14-4624

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

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

Plaintiffs-Appellees,

v.

ACTAVIS plc AND FOREST LABORATORIES, LLC

Defendants-Appellants.

FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK
CASE NO. 14-CV-7473 (RWS)

BRIEF FOR
AMICI BIOSCIENCE ASSOCIATIONS
SUPPORTING APPELLANTS

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RULE 26.1 STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, amici state as follows:

1. Amicus The Texas Healthcare and Bioscience Institute (THBI) is a nonprofit corporation recognized as tax-exempt under IRC 501(c)(6). It has no parent corporation, and no publicly held corporation owns 10% or more of its stock. THBI is composed of biotechnology, medical device and pharmaceutical companies; universities and private research organizations; and companies that provide goods and services to core organizations.

2. Amicus Biotechnology Industry Organization (BIO) is the world's largest biotechnology organization, representing more than 1,000 members in all 50 U.S. states and more than 30 countries around the globe. BIO's members are involved in the most cutting-edge research and development of medical breakthroughs. These members range from entrepreneurial start-ups developing a first product to Fortune 100 multinationals, although the vast majority are small companies. BIO also represents academic research centers, state and regional biotechnology associations, and service providers to the industry, including venture capital firms that fund large segments of the industry. The biotechnology industry as a whole invests more than $20 billion annually on research and development activities, and BIO's mission is to promote a policy, business, and legal environment

in which this massive capital can achieve fully the promise of biotechnology to heal the world of the most life-threatening and debilitating diseases.

3. Amicus BayBio is an independent, nonprofit trade association serving the life science industry in Northern California. It has no parent corporation, and no publicly held corporation owns 10% or more of its stock. Northern California is the birthplace of the biotechnology industry and contains the largest cluster of life sciences companies in the United States. BayBio's membership consists of more than 500 organizations engaged in -- or supportive of -- research, development, and commercialization of life science products. BayBio supports the Northern California bioscience community through advocacy, enterprise support, and the enhancement of research collaboration. It represents the point of view of the life science industry on issues at every level of government, regularly working with legislators, officials, and policymakers.

4. Amicus BioNJ is a 501(c)(6) organization. It has no parent corporation, and no publicly held corporation owns 10% or more of its stock. BioNJ is composed of biotechnology, medical device and pharmaceutical companies; universities and private research organizations; and companies that provide goods and services to core organizations. Its members include Amgen, BMS, Celgene, Johnson & Johnson, Novartis, NPS Pharmaceuticals, Pfizer and Sanofi.

5. Amicus California Healthcare Institute (CHI) is an independent 501(c)(6) organization devoted to researching and advocating policy to forward the interests of California's biomedical community. It represents the State's leading biopharmaceutical, medical device and diagnostics companies, research universities and institutes and service provider firms. CHI's mission is to advance biomedical research, investment and innovation through effective advocacy of policies to improve public health and ensure the continued vitality of the life sciences sector. A list of CHI's current members is available at http://www.chi.org/member-center/current-members/.

6. The Arizona Bioindustry Association (AZBio) is a nonprofit corporation recognized as tax-exempt under IRC 501(c)(6). It has no parent corporation, and no publicly held corporation owns 10% or more of its stock. AZBio is composed of biotechnology, medical device and pharmaceutical companies; universities and private research organizations; healthcare providers; and companies that provide goods and services to core organizations. AZBio works closely with its member organizations to support the discovery, development, and delivery of life sustaining and lifesaving innovations that will benefit patients today and in the future. AZBio advocates on behalf of Arizona's biotech and life science industry at the State and Federal level in support of research and development; in expanding support of entrepreneurial innovation in the life science area; and in supporting

patient access to life science innovations. Arizona inventors have had more than 1,400 patents issued in bioscience-related classes since 2009 and they span a variety of areas in medical devices and drugs and pharmaceuticals.

7. Amicus the HealthCare Institute of New Jersey (HINJ) is a trade association for the research-based biopharmaceutical and medical technology community in New Jersey. HINJ is a New Jersey nonprofit corporation that is tax-exempt under Section 501(c)(6) of the Internal Revenue Code. It has no parent corporation, and no publicly held corporation owns 10% or more of its stock. Founded in 1997, HINJ seeks to advance the development and implementation of sound public health and business policies that support the interests of patients and their ability to access health care, and that foster the innovative environment necessary to research and discover the next generation of treatments and cures for the world's most dreaded diseases. A complete list of HINJ member companies can be found on HINJ's website, www.hinj.org.

8. Amicus NewYorkBIO is a nonprofit corporation that has no parent corporation, and no publicly held corporation owns 10% or more of its stock. As the only statewide association in New York dedicated solely to the issues of the bioscience industry, NewYorkBIO urges legislators to support the industry by focusing on issues that will create a better business climate that will allow companies at all stages of development to grow and succeed. NewYorkBIO is committed to

policies that ensure patient access to the innovative therapies, devices and diagnostics that are being developed by the many bioscience companies across New York.

9. Amicus Oregon Bioscience Association is a Portland, Oregon-based 501(c)(6) nonprofit organization with no parent organization and no shareholders or any kind.

10. Amicus Pharmaceutical Industry Association of PR, Inc. (PIA) is an independent, nonprofit trade organization serving the research-based biopharmaceutical industry established in Puerto Rico. PIA is organized under the laws of the Commonwealth of Puerto Rico. It has no parent corporation, and no publicly held corporations owns 10% or more of its stock.

11. Amicus Industry-University Research Center, Inc. (INDUNIV) is an independent corporation that has no parent corporation, and no publicly held corporation owns 10% or more of its stock.

January 15, 2015 /s/ Jonathan S. Massey
Jonathan S. Massey

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INTEREST OF AMICI CURIAE

Pursuant to Federal Rule of Appellate Procedure 29, amici the Texas Healthcare and Bioscience Institute, Biotechnology Industry Organization (BIO), BayBio, BioNJ, California Healthcare Institute, the Arizona Bioindustry Association, the Healthcare Institute of New Jersey, New YorkBIO, Oregon Bioscience Association, Pharmaceutical Industry Association of PR, Inc., and the Industry-University Research Center, Inc. (INDUNIV), respectfully file this brief amici curiae in support of appellants with the consent of all parties.[1]

Amici have an important interest in this case because they use advocacy as a tool to create a more favorable environment for the life sciences and the patients that depend on them. Amici work with government and industry leaders in the life sciences to promote effective government regulation.

SUMMARY OF ARGUMENT

The injunction entered by the District Court in this case on December 15, 2014, is unprecedented. The Court's order is the first in the United States to use the

[1] Pursuant to Federal Rule of Appellate Procedure 29(c)(5), amici state that no party's counsel authored this brief in whole or in part, and no party or its counsel made a monetary contribution intended to fund the preparation or submission of this brief. No person other than amici curiae, their members, or their counsel, contributed money that was intended to fund preparing or submitting the brief.

Sherman Act to force a brand pharmaceutical manufacturer to sell a product – to use a mandatory injunction to impose an affirmative duty on a drug manufacturer to assist its generic competitors to capture market share. The District Court's order radically re-draws the competitive landscape between brand-name and generic drugs, using the Sherman Act to interfere with an innovator's decisions on how and when to sell its FDA-approved, patent-protected products.

The order is even more extraordinary given the undisputed facts of this case. It is common ground that Forest Labs complied with all relevant FDA rules and regulations when it began selling twice-a-day Namenda IR (immediate release) tablets in 2004 and when it launched its new and improved, once-daily Namenda XR (extended release) capsules in 2013. Similarly, it is undisputed that the new version of the drug at issue (Namenda XR) provides important patient benefits as compared to the old version (Namenda IR) that the District Court's order will force Forest Labs to continue marketing. *See, e.g.*, SA-36 (Decision at ¶ 47) (citing studies demonstrating that "extended-release agents are associated with improved tolerability, greater patient adherence to treatment, reduced total treatment costs, and better long-term clinical outcomes"). In short, the injunction forces Forest to sell its older drug, when it has introduced a newer, better drug.

The District Court's injunction violates the well-settled patent and antitrust principle that a manufacturer has the power to decide which of its products to sell

and how to sell them. Forest Labs' right of exclusivity arises from lawfully-obtained patents and FDA-approved exclusivity, which does not expire until July 2015. Part of a patent right is the entitlement *not* to practice or license the invention. *See Continental Paper Bag Co. v. Eastern Paper Bag Co*., 210 U.S. 405, 429 (1908).

Similarly, under the antitrust laws, a manufacturer has no legal obligation to aid competitors. *See Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408-11 (2004). Forest Labs and other brand manufacturers do not owe any duty to take into account the future market share of generic competitors in making product termination or distribution decisions. They have the freedom not to continue selling an older version of a drug.

The District Court's contrary view is legally unfounded and threatens to chill innovation and harm patients. R&D incentives will be greatly undermined if federal courts have the authority to look over the shoulders of brand manufacturers and second-guess their decisions about which drugs to sell and to whom. Injunctions forcing brand manufacturers to continue selling older versions of their drugs in order to assist generic manufacturers in taking away market share will discourage brand manufacturers from investing the substantial resources necessary to develop new and improved versions of their drugs, even when they promise significant clinical benefits. The District Court's order interferes with a manufacturer's ability to

operate its own business as it sees fit and to make business decisions as needed to recoup its investments.

The extraordinary injunction issued by the District Court also exceeds the institutional competence of the federal courts and effectively commandeers Forest Labs' property. The order requires Forest Labs, until August 10, 2015, to "continue to make Namenda IR (immediate-release) tablets available on the same terms and conditions applicable since July 21, 2013." The District Court did not attempt to define the "terms and conditions" mentioned in its order, which will create confusion and severe problems of judicial administration. Federal courts are not equipped to set prices and micromanage commercial transactions, particularly in an industry as complex as pharmaceuticals. Indeed, if the President lacks the authority to compel the continued operation of industries vital to the war effort in times of national crisis, *see Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 630-31 (1952), then certainly a federal court lacks the authority to compel the continued sale of an older brand-name drug for the benefit of generic competitors. The judiciary does not play a policymaking role in drug regulation.

The District Court's injunction should be vacated and its judgment should be reversed.

ARGUMENT

I. A Brand Manufacturer Has The Freedom To Decide Which Of Its Products To Sell And How To Sell Them.

In its December 15 preliminary injunction, the District Court compelled Forest Labs to continue selling twice-a-day Namenda IR on historical "terms and conditions," until after generic versions of Namenda IR are launched in July 2015. The Court ordered Forest Labs to keep its older product on the market not so that generic competitors could enter the market – they will be able to do so regardless of Forest Lab's decisions and the Court's injunction – but rather so that generic competitors would have a greater ability to take advantage of automatic substitution at pharmacies and thereby capture a greater share of Namenda sales. The Court entered its order even though Forest Labs announced that it was not going to completely remove Namenda IR from the marketplace but rather planned to continue to distribute its older Namenda IR tablets through a nationally-licensed specialty pharmacy provider.

The District Court's order cannot be squared with the fact that Forest Labs' right of exclusivity arises from lawfully-obtained patents and FDA-approved exclusivity, which does not expire until July 2015. The Patent Act vests a patent holder with "the right to exclude others from making, using, offering for sale, or selling the invention." 35 U.S.C. § 154(a)(1). Under the patent laws, a patent owner has no duty to practice or to license its patents. *See Continental Paper Bag Co. v.*

Eastern Paper Bag Co., 210 U.S. 405, 429 (1908) ("As to the suggestion that competitors were excluded from the use of the new patent, we answer that such exclusion may be said to have been of the very essence of the right conferred by the patent, as it is the privilege of any owner of property to use or not use it, without question of motive."); *E. Bement & Sons v. National Harrow Co*., 186 U.S. 70, 90 (1902) ("His title is exclusive, and so clearly within the constitutional provisions in respect of private property that he is neither bound to use his discovery himself nor permit others to use it.") (internal quotation marks and citation omitted). "The heart of [the patentee's] legal monopoly is the right to invoke the State's power to prevent others from utilizing his discovery without his consent." *Zenith Radio Corp. v. Hazeltine Research, Inc*., 395 U.S. 100, 135 (1969).

"Simply stated, a patent holder is permitted to maintain his patent monopoly through conduct permissible under the patent laws." *SCM Corp. v. Xerox Corp*., 645 F.2d 1195, 1204 (2d Cir. 1981). "No court has ever held that the antitrust laws require a patent holder to forfeit the exclusionary power inherent in his patent the instant his patent monopoly affords him monopoly power over a relevant product market." *Id*.; *see also Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1547 (Fed. Cir. 1995) ("A patent is granted in exchange for a patentee's disclosure of an invention, not for the patentee's use of the invention. There is no requirement in this country that a patentee make, use, or sell its patented invention.") (citing *Continental Paper*

Bag Co.). Thus, part of a patent right is the entitlement *not* to practice the invention. A brand manufacturer has the freedom not to continue selling an older version of a patented drug. But as noted above, even though Forest has this right, it has not chosen to fully discontinue selling the older product, but only to alter how it sells such product in light of other products Forest has developed.

Similarly, under the antitrust laws, brand manufacturers do not owe any duty to take into account the impact on future market share of generic competitors in making product termination or distribution decisions. "The purpose of the antitrust laws . . . is 'the protection of *competition*, not *competitors*.'" *Leegin Creative Leather Products, Inc. v. PSKS, Inc.*, 551 U.S. 877, 906 (2007) (citation omitted; emphasis in original). "Thus, as a general matter, the Sherman Act 'does not restrict the long recognized right of [a] trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal.'" *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408 (2004) (quoting *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919)). In *Trinko*, the Supreme Court made clear that the antitrust laws impose "no duty to aid competitors." 540 U.S. at 411; *see also id.* at 410 ("[A]lleged insufficient assistance in the provision of service to rivals is not a recognized antitrust claim . . . .").

Two years after *Trinko*, the Supreme Court reaffirmed that a defendant has no antitrust duty to operate under conditions that "rivals find commercially advantageous." *Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438, 449-50 (2009). "[A] defendant with no antitrust duty to deal with its rivals has no duty to deal under the terms and conditions preferred by those rivals." *Id.* at 457.[2]

This Court's precedent is to the same effect. In *In re Adderall XR Antitrust Litig.*, 754 F.3d 128 (2d Cir. 2014), this Court held that a holder of patent for a drug used in the treatment of attention-deficit-hyperactivity-disorder had no antitrust duty to deal with generic manufacturers to assist their entry into the market. The defendant's customers sought to impose an antitrust duty on the pharmaceutical

[2] The Supreme Court has recognized very limited duties to deal with rivals in exceptional circumstances, as in *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985), which *Trinko* described as lying "at or near the outer boundary of § 2 liability." 540 U.S. at 409. This case is nothing like *Aspen Skiing*, which involved a defendant's decision to cease participation in a cooperative venture creating a joint ticket among Colorado ski resorts. 472 U.S. at 608, 610-611. The unilateral termination of the voluntary (and thus presumably profitable) course of dealing suggested a willingness to forsake short-term profits to achieve an anticompetitive end. Indeed, the defendant was unwilling to renew the joint ski ticket even if compensated at retail price, which *Trinko* described as "reveal[ing] a distinctly anticompetitive bent." 540 U.S. at 409. Here, by contrast, Forest Labs has not terminated a prior joint venture with generic manufacturers and is in no way blocking generic competitors from entering the market when patent and FDA exclusivity expires in July 2015. Nor is there is any doubt that the improvement from NAMENDA IR to NAMENDA XR represents genuine, not sham, innovation. *See In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 134-35 (2d Cir. 2014) (noting the limited applicability and special facts of *Aspen Skiing*).

manufacturer to deal with generic firms that had purchased raw materials from the defendant. *Id.* at 130-31. This Court declined to recognize an antitrust duty for the pharmaceutical company to "cooperate with competitors," even where there was a preexisting contractual duty under a settlement agreement. *Id.* at 135. This case follows *a fortiori*, because here Forest Labs was never under a contractual duty with respect to its generic competitors. *See also RxUSA Wholesale Inc. v. Alcon Labs.*, 391 F. App'x 59, 60 (2d Cir. 2010) (summary order) (declining to create duty to deal with competitors in pharmaceutical case).

Similarly, in *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263 (2d Cir. 1979), this Court held that a defendant did not have an obligation, merely because it introduced its film and camera products in a new format, to make any predisclosure to its camera-making competitors, nor did its earlier use of its film monopoly to foreclose format innovation by those competitors create such a duty where none had existed before. This Court cited the settled antitrust rule that "any firm, even a monopolist, may . . . bring its products to market whenever and however it chooses." *Id.* at 286. Courts "must always be mindful lest the Sherman Act be invoked perversely in favor of those who seek protection against the rigors of competition." *Id.* at 273.[3]

[3] The District Court cited dictum in *Berkey Photo* stating that "the situation might be completely different if, upon the introduction of the 110 system, Kodak

II. Creating A Duty To Aid Generic Competitors Would Chill Innovation And Hurt Patients.

The courts have articulated powerful reasons *not* to impose a duty to aid competitors, and those reasons are fully applicable here. In *Trinko*, for example, the Supreme Court cited the ability of regulatory agencies to oversee markets more effectively than courts. *See* 540 U.S. at 412. In *Trinko*, the relevant agency was the Federal Communications Commission; here, it is the FDA. There is no dispute that Forest Labs complied with all relevant FDA rules and regulations when it began selling twice-a-day Namenda IR tablets in 2004 and when it launched its new and improved, once-daily Namenda XR capsules in 2013. Assessing the benefits of the new, improved version of Namenda is a task for the FDA, not a court.

Further, *Trinko* stressed that recognizing a duty to aid rivals would risk creating barriers to competition. Mistaken inferences and false condemnations "'are especially costly, because they chill the very conduct the antitrust laws are designed

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had ceased producing film in the 126 size, thereby compelling camera purchasers to buy a Kodak 110 camera. . . . In such a case the technological desirability of the product change might bear on the question of monopolistic intent." 603 F.2d at 287 n.39. But that dictum is inapposite here. It addresses the issue of tying arrangements, which could require the purchase of one product if another product is purchased. This case does not involve any issue of tying. Further, even in the tying hypothetical proposed in *Berkey Photo*, this Court suggested merely that "the technological desirability of the product change" would become relevant. Here, there is no dispute that NAMENDA XR offers important benefits over NAMENDA IR.

to protect.'" *Id.* at 414 (*quoting Matsushita Elec. Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986)). This Circuit has similarly recognized that the antitrust laws protect innovation and that "[a] monopolist is permitted, and indeed encouraged, by § 2 to compete aggressively on the merits, any success that it may achieve through 'the process of invention and innovation' is clearly tolerated by the antitrust laws." *Berkey Photo*, 603 F.2d at 281 (citation omitted).[4] In addition, this Court has stressed the importance of "safeguard[ing] the incentive to innovate." *Adderall*, 754 F.3d at 133 (internal quotation marks and citation omitted).

Those lessons are especially salient here, because the District Court's order risks chilling innovation and product improvements in pharmaceutical markets – an industry whose very life blood is discovery and scientific advance. If federal courts have the authority to look over the shoulders of brand manufacturers and second-guess their decisions about which drugs to sell and to whom, R&D incentives will be drastically reduced. A company that believes a federal court will order it via an injunction to continue selling older versions of its drugs in order to assist generic manufacturers in taking away its market share will have little reason to invest the

[4] In *Berkey Photo*, this Court opined that the challenge to Kodak's new product was particularly inappropriate because the new product offered benefits over the old product. *See* 603 F.2d at 282-83 & n.25 ("red-eye" problem experienced by users of new system did not "detract from the fact that the new camera was . . . more convenient than its predecessors"). The same is true here: NAMENDA XR offers important benefits over NAMENDA IR.

substantial resources necessary to develop superior versions of its drugs, even when they promise significant clinical benefits. And if a brand manufacturer has a duty to aid generic competitors, must it start "taking it easy" on the generics prior to the expiration of its patent and FDA exclusivity, as the District Court effectively directed in this case? As a matter of patent and regulatory exclusivity, being forced to "look over one's shoulder" in this manner reduces the likely financial return of the patent grant and regulatory exclusivity. The District Court's order also hampers a manufacturer's ability to operate its own facilities as it sees fit and to make business decisions as needed to recoup its investments. Indeed, under the District Court's injunction, the manufacturer would have reduced incentive to bring even the initial version of the drug to market in the first place, given the investment uncertainty created by judicial management of product decisions.

This case illustrates the danger to innovation. Not only did Forest Labs develop the improved drug Namenda XR (launched in 2013), but Forest Labs continued to innovate, and it developed a third generation version of Namenda – the fixed-dose Namenda XR combined with the molecule found in Aricept (donepezil), which is an acetylcholinesterase inhibitor. On December 24, 2014, the FDA approved this new drug for the treatment of moderate to severe Alzheimer's disease.[5]

[5] Press Release, Actavis, Actavis and Adamas Announce FDA Approval of Namzaric™, a Fixed-Dose Combination of Memantine Extended-Release and Donepezil Hydrochloride, (December 24, 2014),

The District Court's injunction interferes with Forest Labs' ability to focus its resources on the production and roll out of the third generation of Namenda (plus the 2013 drug, Namenda XR), by imposing a burdensome and ambiguous obligation on the company to continue selling a ten-year-old drug (Namenda IR). The FDA has certified only one Forest Labs plant to make Namenda, and the same employees and equipment are involved in making each of the versions. Accordingly, the injunction will force Forest Labs to change the way it operates its facility and will delay the launch of the third generation of Namenda.

The District Court's injunction will thus discourage the very innovation that is critical to advancing medicine and providing vital benefits to patients. Brand-name drug manufacturers play a critical role in developing new products that advance the practice of medicine and provide life-saving treatments. The World Health Organization recognizes over 12,400 disease, only two of which, smallpox and rinderpest, have been successfully eliminated.[6]

Medical innovation is not limited to radically new advances; it also proceeds in small steps. As Dr. Kristina Lybecker, Associate Professor of Economics at Colorado College, has written, those who deny the significance of "incremental

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http://www.actavis.com/news/news/thomson-reuters/actavis-and-adamas-announce-fda-approval-of-namzar.

[6] World Health Organization, "International Classification of Diseases," available at http://www.who.int/classifications/icd/en/.

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."[7]

Many existing therapies are incremental innovations. For example, 63 percent of the drugs on the World Health Organization's Essential Drug Lists are so-called "follow-on" drugs.[8] Almost one-quarter of the therapeutic indications described are treated by drugs initially indicated to treat a different disease or condition.[9] As noted by the World Intellectual Property Secretariat (WIPO), "many follow-on and patented innovations might contribute in a positive way to the improvement of public health and also to economic development, and . . . some forms of adaptive innovation may be especially relevant to meeting neglected health needs."[10]

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[7] Dr. Kristina Lybecker, *The Case for Incremental Innovation: The Importance of Protecting Follow-on Pharmaceutical Discoveries*, IPWATCHDOG, (June 23, 2014), http://www.ipwatchdog.com/2014/06/23/the-case-for-incremental-innovation/id=50155/.

[8] J. Cohen and K. Kaitin, *Follow-On Drugs and Indications: The Importance of Incremental Innovation to Medical Practice*, 15 AMERICAN J. THERAPEUTICS 89-91 (2008).

[9] L.J. Wastilla, M.E. Ulcickas, and L. Lasagna. *The World Health Organization's Essential Drug List. The Significance of Me-Too and Follow-On Research*, 3 J. CLINICAL RESEARCH & DRUG DEVELOPMENT 105-15 (1989).

[10] World Intellectual Property Secretariat (WIPO), "Follow-on Innovation and Intellectual Property," WIPO submission to the World Health Organization's

Product improvements have provided many clinical benefits, including reducing per-day dosage. For example, innovation led to the development of a new formulation of two anti-malarial drugs, artesunate and amodiaquine, reducing dosing regimens from eight tablets a day to two.[11] Similarly, in the HIV context, for example, efavirenz/emtricitabine/tenofovir DF represented the first-ever single-pill HIV treatment. It combines three drugs into one pill, simplifying the dosing regimen and increasing patient compliance.[12] In fact, HIV illustrates the critical benefits of incremental pharmaceutical innovation. When it emerged,[13] it was an incurable and fatal disease. A series of medical advances culminated in a "cocktail" combining multiple therapies, which offered live-saving benefit to patients, though the combined "cocktail" was a tedious and burdensome process that was prone to error. In the final innovation, a single drug combined numerous therapies into a single treatment – offering untold benefit to millions.

Commission on Intellectual Property Rights, Innovation, and Public Health, May 20, 2005.

[11] International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). "Incremental Innovation: Adapting to Patient Needs" (Jan. 2013).

[12] J. Cohen and K. Kaitin, *Follow-On Drugs and Indications: The Importance of Incremental Innovation to Medical Practice*, *supra*, at 89-91.

[13] The earliest known case of infection with HIV-1 in a human was detected in a blood sample collected in 1959; in 1983, scientists discovered the virus that causes HIV. *See* The AIDS Institute, "Where Did HIV Come From?" available at http://www.theaidsinstitute.org/node/259

This case offers another example of the benefits of pharmaceutical innovation. Namenda XR needs to be taken only once a day, as opposed to twice a day for Namenda IR, the older drug. The Alzheimer's Association reports that "Alzheimer's caregivers frequently report experiencing high levels of stress," and many experience anger, exhaustion, and lack of concentration that makes it difficult to perform even routine tasks.[14] The reduction of the dosage regimen provided by Namenda XR represents a significant benefit for Alzheimer's patients and their caregivers. *See, e.g.*, SA-36 (Decision at ¶ 47) (citing studies demonstrating that "extended-release agents are associated with improved tolerability, greater patient adherence to treatment, reduced total treatment costs, and better long-term clinical outcomes").

By chilling pharmaceutical innovation, the District Court's injunction will ultimately harm (rather than help) patients.

III. Judicial Micromanagement of Product Sales, Terms, and Conditions Is Improper.

The District Court's injunction requires that, from the date of issuance until August 10, 2015, "the Defendants shall continue to make Namenda IR (immediate-release) tablets available on the same terms and conditions applicable since July 21,

[14] ALZHEIMER'S ASSOCIATION, "Caregiver Stress," available at http://www.alz.org/care/alzheimers-dementia-caregiver-stress-burnout.asp.

2013." There is no definition or explanation of the relevant "terms and conditions" under which Forest Labs must continue to sell Namenda IR. *Cf. Liquid Magnetix Corp. v. Therma-Stor LLC,* 2014 WL 1389984, *3 (D. Colo. April 9, 2014) (noting that "a vague reference to 'terms and conditions consistent with past practices'" was not enforceable in contract context). There is no finding that the same "terms and conditions" applicable on July 21, 2013 are appropriate today, when economic and market conditions are assuredly different. Nor is there any provision in the injunction for modifications in the "terms and conditions" on the basis of changes circumstances between now and August 2015. Moreover, this suit – brought by the attorney general of a single State – raises the specter of a host of varying or even conflicting injunctions issued by different courts, all seeking to impose on Forest Labs some variant of a duty to aid its generic competitors.

The practical problems created by the injunction underscore a larger point: courts lack the capacity to manage "forced sales" provisions through the imposition of a duty to assist competitors. Courts cannot accurately determine the "terms and conditions" under which a manufacturer should make its products available, and the difficulty is especially pronounced where the "terms and conditions" are historical ones that a manufacturer used in different circumstances in the past. As the Supreme Court warned in *Trinko,* courts are ill suited "to act as central planners, identifying the proper price, quantity, and other terms of dealing." 540 U.S. at 408. "'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.'" *Id.* at 415 (*quoting* Phillip Areeda, *Essential Facilities: An Epithet in Need of Limiting Principles*, 58 ANTITRUST L.J. 841, 853 (1989)). The *Trinko* Court criticized a proposed injunction that was, if anything, clearer and easier to administer than the one in this case. *See id.* ("[R]espondent has requested an equitable decree to '[p]reliminarily and permanently enjoi[n] [Verizon] from providing access to the local loop market ... to [rivals] on terms and conditions that are not as favorable' as those that Verizon enjoys. An antitrust court is unlikely to be an effective day-to-day enforcer of these detailed sharing obligations."); *see also Town of Concord v. Boston Edison Co.*, 915 F.2d 17, 25 (1st Cir. 1990) (Breyer, C.J.) ("[A]ntitrust courts normally avoid direct price administration, relying on rules and remedies ... that are easier to administer").

The District Court's order fails to respect the limits of the judiciary's institutional competence. A court's assessment of "medical need" is not mentioned in the antitrust laws as a valid factor in Sherman Act analysis. The injunction also has the extraordinary effect of forcing Forest Labs to continue manufacturing an older drug for the benefit of its generic competitors. Such far-reaching relief effectively commandeers Forest Labs' private property for the benefit of its

competitors – a remarkable step that raises grave questions of constitutional dimension. Thus, in *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 630-31 (1952), the Supreme Court denied President Harry Truman the authority to seize steel mills during the Korean conflict and continue to operate them for the benefit of the public. The Court so held, even though Truman justified his action by citing national security and the need to prevent labor strife from disrupting the war effort – a much more substantial justification than presented by this case.[15] It is well settled that the Takings Clause requires just compensation where private "property has been taken over for continued operation by a governmental authority," *Kimball Laundry v. United States*, 338 U.S. 1, 12 (1949), or where the government commandeers a patent for public use. *Richmond Screw Anchor Co., Inc. v. United States*, 275 U.S. 331, 343-45 (1928). "Forced sharing" arrangements also are familiar forms of takings,[16] and judicial orders no less than other forms of governmental action can

[15] Truman's order did not involve physical invasion as such of the mills by government agents. Rather, the presidents of the various mills were deputized as "operations managers" and directed to carry on their activities in accordance with regulations and directions of the Secretary of Commerce. 343 U.S. at 583. In other words, Truman's order operated to usurp the decision making and management of private enterprise in much the same way as the District Court's injunction in this case.

[16] *E.g.*, *Dolan v. City of Tigard*, 512 U.S. 374, 385-86 (1994) (condition forcing right to public access to greenway was a taking); *Nollan v. California Coastal Comm'n*, 483 U.S. 825, 832-33 (1987) (condition forcing right of public access to beachfront property was a taking); *Kaiser Aetna v. United States*, 444 U.S. 164, 176 (1979) (requiring public access to marina was a taking).

work a taking. *Stop the Beach Renourishment, Inc. v. Florida Dept. of Environmental Protection*, 560 U.S. 702, 714-15 (2010). The District Court's injunction is an extraordinary remedy that flies in the face of these settled limits on its authority.

By compelling Forest Labs to continue making Namenda IR, the District Court sought to advance its conception of the public interest, while singling out Forest Labs to bear all the costs — and relieving Forest's commercial competitors from the costs of competing on the merits. The Court's conception of the public interest was mistaken, but even more fundamentally it exceeded its institutional competence. And the purpose of the Fifth Amendment is "to prevent the government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole." *Eastern Enters. v. Apfel*, 524 U.S. 498, 522-23 (1998); *see also Armstrong v. United States*, 364 U.S. 40, 49 (1960).

CONCLUSION

The District Court's injunction should be vacated and its judgment should be reversed.

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CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE 32(a)

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