Act, 21 U.S.C. § 355, balances incentives for innovations that result in new pharmaceutical products against enhanced access to existing products through generic drugs and has led to a boom in generic market share. The low costs and large incentives to challenge patents, combined with the unpredictable nature of litigation and the lack of damages exposure, encourage generic firms to challenge patents without regard to the likelihood of prevailing.[49] State laws requiring automatic substitution of generic drugs by pharmacists – such as the New York statute at issue in this litigation – tip this balance even more toward generic manufacturers. As expected, the share of generics in the

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[48] William J. Baumol, *The Free-Market Innovation Machine: Analyzing the Growth Miracle of Capitalism* (2002); Sanford J. Grossman & Joseph E. Stiglitz, *Information and Competitive Price Systems*. 66 AM ECON. REV. 246, 253 (1976); Robert Bloomfield & Maureen O'Hara, *Market Transparency: Who Wins and Who Loses?*, 12 REV. OF FIN. STUDIES 5, 35 (1999).

[49] *See generally* Henry G. Grabowski & Margaret Kyle, *Generic Competition and Market Exclusivity Periods*, 28 MANAGERIAL & DECISION ECON. 491, 495–96, 501 (2007); *see also* Kelly Smith & Jonathan Gleklen, *Generic Drugmakers Will Challenge Patents Even When They Have a 97% Chance of Losing: The FTC Report that K-Dur Ignored*, 9 CPI ANTITRUST CHRON., at 6 (Sept. 2012).

marketplace has increased dramatically over time.[50] As of 2013, generic usage stood at 86 percent, a more than fourfold increase since Hatch-Waxman was enacted.[51] Simply put, the Hatch-Waxman Act has been extremely successful in increasing access to generic drugs.[52]

Against this backdrop, it is especially harmful to use the antitrust laws to bar discontinuation of older products because doing so forces the branded companies to subsidize the *marketing and sales efforts* of the generic companies. Courts have recognized that competitors are "expected to make their own way in the market, by advertising or other means or promotion . . . [a firm] ha[s] no right under antitrust law to take a free ride on its competitor's sales force. You cannot conscript your competitor's salesman to sell your product even if the competitor has monopoly power and you are a struggling new entrant." *Olympia Equip. Leasing Co. v. Western Union Tel. Co.*, 797 F.2d 370, 377-378 (7th Cir. 1986). Branded

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[50] *See* Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 NEW ENG. J. MED. 1993, 1993–96 (2007).

[51] IMS Institute for Healthcare Informatics, Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2013, at 30 (2014) *available* at http://www.imshealth.com/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/IHII_Medicines_in_U.S_Report_2011.pdf.

[52] *See* Ernst R. Berndt & Murray L. Aitken, *Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century after the 1984 Waxman-Hatch Legislation*, 18 INT'L J. ECON. BUS. 177, 177–78, 181–198 (2011). *See also* Ernst R. Berndt, *Pharmaceuticals in U.S. Health Care: Determinants of Quantity and Price*, 16 J. ECON. PERSP. 45, 62–63 (2002).

pharmaceutical companies spend very large amounts of money to educate physicians and pharmacists about their products. They must make these strategic investments very carefully because, as noted before, they operate in a very competitive industry and resources are constrained. If a company has developed a new, better product, it typically makes sense for that company to focus its marketing resources on educating physicians and pharmacists about that new product. To require Forest to continue investing in its old product is both a waste of resources, and an inappropriate subsidization of the generic companies.

CONCLUSION

The antitrust laws should not be used to prevent an innovator firm from making production, distribution, pricing, and marketing decisions that maximize the value of its products in the competitive marketplace. It undermines rather than promotes competition to force a company to support a product that is no longer efficient to support. Few companies can support all of their old products while introducing new ones, and no company should be required to produce and promote a product that may be automatically substituted with someone else's product at the point of sale.

In these circumstances, the antitrust laws should be applied to promote innovation. Allowing Forest to cease mass production of Namenda IR without the risk of antitrust liability is the approach that most efficiently allows the judicial system to maintain the balance intended when Congress enacted the Hatch-Waxman Act – facilitating generic entry, but also recognizing the importance of protecting innovation. Furthermore, forcing one company to subsidize another is anti-competitive and derails the very market forces that antitrust laws were designed to protect.

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 29(d) and 32(a)(7)(B)-(C), the undersigned counsel certifies as follows:

1. This brief complies with the type-volume limitation for an *amicus* brief under Fed. R. App. P. 32(a)(7)(B) (setting the maximum length for a party's principal brief at 14,000 words) and Fed. R. App. P. 29(d) (setting the maximum length of an amicus brief at one-half the maximum length for a party's principal brief) because this brief contains, according to the word count of the word processing system used to prepare this brief, 6,145 words, excluding those portions of the brief exempted by Fed. R. App. P. 32 (a)(7)(B)(iii).

2. 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 Office Word 2010 Professional Plus Edition in 14-point Times New Roman font.

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