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
Plaintiff-Appellee,

v.

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

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK (CIVIL ACTION NO. 1:14-07473)

BRIEF OF ANTITRUST ECONOMISTS AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS-APPELLANTS

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The Antitrust Economists ("*amici*") respectfully submit this *amici curiae* brief in support of the request of Appellants, Actavis, plc, and Forest Laboratories, LLC ("collectively Forest"), that the decision of the district court be reversed. Pursuant to Federal Rule of Appellate Procedure 29(a), *amici* state that all parties have consented to the filing of this brief.

INTEREST OF THE *AMICI CURIAE*

Amici curiae are economists who teach at leading colleges and universities throughout the United States and who work as consultants with experience in the economics of the pharmaceutical industry.[1] (A list of the *amici curiae* is attached as Addendum A.) As economists and scholars, *amici* have a strong interest in the application of antitrust laws for their intended purposes: to promote efficient, vigorous, and innovative competition, for the benefit of consumers and the economy as a whole. They write to inform the court of economic analysis relevant to the importance of preserving a pharmaceutical company's freedom to decide which products to sell or not to sell, the selling price, the quantity to be sold, the appropriate time to sell, and the distribution channel to be used. In a competitive market, as exists here, these decisions should be made by the business, in response

[1] Pursuant to Fed. R. App. P. 29(c)(5) and Local Rule 29.1(b), *amici* state that no party or party's counsel authored the brief in whole or in part. *Amici* further state that no party, party's counsel, or any other person other than *amici* and *amici's* counsel contributed money that was intended to fund preparing or submitting this brief. *Amici's* counsel also received no payment for their representation in this matter.

to normal market forces and profit-maximization incentives, and not by governmental fiat. *Amici* believe that this court should reverse and vacate the district court's preliminary injunction, (the "Injunction") forcing Appellant to continue making and selling Namenda IR until 30 days after July 11, 2015.

SUMMARY OF THE ARGUMENT

Forcing Forest to continue to produce and market Namenda IR until thirty days after generic versions launch in July 2015 will impose significant economic costs that will not be outweighed by any economic benefit. With respect to cost, forcing Forest to produce Namenda IR after its natural life cycle, and the precedent created by that decision, undermine incentives to innovate in the pharmaceutical industry. Additionally, imposition of this injunction will not produce any offsetting benefits. As an initial matter, Forest has already agreed that Namenda IR will remain on the market through the pharmacy Foundation Care until the time of generic launch, with no limits on the amount of Namenda IR Foundation Care can provide. But even if Forest had not agreed to continue production of Namenda IR, competitive forces in the pharmaceutical industry are strong enough to ensure that additional government intervention is not required. In particular, payors in the pharmaceutical industry are typically large and sophisticated insurance companies that regularly shift market share to lower cost therapeutic alternatives when they believe that it is warranted.

ARGUMENT

I. MARKET FORCES AND PAYOR PURCHASING POWER ADEQUATELY PROTECT GENERIC COMPETITION, WITHOUT THE NEED FOR GOVERNMENT MARKET INTRUSION.

The district court's unprecedented opinion, adopting New York's economic theories, disregards the important economic realities of the pharmaceutical market and the costs associated with the court's intervention. The district court's decision fails to recognize that in the highly complex and competitive market for pharmaceuticals, there are a dozen generic memantine manufacturers preparing to enter this dynamic market,[2] all of whom are well-equipped to compete with Namenda IR and XR – without the benefit of the court's sweeping Injunction and regardless of how the relevant product market is defined. Advancing theories that ignore the economic realities, New York prevailed upon the district court to artificially simplify those realities and adopt an ill-conceived remedy that misjudges and discounts the balance of competitive forces. Nonetheless, the reality remains: the Injunction is unwarranted, unnecessary, and harms both competition and innovation.

[2] By agreement, five generic manufacturers are permitted to enter the market prior to the end of Forest's exclusivity and may start selling generic memantine as of July 11, 2015. *See* Op. ¶ 41, *New York v. Actavis*, No. 14-7473, (S.D.N.Y. Dec. 11, 2014), Docket No. 80. An additional seven generic manufacturers may enter the market as early as October 11, 2015. *Id.*

A. Regardless of Forest's Proposed Plans, Namenda IR Will Remain On the Market And Will Face Generic Competition.

As the district court acknowledges, Forest has not withdrawn Namenda IR from the marketplace or the Orange Book, and there is no allegation or finding that Forest removed Namenda IR from the National Drug Data File. On the contrary, it is undisputed that Forest will continue to supply Namenda IR in both liquid and tablet form.[3] Generic memantine will be AB-rated to Namenda IR, an established and trusted product for treating Alzheimer's disease.[4] As Dr. Kolassa aptly noted: "If the marketplace does not put much value on the advantages of once-a-day Namenda XR, then third-party [payors] will make twice-a-day memantine IR the product with a leg up in the marketplace."[5]

1. Namenda IR tablets will be available through Foundation Care.

The tablet form of Namenda IR would be supplied through Foundation Care, an independent full-service retail pharmacy able to fill prescriptions issued anywhere in the United States.[6] Foundation Care provides reimbursement coverage for most commercial health care plans as well as Medicaid and Medicare.[7] To dispense Namenda IR tablets, Foundation Care requires only a

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[3] *See* Hr'g Tr. (Lah) 64:24-65:4; 100:5-14, Pace Decl. Ex. 1, (ECF No. 41-2).
[4] Kolassa Decl. ¶ 5, Pace Decl. Ex. 23, (ECF No. 41-6).
[5] *Id*.
[6] *See* Op. ¶ 102; Blakeley Decl. ¶ 2, Pace Decl. Ex. 20, (ECF No. 41-6).
[7] *See* Op. 64; Blakeley Decl. ¶ 4.

prescription, basic patient and physician information, and a one-page Medical Necessity Form containing a physician certification that "Namenda [IR] tablets are medically necessary."[8]

Nothing in Forest's agreement with Foundation Care or on the Medical Necessity Form requires the physician to prescribe Namenda IR as "dispense as written" or otherwise precludes substitution of generic memantine for Namenda IR.[9] Instead, Foundation Care – like any other pharmacy – is obligated to follow the generic substitution laws of the state to which the prescription is delivered, and it will substitute generic memantine whenever it is permitted or required.[10]

2. Forest's agreement with Foundation Care imposes no limits on the availability of Namenda IR.

To the extent the Injunction opinion is driven by a concern that patients who need Namenda IR will have limited access to it, this concern is misplaced. Foundation Care is not subject to any supply limitation with respect to Namenda IR and, in fact, has expanded its facilities and hired additional staff to ensure sufficient capacity to meet demand.[11] Moreover, Foundation Care has a "significant financial incentive" to substitute generic memantine for branded

[8] *See* Op. ¶¶ 103, 105; Hr'g Tr. (Kane) 553:9-534:4; 534:10-15.
[9] Blakeley Decl. ¶ 6.
[10] *See id.*
[11] *See id.* ¶¶ 7-9; Hr'g Tr. (Kane) 553.

Namenda IR prescriptions once generic entry occurs.[12] Because the end-date of Foundation Care's Namenda agreement with Forest coincides with generic entry, Foundation Care can only maintain its Namenda IR customers if it offers generic memantine tablets as soon as they are available.[13]

The type of agreement that Forest has made with Foundation Care is not generally considered anticompetitive. The district court's determination of probable success on New York's argument that Forest's vertical distribution agreement with Foundation Care violates Section 1 of the Sherman Act makes little economic sense. The court cites none of the traditional kinds of economic evidence that must be considered in such an analysis. Rather, it erroneously suggests that a garden-variety vertical distribution agreement with a downstream buyer – unlimited and uncapped with respect to volume of the product to be distributed – is "tainted" in some unspecified manner by the patentholder's upstream distribution strategy, and is therefore an unlawful restraint of trade and commerce, even though without such a distribution agreement there would be no trade and commerce in the product at all.

Aside from the continued availability of brand name Namenda IR (in both tablet and liquid forms), the industry characteristics confirm that generic memantine can compete with Namenda IR and XR. Forest's improvement of

[12] *See* Blakeley Decl. ¶ 6.
[13] *Id.*

Namenda from twice-a-day IR to once-a-day XR does not deprive patients, prescribing physicians, or pharmacists of the option to choose generic memantine and, in fact, the dozen companies poised to enter with generic memantine – and, significantly, third-party payors – have ample tools to ensure that these consumers make that choice.

B. Third-party Payors Have the Power to Shift Sales From Brand Drugs to Generics.

The fact that Namenda IR will remain on the market aside, concerns regarding the impact of its presence or absence on generic competition are, in fact, red herrings. It is undisputed, and widely known, that generic memantine will be available from numerous suppliers beginning in July 2015. Upon generic entry, various market players, discussed below, can influence utilization of available memantine products, regardless of whether Namenda IR remains available and without the need for judicial intervention.

In the complex Hatch Waxman[14] world, insurance companies, health plans, public payors (such as Medicare and Medicaid), and pharmacy benefit management companies ("PBMs") (collectively, "third-party payors") play an increasingly pivotal role in the pharmaceutical industry. The pharmaceutical supply system is complex, involving multiple entities playing different but

[14] Referring to the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) ("Hatch Waxman").

sometimes overlapping roles in drug distribution, contracting, and pricing.[15] *See* Addendum B.[16] In this framework, third-party payors have a broad range of effective mechanisms to drive prescription drug utilization toward lower cost generic drugs (and preferred brand name drugs) in place of more costly (or less preferred) brand name drugs.

Pharmaceutical manufacturers, such as Forest, distribute drugs to pharmacies in the U.S. directly and through wholesalers. Most "brand name" manufacturers distribute their products through three wholesalers – McKesson Corporation, Cardinal Health, and AmerisourceBergen Corporation (the "Big 3") – that together account for more than 85% of wholesale distribution.[17] The Big 3 and other smaller wholesalers handle most of the distribution to retail pharmacies, mail-order pharmacies, hospital pharmacies, long-term care facilities, and others.[18] Similarly, several large national chains play a key role in retail pharmaceutical distribution.[19] The national pharmacy chains, as well as specialty and mail-order

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[15] Health Strategies Consultancy LLC, The Kaiser Family Foundation, *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain* 8 (2005), *available at* http://kaiserfamilyfoundation.files.wordpress.com/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf [hereinafter *Follow the Pill*].

[16] *Id.* at 3.

[17] *Id.* at 8.

[18] *Id.*

[19] According to a recent study, national chains accounted for 52% of all prescriptions filled through retail pharmacies. *Id.* at 11.

pharmacies, have the operational infrastructure to bypass the wholesaler and obtain drugs directly from the manufacturer.[20]

Most prescriptions filled in the U.S. are covered in whole or in part by a prescription drug health benefit offered by an insurance plan, employer, public payor (such as Medicare or Medicaid), or other health plan sponsor.[21] As of 2008, approximately 80 percent of prescription drug expenditures were paid by public programs and private insurers.[22] In addition, many health insurance plans – including Medicare – retain a PBM to manage the pharmacy portion of the benefits they provide.[23]

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[20] *Id.* at 10.

[21] *See National Health Expenditure (NHE) Historical and Projections Dataset 1965-2021*, Centers for Medicare & Medicaid Services, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/nhe65-21.zip (last visited Jan. 13, 2015).

[22] U.S. government programs – including Medicare and Medicaid – now account for about 37 percent of prescription drug spending in the U.S. *See id.* Private payors, such as private health insurers, account for a large proportion of remaining drug expenditure. In the U.S., private insurance coverage for outpatient drugs is paid for primarily by employer health care plans. Janet Lundy, The Kaiser Family Foundation, *Prescription Drug Trends* 5 (2010), *available at* http://kaiserfamilyfoundation.files.wordpress.com/2013/01/3057-08.pdf; *see also Report to the President: Prescription Drug Coverage, Spending, Utilization, and Prices*, Department of Health & Human Services, Ch. 2 (2000), http://aspe.hhs.gov/health/reports/drugstudy/chap02.htm.

[23] The size of a PBM is often measured by the number of patients for which it provides its services, referred to as "covered lives." In 2011, the three largest PBMs (by annual prescription volume) – Express Scripts, CVS Caremark, and Medco Health Solutions – controlled 90, 85.1, and 69.5 million covered lives, respectively. *See Top 10 Pharmacy Benefit Management Companies and Market*

PBM's play an integral role in consumer drug purchases, and according to a 2004 report, manage prescription drug benefits for as much as 57% of the population.[24] Working with third-party payors, PBM's define which drugs will be paid for, the payments pharmacies will receive, and how much consumers must pay out-of-pocket for prescriptions.[25] Among other core tools and services, PBMs develop and manage drug formularies, preferred drug lists, step therapy, and prior authorization programs designed to shift utilization to lower cost generic and preferred brand name drugs.[26]

1. Formularies and reimbursement coverage promote generic use.

One of third-party payors' key tools for controlling drug costs is the drug formulary – a list of approved drugs that will be reimbursed by the payor to the patient/pharmacy when prescribed.[27] Drug formularies typically dictate what drugs

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Share by Membership, as of 2nd Quarter 2011, Pharmacy Benefit Management Institute (2012), http://pbmi-com.web33.winsvr.net/PBMmarketshare1.asp. In 2011, these three PBMs processed 656.1, 584.8, and 740.1 million prescriptions, respectively. *See Top 10 Pharmacy Benefit Management Companies and Market Share by Annual Prescription Volume, as of 2nd Quarter 2011*, Pharmacy Benefit Management Institute (2012), http://pbmi-com.web33.winsvr.net/PBMmarketshare2.asp.

[24] *Follow the Pill*, *supra* note 15, at 13-14 (*citing* Atlantic Information Services (AIS), Inc., *A Guide to Drug Cost Management Strategies* 329 (2d ed. 2004)).

[25] *Id.* at 14-15.

[26] *Id.* at 14.

[27] Academy of Managed Care Pharmacy, *Formulary Management*, http://amcp.org/WorkArea/DownloadAsset.aspx?id=9298 (last visited Jan. 14, 2015).

are covered as well as the level of cost sharing (generally co-payments) required from the patient.

Many formularies also use a tiered system of increasing copayments, with the first tier (and lowest co-payment) typically reserved for generic drugs; the second tier, with a higher co-payment, for preferred branded drugs; and the third tier and even greater co-payment for non-preferred branded drugs.[28] Moreover, many branded drugs are not contained on any formulary tier. Drugs that are not on the formulary are generally ineligible for reimbursement by the health insurance company. [29] Because reimbursement coverage and co-payment costs have a substantial influence on consumers' drug purchases, drug manufacturers compete vigorously to be on formulary and in a preferred tier, often by providing substantial rebates to third-party payors. Thus, the formulary system is an effective mechanism for driving prescription sales toward generic drugs.

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[28] The Kaiser Family Foundation and Health Research & Educational Trust, *Employer Health Benefits: 2012 Annual Survey* 4 (2012), *available at* https://kaiserfamilyfoundation.files.wordpress.com/2013/03/8345-employer-health-benefits-annual-survey-full-report-0912.pdf. These trends have increased the relative bargaining power of PBMs over manufacturers. *See* Patricia M. Danzon & Sean Nicholson, *The Oxford Handbook of The Economics of the Biopharmaceutical Industry* 241-45 (2012).

[29] *See, e.g.*, CVS/Caremark, 2015 Formulary Drug Removals (July 31, 2014), http://www.caremark.com/portal/asset/Formulary_Exclusion_Drug_List.pdf; Express Scripts, 2015 Preferred Drug List Exclusions (Aug. 1, 2014), https://host1.medcohealth.com/art/open_enrollment/DrugListExclusionsAndAlternatives.pdf. Over time, the number of tiers in each formulary and the copayment amounts for each drug tier have increased.

2. Third-party payors incentivize physicians and pharmacists to prescribe and dispense generic drugs

The influence of third-party payors extends beyond their formularies and directly reaches the physicians who prescribe, and the pharmacists who dispense, prescription drugs.[30] Financial incentives created by third-party payors influence pharmacies to persuade physicians and patients to substitute a lower-cost generic drug for the prescribed, but not preferred, brand name drug. Pharmacies typically realize a higher profit margin on generic drugs and thus have a financial incentive to promote generic utilization.[31] Third-party payor incentives include payments to pharmacies that meet certain dispensing standards based on, for example, dispensing of generics or preferred brand-name drugs on the formulary.

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[30] Third party payors also engage in efforts to raise consumers' and physicians' awareness of available generic drugs. These efforts include sponsoring broad media campaigns, displaying signs at pharmacies, providing free generic samples to physicians, and communicating directly with consumers or physicians. *See* Jack Hoadley, The Kaiser Family Foundation, *Cost Containment Strategies for Prescription Drugs: Assessing the Evidence in the Literature* 69 (2005), *available at* http://kaiserfamilyfoundation.files.wordpress.com/2013/01/cost-containment-strategies-for-precription-drugs-assessing-the-evidence-in-the-literature-report.pdf.; Sara Calabro, *CAMPAIGNS: General education push helps Medco trumpet generics*, PR Week (January 6, 2003), http://www.prweekus.com/campaigns-general-education-push-helps-medco-trumpet-generics/article/46094/.

[31] John E. Dicken, U.S. GAO, *Drug Pricing: Research on Savings from Generic Drug Use* 8 (2012), *available at* http://www.gao.gov/assets/590/588064.pdf (PBMs provide "financial incentives for physicians and pharmacists to choose generics"); Trefis Team, *CVS Fortifies Its Margins by Selling More Generic Drugs*, Forbes (Aug. 7, 2013, 5:37 PM), http://www.forbes.com/sites/greatspeculations/2013/08/07/cvs-strengthens-margins-by-selling-more-generic-drugs/.

Pharmacies, and in particular mail-order pharmacies, can reap the benefits of these incentives by advising the prescriber of the preferred formulary alternative that will treat the patient's condition at a lower cost. Regardless of whether the pharmacy is retail or mail-order, substitution of generic drugs that treat chronic conditions will affect not only the initial prescription but many future prescriptions. Other third-party payor programs are directed at physicians and provide financial incentives rewarding those who prescribe generic drugs and disadvantaging those who do not.[32]

3. Third-party payors promote generic use through step therapy, therapeutic substitution and prior authorization requirements.

Step therapy is a mechanism that third-party payors use to restrict reimbursement for a drug until the patient first tries other drug therapies, in many instances, a lower cost generic product that treats the same condition.[33] For example, some formularies may choose to make coverage of Namenda XR

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[32] *See, e.g.*, Blue Cross Blue Shield of Michigan, *Physician Group Incentive Program 2012 Program Year: Increasing the Use of Generic Drugs Initiative* 5 (2012), *available at* http://thephysicianalliance.org/wp-content/uploads/2012/11/GDR_External_Initiative_Plan.pdf (The Generic Drugs Initiative is a "pay for performance program" that includes semi-annual, quarterly and monthly reporting on, among other thing, physicians' generic dispensing rate.").

[33] Third-party payors have become increasingly reliant on this mechanism to enforce therapeutic substitution and drive utilization towards low cost alternatives. *See* John Carroll, *Will Therapeutic Interchange Be Put Off Limits by States?*, Managed Care (Jan. 2011), http://www.managedcaremag.com/archives/1101/1101.regulation.html.

available only to patients who do not respond successfully to immediate release generic memantine.

Similarly, prior authorization policies require patients to obtain third-party payor authorization for reimbursement of a particular prescription. When prior authorization is used in combination with step therapy, patients are given prior authorization for a drug only after they have tried other drug therapies.

Using the mechanisms outlined above, third-party payors can and do drive utilization from branded drugs toward cheaper generic drugs. These shifts take place even when the generic drug does not have the same active ingredient as the branded drug.

C. The District Court's Focus on AB-rated Substitution is Misplaced.

The district court's decision rests in large part on the faulty premise that generic drugs cannot compete in the absence of AB-rated substitution. That premise is belied by the market and economic realities.

1. Third-party payors can shift utilization to generics without AB-rated substitution.

As explained above, third-party payors have numerous tools to drive utilization from a brand name drug to a generic alternative. Thus, manufacturers of generic memantine have an incentive to inform third-party payors about the availability of a lower cost alternative to Namenda. Similarly, third-party payors

that cover Namenda have an incentive to place generic memantine in the most favorable formulary tier.

Moreover, third-party payors' key criterion for shifting utilization from a branded drug to a generic (or a preferred brand) is not whether the generic is AB-rated by the FDA, but whether the drugs are therapeutically interchangeable. The district court's decision proceeds from the premise that without AB-rated substitution, there will be little or no substitution of generic memantine. While the absence of an AB-rated generic for Namenda XR may result in less automatic substitution, the court's premise is flawed in its apparent requirement that substitution must be passive rather than the result of a choice among available memantine alternatives. As noted above, generic memantine will be AB-rated to Namenda IR, which, despite a different dosing regimen, is therapeutically interchangeable with Namenda XR.[34] Thus, when considering a prescription for Namenda XR, patients, physicians, pharmacies, and third-party payors will have not only the option, but various incentives, to choose generic memantine as a less-costly alternative.

2. Generic firms do not wait passively for AB-rated substitution.

Generic firms do not market through passive AB substitution alone. First, generic firms manage the lifecycle of their products and regularly make decisions

[34] Op. ¶ 67

about: (i) which forms, doses, and routes of administration to register and manufacture; (ii) when and where to promote their products; (iii) which third-party payor formularies to participate in; and (iv) how to negotiate pricing and volumes.

Second, generic firms have the ability to negotiate favorable terms with third-party payors and distributors by providing evidence of their capacity to meet volume demands at high levels of quality and to augment those supply capabilities with promotional capabilities. In fact, a generic firm's ability to provide quality, price, volume, and promotional capabilities can differentiate it from its generic competitors.

Third, rather than passively relying upon AB-rated substitution to sell their products, generic firms regularly produce: (i) novel dosage forms or formulations of off-patent drugs; (ii) off-patent drugs with a trade name, also referred to as "branded generics"[35]; and (iii) off-patent drugs without a trade name.[36] Generic manufacturers also promote their products using a variety of tactics, including professional sales forces, written sales aids, generic and branded generic samples, and other activities directed at third-party payors, wholesalers, and retailers.

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[35] Examples of "branded generics" include Mylan's Amnesteem and Andrx's Altocor. *Beyond Commodity Drugs: Strategic Diversification in the Genetics Industry, in Wiley Handbook of Current and Emerging Drug Therapies* 97, 106, 108 (2006).

[36] 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. J. of the Economics of Business 177, 181 (2011).

Considering the array of tools that third-party payors employ to drive consumption of generic pharmaceutical products, and the district court's narrow focus on AB-rated substitution, the Injunction's protective umbrella over generic competitors is redundant and unnecessary, and is a disruptive, unwarranted departure from competitive market principles.

II. UNLESS PROMPTLY VACATED, THE INJUNCTION WILL CAUSE SIGNIFICANT ECONOMIC HARM.

The district court's Injunction commands:

> Defendants shall continue to make Namenda IR (immediate-release) tablets available on the same terms and conditions applicable since July 21, 2013 (the date Namenda XR entered the market). . . . In order to allow for an orderly transition, this injunction shall be effective from the date of issuance until thirty days after July 11, 2015 (the date when generic memantine will first be available) (the 'Injunction Term').[37]

Enforcement of such a vague and unworkable Injunction will cause far-reaching economic harm by creating inefficiencies and stifling innovation.

A. Forcing Forest to Produce Namenda IR after Its Natural Life cycle, and the Precedent Created, Undermine Incentives to Innovate in the Pharmaceutical Industry.

What is ultimately at stake in this case? One economic study concludes that:

> *Gains in life expectancy over the [twentieth] century were worth over $1.2 million per person to the current population. From 1970 to 2000, gains in life expectancy added about $3.2 trillion per year to national wealth[.]*[38]

[37] *New York v. Actavis*, No. 14-7473 (S.D.N.Y. Dec. 15, 2014), Docket No. 84.
[38] Kevin M. Murphy & Robert H. Topel, *The Value of Health and Longevity*, 114 J. Political Econ., 871, 872 (2006).

Protected innovation "allow[s] producers to harvest a portion of consumers' surplus in the short term, yet increase consumers' surplus in the long term via new and improved goods and services."[39] Innovation results in new products and, in many cases, the introduction of new products leads to withdrawal of older products. When competition is unrestricted, the market decides what innovations to accept or reject. While examples exist of commercially unsuccessful innovations (*e.g.* Apple Newton or Sony Betamax) or poorly-received innovations (*e.g.* Microsoft's Vista or Ford's Edsel), there is no question that innovation is a key source of improved productivity and quality of life. Not surprisingly, innovation often supplants older methods of doing things, regardless of whether the innovation is radical (*e.g.* cars replaced horses) or incremental (*e.g.* iPhone replaced the Blackberry, and even new versions of the iPhone replace older versions on an annual basis). As a result, the legacy supplier suffers – but consumers gain. Indeed, incremental innovations, specifically in the pharmaceutical industry, cannot be overlooked as insignificant: nearly half of the health gains from pharmaceutical innovation in the past decade have come from incremental innovations.[40]

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[39] ABA Section of Antitrust Law, *Intellectual Property and Antitrust Handbook* 36 (2007).

[40] Incremental innovations are either new FDA-approved drugs created from an already existing molecule or FDA-approved modifications to existing drugs.

Here, the creation of Namenda XR is an example of innovation – the very kind of innovation that patent laws and antitrust laws are designed to encourage and reward, to the benefit of consumers. Forest seeks to respond to doctors' and caregivers' identified preference for its new once-a-day Namenda XR.[41] Many studies in the medical literature find significant benefits from a once-daily dosing schedule with respect to patient compliance. For example, a 2009 study found that in comparison with daily dosing, patients who received twice-daily dosing had up to 44 percent more days in which they were adherent to their prescribed daily dosing schedule.[42] New York, on the other hand, seeks to block natural market forces by prohibiting Forest from responding to the market by focusing on its newest, most innovative product. New York's campaign to force an innovator to continue to produce an old product when it has a new replacement could

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Incremental innovations can generate value by: creating new drugs that use existing molecules to treat different diseases; changing the chemical formulation or active ingredient of a drug to increase the drug's efficacy and reduce side effects; creating combination drugs or reducing the number of pills or doses; and creating new delivery methods for certain patients who could not take the drug in its originally approved form.

[41] Hr'g Tr. (Kane) 489:20-499:7 ("In considering whether and how to discontinue its older Namenda IR tablets in favor of once-daily Namenda XR capsules, Forest conducted extensive surveys of physicians, caregivers and pharmacists about their views of Namenda XR and whether Namenda IR still need to be available. Support for Namenda XR was very strong among physicians, caregivers and pharmacists."); Hr'g Tr. (Berndt) 441:12-14 (Dr. Berndt agreeing that there is likely a preference for once-daily Namenda).

[42] Sameer D. Saine, M.D. *et al.*, *Effect of Medication Dosing Frequency on Adherence in Chronic Diseases*, Am. J. Managed Care 6, 27 (2009).

undermine incentives to innovate, which ultimately costs society by reducing consumer welfare. In the long-run, if the Injunction stands, it could serve as a precedent for the entire pharmaceutical industry. The result could be increased cost of new drugs and reduced development of new drugs. This sort of profound economic impact may be an unintended consequence of the court's decision.

1. Diminished protection will reduce incentives to innovate.

Forcing Forest to produce Namenda IR, a drug on which it indisputably has a valid patent, impairs its patent rights and takes its intellectual property.[43] This precedent, if permitted to stand, will chill innovation in the pharmaceutical industry, where empirical evidence shows that patents and the profits to be earned from them are the crucial incentive for innovation.[44] Branded pharmaceutical manufacturers that are incentivized to invest heavily in research and development of new drugs in the hope of obtaining a patent will be forced to recalculate the benefits of such expenditures if courts are free to impair, reduce, and condition the exercise of their patent rights on the continued making and marketing of drugs they

[43] A patent holder has no obligation to use its patent. *See e.g., Hartford-Empire Co. v. United States*, 323 U.S. 386, 432 (1945) ("A patent owner is not in the position of a quasi-trustee for the public or under any obligation to see that the public acquires the free right to use the invention. He has no obligation either to use it or to grant its use to others."); *United States v. United Shoe Mach. Co. of N.J.*, 247 U.S. 32, 57 (1918) ("[A patent's] strength is in the restraint, the right to exclude others from the use of the invention ").

[44] James Bessen & Michael Meurer, *Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovations at Risk* 106 (2008).

wish to discontinue. The effect on innovation could be significant because without the ability for innovators to benefit from patent protection in the pharmaceutical industry, it is likely that innovation would be curtailed.[45]

2. Added costs of barriers to exit will reduce incentives to innovate.

The Injunction conditions the introduction of Forest's innovative product – Namenda XR – on Forest's continued manufacturing, distributing, and marketing of a superseded product – Namenda IR. This condition imposes a novel barrier-to-exit on a brand name pharmaceutical manufacturer.[46] Any brand name pharmaceutical manufacturer facing imminent generic entry could now face a similar barrier-to-exit. As a result, firms must consider these added costs when

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[45] Mark A. Lemley, *Industry-Specific Antitrust Policy for Innovation* , Stanford Law and Econ. Olin Working Paper No. 397 1 5-6 (2010), *available at* http://ssrn.com/abstract=1670197 (explaining that the high research and development costs, the large ration of innovator costs to imitator cost, and limited first-mover advantages make patent protection extremely important to innovation in pharmaceuticals); James W. Hughes, Michael J. Moore, and Edward A. Snyder, *"Napsterizing" Pharmaceuticals: Access, Innovation, and Consumer Welfare*, Nat'l Bureau of Econ. Res. Working Paper No. 9229 (2002).

[46] A barrier-to-exit is a cost that only an incumbent firm must bear if it seeks to exit. In this case, it is the cost of continuing to manufacture the product beyond the dated of desired exit and the cost of threatened litigation. It is an additional cost that pharmaceutical suppliers will take into account when pricing their products, and when deciding whether or not to research and develop new products. Ultimately, this cost will be borne by consumers (perhaps insurance companies and/or employers will pay a portion in the short run, but eventually the consumer bears the cost.) Because it creates a differential cost structure across competitors (that is, presumably generics can enter and exit at will, with no government intervention), it would impose a competitive disadvantage on the affected firm.

deciding whether to innovate and how much to invest. Such a precedent compels firms to consider delaying or abandoning research and development into incremental innovations of their brand-name drugs to avoid facing similar barriers-to-exit. Alternatively, a firm may feel compelled to introduce an improved follow-on product early in time after a new product is introduced but before an optimal follow-on product can be developed and clinically tested. Either way, barriers-to-exit can have an adverse effect on drug innovation.

3. Insulating generics from competition with improved products will reduce incentives to innovate.

The central objective of Hatch Waxman is to balance the incentives for generic competition, by allowing generics to rely on the innovator's safety and efficacy data in an abbreviated FDA application, while restoring some of the innovator's lost patent time during regulatory testing and review. State substitution laws have further tilted incentives in favor of generic utilization by mandating or promoting generic substitution. These legislative actions, along with managed care formularies and other generic utilization incentive programs discussed above, have resulted in generic drugs now accounting for the vast majority of prescriptions dispensed in the United States. However, economic research suggests that increased generic competition also has caused a decline in

the number of early stage and first-in-class innovations.[47] Additionally, a 1998 Congressional Budget Office study found that Hatch Waxman increased generic competition but also resulted in lower returns to research and development investment. In particular, it estimated Hatch Waxman resulted in a tweleve percent decline in the present value of returns from research and development in the first decade after it was passed.[48]

The Injunction would further disrupt the incentives for innovation by insulating generic competition from improved products. If the Injunction is not vacated, the rewards for innovation will be reduced. Reduced rewards will be reflected in reduced investment in research and development. Reduced investment will result in reduced innovation, and fewer new drugs or incremental improvements to existing drugs, to the public's ultimate long-term detriment.

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[47] Lee Branstetter, Chirantan Chatterjee, and Matthew J. Higgins, *Starving (or Fattening) the Golden Goose?: Generic Entry and the Incentives for Early -Stage Pharmaceutical Innovation*, NBER Working Paper No. 20532 (2014) (Research indicates that a 10 percent increase in generic penetration in a given market is associated with a 7.9 percent decline in the number of early-state innovation, and a 4.6 percent decline in the number of "first-in-class" pharmaceutical innovations in the market.)

[48] Congress of the United States Congressional Budget Office, *How Increased Competition from Generics Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, 49-50 (July 1998).

B. Restrictions on "Terms and Conditions" are Price and Quantity Controls.

The Injunction directing that Forest "shall continue to make Namenda IR (immediate-release) tablets available on the same terms and conditions applicable since July 21, 2013 (the date Namenda XR entered the market)" represents a stark departure from the fundamentals of economics:

> *Ideally, the purpose of antitrust and regulation policies is to foster improvements judged in efficiency terms. We should move closer to the perfectly competitive ideal than we would have in the absence of this type of intervention. The object is to increase the efficiency with which the economy operates, recognizing that we may fall short of the goal of replicating a perfectly competitive market, but nevertheless we can achieve substantial improvements over what would prevail in the absence of such government intervention.*[49]

The district court's Injunction interferes with and supplants free competition and therefore warrants close scrutiny. Moreover, the district court failed to provide any guidance on what "terms and conditions applicable since July 21, 2013" means in the context of the Injunction. Under one possible reading, Forest must produce the same quantity of Namenda IR that it produced in July 2013 and must be ready to sell Namenda IR for the same price it sold for in July 2013. An even broader reading could additionally require Forest to promote and market Namenda IR as it did in July 2013 – a "central planning-like" approach, with all of its attendant

[49] W. Kip Viscusi, Joseph E. Harrington, and John M. Vernon, *Economics of Regulation and Antitrust* 9 (2 ed. 2005).

problems and inefficiencies.[50] Essentially, the court's Injunction replaces the operation of the competitive market with its own assessment of what the market needs and how these needs are to be met – imposing not only price controls and quantity requirements on Forest, but also taking control of Forest's marketing department for the benefit of generic manufacturers. Enforcement of such terms will lead to inefficiencies and market distortion.

Due to the unique methods of pricing in the pharmaceutical industry, imposing a price control is impossible to implement and enforce. A drug manufacture first develops a wholesale acquisition cost ("WAC") based on algorithms that account for expected demand for the product, future competition for the product, and projected marketing costs. Still, the WAC is not the "price" that the manufacturer charges. The "price" depends on how various entities interact with the manufacturer to negotiate discounts and rebates. Wholesale distributors negotiate with the manufacturer to obtain volume discounts, prompt payment discounts, discounts related to the sale of short-dated products, and chargebacks.[51] Independent of these negotiations, pharmacies negotiate with

[50] *See* Bessen & Meurer, *supra* note 15, at 73 ("While centralized economies have mustered impressive economic efforts, especially during times of war, they have generally failed to provide a high and rapidly growing standard of living.")

[51] A "chargeback" allows wholesalers to carry products destined for customers paying very different prices to the manufacturer. The wholesaler keeps track of sales to various customers under prices negotiated between the manufacturer and the customer. The wholesaler then "charges back" the manufacturer for any

manufacturers for additional discounts based on the pharmacies' ability to sell specific volumes or achieve a certain share of the specified market. Finally, manufacturers also negotiate with PBMs by offering discounts in exchange for the drug's inclusion on a formulary or in a preferred tier. Naturally, the discounts provided to each entity are continuously changing based on a number of factors, including volume and market share. Consequently, money is constantly flowing back and forth between all of these entities – making the ultimate "price" ever-changing.[52] The Injunction ignores these intricacies.

Under one conceivable reading of the Injunction, Forest would have to determine what "price" was charged in July 2013 and keep that "price" the same from now until August 10, 2015. Imposing such a strict price control in a market where price is normally continuously changing creates difficulties for market participants. Forest may be unable to adjust prices down or up when changes in the market warrant it. Some entities may continue to obtain discounts they do not qualify for: a wholesaler that had a 15% volume discount may continue to receive that discount regardless of how much Namenda IR it purchases. Conversely, entities that qualify for new discounts may not receive them: a pharmacy that sold a qualifying share of the market may not obtain an additional discount. In these

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difference between the negotiated prices paid by the customer and the WAC. *Follow the Pill*, *supra* note 15, at 19.

[52] *See* Addendum B.

examples, Forest might want to discontinue the wholesaler's discount or give an additional discount to the pharmacy. But under the Injunction, Forest's flexibility could be eliminated because such action might depart from the "same terms and conditions applicable since July 21, 2013."

The court's static control of price may also prohibit actions the district court found to be permissible competitive behavior.[53] A price control may inhibit Forest from conducting a customary "soft switch," although New York's own expert could not offer a valid pro-competitive rationale for this restriction. Normally, when a brand manufacturer rolls out a new version of a drug, it raises the price and stops promotion of the old version, in an effort to encourage patients, physicians, and third-party payors to try the new drug. This is normal competitive behavior.[54] Yet, the Injunction could be read to prohibit this behavior. This would force Forest to charge a static price for Namenda IR, instead of raising its price to encourage doctors to prescribe and patients to try Namenda XR or to capture the incremental revenue from consumers who are price-insensitive. To avoid these types of inefficiencies, regulation of price is an antitrust remedy that has traditionally been

[53] Op. ¶¶ 36, 166.

[54] Dr. Berndt agreed that "as a matter of competition economics . . . it is fine to do a soft switch by raising the praise [sic] of the older drug significantly." Hr'g Tr. (Berndt) 459:4-11.

avoided. Even New York's expert, Dr. Berndt, agreed that price controls are an unusual antitrust remedy, to be avoided.[55]

Finally, the court's arguably static specification of production quantity will also result in inefficiencies because of a mismatch of supply and demand. In any market, supply and demand fluctuate and, under normal circumstances, price and quantity adjust to equate to supply and demand. Forced production of Namenda IR at July 2013 quantities, regardless of current demand, can lead to surplus production and/or shortages – inefficiencies and waste that the free operation of market forces automatically corrects. For instance, there may be a decrease in demand for IR because of the introduction and marketing of XR. If more patients taking IR convert to XR, yet IR is still being produced at July 2013 rates when patients were not converting to XR, the result will be a surplus of IR.

CONCLUSION

Forest has focused its efforts on the production, marketing, and sale of an innovative product, Namenda XR, that it judges is superior to the older version. Other drug manufacturers will have the unqualified right to manufacture generic versions of Namenda IR within a short interval of time. Hence, consumers demand for the older version as well as the new version can be met without this Injunction. Any advantages that Forest gains in the marketplace from its decision to focus on

[55] Hr'g Tr. (Berndt) 493:1-5.

Namenda XR, which has clear benefits to end-users given the nature of the treatment involved, can be reversed when generic drug manufacturers have the opportunity to market generic Namenda IR to consumers, including third-party payors, which are sophisticated buyers more than capable of deciding what versions of drugs to purchase.

The court's decision is, at its core, regulatory and not motivated by an interest in protecting competition. The decision is, to our knowledge, the first to use of the Sherman Act to require the manufacture and sale of a product at a set price and quantity. The decision will impose significant economic costs by creating a new duty that innovators maintain an older product when marketing a new product. These costs will chill innovation with no offsetting benefits – ultimately harming consumer welfare. Furthermore, the Injunction and its costs are unnecessary because actual competition between the old and new versions can be realized without the Injunction if the demand for Namenda IR from health plans and ultimate consumers exists. In short, this mistaken Injunction: (i) is not required to support actual competition between the new and old products; and (ii) harms competition and the innovative process.

The Injunction should be promptly vacated.

Respectfully submitted,

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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, 6,926 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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CERTIFICATE OF SERVICE

I hereby certify that the foregoing brief was electronically filed with the Clerk of the Court using the Court's ECF system, pursuant to Second Circuit Local Rule 25.1(h)(1)-(2). Counsel for Appellant and counsel for the Appelles are registered in this case on ECF and will be served with the brief via the ECF system.

I hereby certify that six hardcopies of the foregoing brief were sent via Federal Express to:

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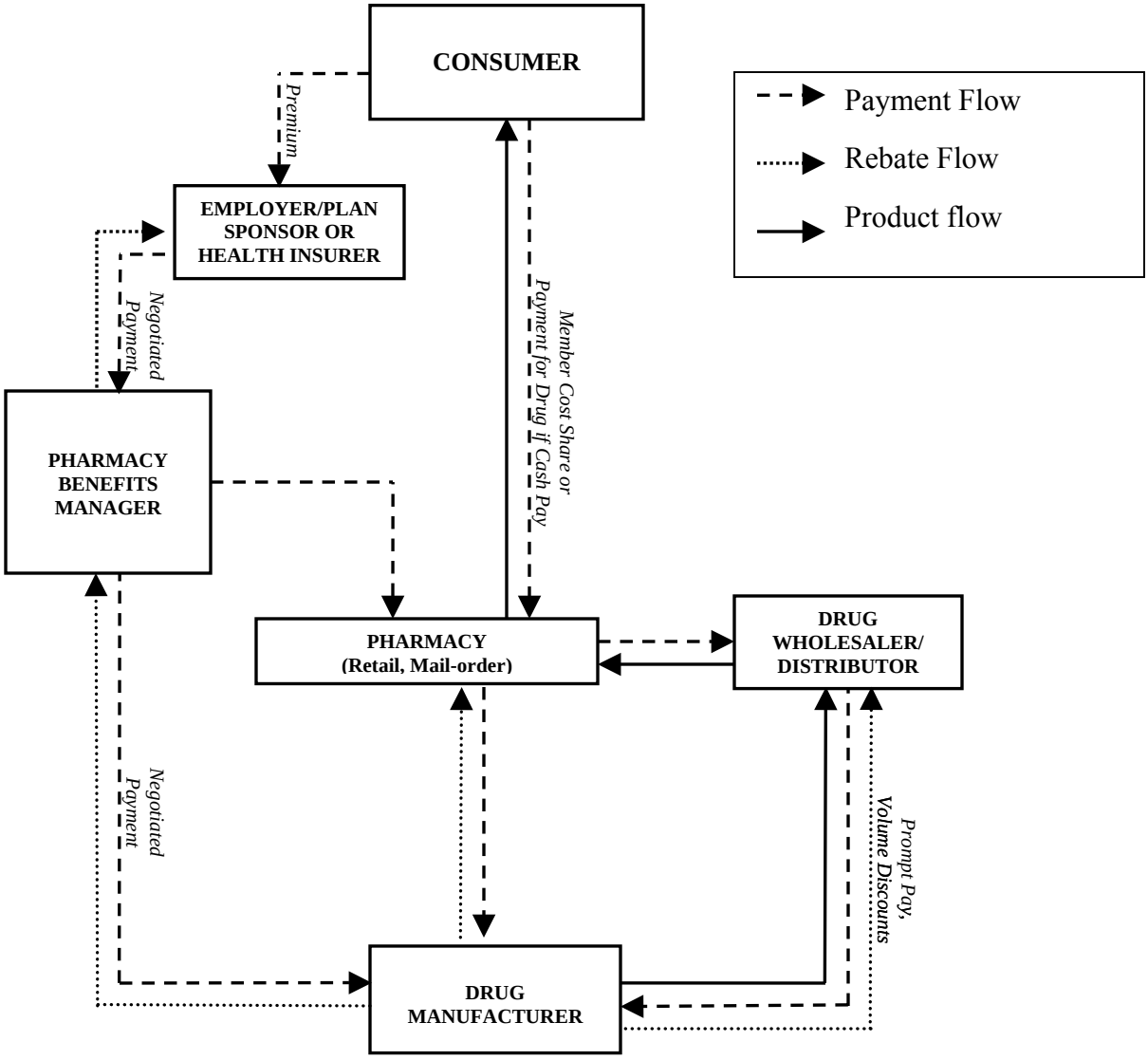
ADDENDUM B

Exhibit 1. Flow of Goods and Financial Transactions Among Players in the U.S. Commercial Pharmaceutical Supply Chain



Source: The Health Strategies Consultancy LLC