15-2236

United States Court of Appeals

for the Third Circuit

MYLAN PHARMACEUTICALS INC.,

Appellant,

v.

WARNER CHILCOTT PUBLIC LIMITED COMPANY, WARNER CHILCOTT COMPANY, LLC; WARNER CHILCOTT US, LLC; MAYNE PHARMA GROUP LIMITED; MAYNE PHARMA INTERNATIONAL PTY, LTD.,

Appellees.

On Appeal from the United States District Court
for the Eastern District of Pennsylvania

BRIEF FOR INTELLECTUAL PROPERTY AND ANTITRUST PROFESSORS AS AMICI CURIAE IN SUPPORT OF APPELLANT

PHILLIP R. MALONE
JEF PEARLMAN
Juelsgaard Intellectual Property and
Innovation Clinic
559 Nathan Abbott Way
Stanford, CA 94305
(650) 725-6369

Attorneys for Amici Curiae

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STATEMENT OF INTEREST OF AMICI CURIAE

Amici are professors of intellectual property (IP) and antitrust law. Their sole interest in this case is to help ensure that patent and antitrust law develop in a way that serves the public interest by promoting both innovation and competition.[1]

Amici[2] are among the leading scholarly experts on the application of IP and antitrust law in regulated industries. They include co-authors of the seminal treatises on IP and antitrust law and on antitrust law generally, as well as authors of the primary academic articles analyzing pharmaceutical product hopping and other anticompetitive conduct in the context of the Hatch-Waxman Act.

Amici have closely studied the underlying legal issues material to this appeal and submit this brief to assist the court in analyzing how antitrust law may apply in the context of product hopping. In particular, amici explain that antitrust law is an appropriate means to protect Hatch-Waxman's carefully crafted statutory scheme—designed to promote generic competition—from predatory regulatory gaming behavior that can produce serious anticompetitive harm and raise drug prices for consumers, the government, and third-party payers.

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[1] Amici certify that counsel for both appellants and appellee consented to the filing of this brief. Amici also certify that no party's counsel authored this brief in whole or in part, and that no person, including any party or party's counsel, contributed money that was intended to fund preparing or submitting this brief.

[2] See Appendix for brief biographies of amici, Professors Michael A. Carrier, Stacey L. Dogan, Harry First, C. Scott Hemphill, Herbert Hovenkamp, Mark A. Lemley, and Christopher Leslie.

Various of the amici previously filed an amicus *curiae* brief in this case at the summary judgment stage. Some amici also filed an amicus brief in the Second Circuit's recent product-hopping case, *N.Y. ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015) [hereinafter *Namenda*].

SUMMARY OF ARGUMENT

Seeking to correct the dearth of competition in the pharmaceutical industry that arose from duplicative and prohibitively expensive testing requirements, Congress enacted the Hatch-Waxman Act in 1984. Hatch-Waxman was intended to recalibrate the balance between innovation and competition by crafting a compromise that facilitated generic entry into the market while strengthening enforceability of brand patents. States supplemented this effort by liberalizing drug substitution laws to reduce market friction and facilitate price competition at the pharmacy counter.

Hatch-Waxman has been largely successful at promoting meaningful competition in the pharmaceutical marketplace, but it has also created a regulatory system that brand-drug monopolists can game to produce anticompetitive effects. Because the Food and Drug Administration (FDA) approval process examines only the safety of new drugs and not their effects on competition, brand-drug manufacturers can manipulate the regulatory system to exclude generic competitors and artificially extend the limited monopoly power created by their patent rights.

The Supreme Court made clear in *FTC v. Actavis* that antitrust law applies to the anticompetitive subversion of Hatch-Waxman's purpose and mechanism through one form of regulatory gaming: reverse-payment settlements. Another type of regulatory gaming, at issue in this appeal, is so-called "product hopping." In product hopping, a brand-drug manufacturer restrains generic competition by switching the market away from the earlier version of its drug to which generics were therapeutically equivalent, thereby effectively thwarting generic entry that would otherwise have flourished through Hatch-Waxman equivalence and state drug substitution laws. While product hopping may take various forms, amici here focus on the "forced switch" at issue in this case, where the earlier version of the drug is effectively withdrawn from the market.

Product hopping of this sort—making minor product changes and then withdrawing previous versions from the market, effectively forcing consumers to switch to the new versions—undermines the generic entry and competition intended and facilitated by the operation of Hatch-Waxman and state drug substitution laws. This exclusionary conduct can violate Section 2 by foreclosing competition and reducing consumer choice when it is undertaken without a purpose other than eliminating competition or when its anticompetitive effect outweighs any business purpose.

ARGUMENT

I. Product Hopping Manipulates the Hatch-Waxman Regulatory Framework to Exclude the Generic Competition the Act Is Designed to Enable

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act,[3] to facilitate market entry of low-cost generic drugs while increasing the incentives for pharmaceutical companies to invest in developing new drugs.[4] The Act was squarely aimed at preventing the "practical extension of the monopoly position of the patent holder beyond the expiration of the patent."[5] Around the same time, all 50 states passed laws that allow—and in many cases, require—pharmacists to substitute a generic drug when presented with a prescription for its branded equivalent, unless a

[3] 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 (2006)).

[4] The legislative history of Hatch-Waxman confirms that the Act was intended to mitigate the "serious anti-competitive effects" of FDA rules on generic drug approval. H.R. Rep. No. 98-857(II), pt. 1, at 4 (1984); *see* Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich. L. Rev. 37, 42-45 (2009) (explaining how Congress promoted generic competition through an experimental use defense, a new abbreviated approval process, and a 180-day period of marketing exclusivity for the first generic to challenge a brand firm's patent; balanced with patent term extensions, periods of market exclusivity not based on patents, and an automatic 30-month stay of FDA approval).

[5] H.R. Rep. No. 98-857(II), pt. 1, at 4 (1984).

physician directs or the patient requests otherwise.[6] Together with Hatch-Waxman, these state substitution laws "create a regulatory framework designed to reduce costs to consumers by lowering generic costs."[7] Substitution laws and Hatch-Waxman have been remarkably successful in facilitating competition in pharmaceutical markets and generating large savings for patients, health care plans, and the government.[8]

In response to these competition-promoting regulatory mechanisms mandated by Congress and the states, some brand-drug manufacturers have employed strategies to delay or effectively exclude the intended generic competition. One strategy brand manufacturers use to game this carefully tailored regulatory system is product hopping, forcing the market to switch to a new, protected (by patent and/or

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[6] See, e.g., N.Y. EDUC. LAW § 6816-a (McKinney 2014). *See also Namenda*, 787 F.3d at 644-45; Michael A. Carrier, *A Real World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 Fla. L. Rev. 1010, 1017 (2010).

[7] Br. for Fed'l Trade Comm'n as Amicus Curiae at 7, *Mylan Pharm., Inc. v. Warner Chilcott Pub. Co.*, No. 12-3824, 2013 WL 5692880 (E.D. Pa. June 12, 2013) [hereinafter FTC Amicus], JA 188-207.

[8] In 2013 alone, the use of generic drugs saved consumers $239 billion. Generic Pharmaceutical Association, *Generic Drug Savings in the U.S.* (6th ed. 2014) at 1, *available at* http://www.gphaonline.org/media/cms/GPhA_Savings_Report.9.10.14_FINAL.pdf . *See also* C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 Antitrust L.J. 947, 952 (2011) (stating that "once multiple generic firms enter the market, prices fall, often dramatically" and providing data to show that prices for a cholesterol-reducing drug dropped from $150 pre-generic entry to $7 post-entry).

FDA approval) version of their brand drug, for which generics do not have Hatch-Waxman equivalence, thereby thwarting Hatch-Waxman and substitution laws and restraining generic competition.[9]

A. Congress Created the Hatch-Waxman Framework to Promote Generic Competition Following Patent Expiration

Congress enacted Hatch-Waxman in response to the high costs of pharmaceuticals that resulted from patent monopolies on branded drugs and from delayed generic market entry.[10] Before the Act, generics could not cost-effectively enter markets to compete because of the need for expensive duplicative testing.[11] Branded drugs continued to reap monopoly profits long after patents expired because of the de facto extension of their patent term. Congress therefore sought to increase the availability of generic substitutes to reduce both healthcare costs and the high percentage of individual income spent on pharmaceuticals.[12] As the Supreme Court

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[9] See Section II.B., *infra*.

[10] In 1983 alone, the Federal Government spent $2.4 billion for drugs through Medicaid and in veterans and military hospitals. Then-President Ronald Reagan stated that Hatch-Waxman would enable "the Federal Government, the largest single consumer of drugs, [to] be able to purchase generic drugs at significantly lower cost." Ronald Reagan, President of the United States, Remarks on Signing S. 1538 into Law (Sep. 24, 1984).

[11] H.R. Rep. No. 98-857(II), pt. 1, at 5 (1984) (stating that "the inability of generics to obtain approval . . . without enormous expenditures of money for duplicative tests" resulted in a practical extension of the patent monopoly).

[12] The legislative history notes that the reduction in drug prices would be "especially important to the poor, the under-insured, and the elderly. The government itself, as

has explained, Hatch-Waxman's purpose was to "speed the introduction of low-cost generic drugs to market, thereby furthering drug competition." *FTC v. Actavis*, 133 S. Ct. 2223, 2228 (2013).

The proponents of Hatch-Waxman urged its adoption as the best possible compromise between the competing economic interests of patentees and generic manufacturers.[13] Hatch-Waxman granted generic manufacturers expedited entry to the market.[14] Rather than submitting full safety and efficacy data to the FDA, a generic manufacturer can now obtain faster and cheaper approval by filing an Abbreviated New Drug Application (ANDA), which certifies the bioequivalence of its generic to an existing branded drug.[15] This path for expedited entry represents Hatch-Waxman's mechanism to correct the market failures of the highly regulated pharmaceutical market that effectively prevented generic competition. In return, Hatch-Waxman provided substantial benefits for brand manufacturers, including

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purchaser of prescription drugs, [would] also save money as a result." H.R. Rep. No. 98-857(II), pt. 1, at 29 (1984).

[13] Hemphill & Lemley, *supra* note 8, at 947 ("The Hatch-Waxman Act gave additional protection to the inventors of new drugs, both by lengthening patent terms and by providing guaranteed terms of data exclusivity. In exchange, Hatch-Waxman made it easier for generic drug manufacturers to enter the market with a copy of the drug.").

[14] H.R. Rep. No. 98-857(II), pt. 1, at 11 (1984); Herbert Hovenkamp, Mark D. Janis, Mark A. Lemley, & Christopher R. Leslie, *IP & Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* § 15.3c, at 15-77 (2d ed. Supp. 2013) [hereinafter *IP & Antitrust*].

[15] 21 U.S.C. § 355(j) (2006).

extending the terms of certain drug patents, "creat[ing] incentives for increased research expenditures" by patentees.[16] The very nature of the highly regulated pharmaceutical market necessitated this compromise.[17]

B. State Generic Substitution Laws Effectuate Hatch-Waxman's Purpose

One unique element of this highly regulated market is the prescription drug system. Unlike in other markets where consumers have direct access to products in the marketplace, pharmaceutical products only reach consumers through physician prescriptions that are filled by pharmacists. Physicians prescribe drugs they are aware of and usually hesitate to change prescriptions for patients who have a productive routine. Physicians often become familiar with the brand name drug and continue to prescribe it by name, even following patent expiration and entry of generics.[18] Given these factors, pharmaceutical markets historically suffered from a high degree of market friction and product "stickiness" that had little correlation to

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[16] H.R. Rep. No. 98-857(II), pt. 1, at 10 (1984.

[17] H.R. Rep. No. 98-857(II), pt. 1, at 9 (1984) (stating that the Hatch-Waxman Act was designed to "implement the policy objective of getting safe and effective generic substitutes on the market as quickly as possible after the expiration of the patent.").

[18] Douglas A. Lundin, *Moral Hazard in Physician Prescription Behavior*, J. Health Econ. 19; 5, 639-62 (Sept. 2000) (physicians may continue prescribing brand drugs after patent expiration for a number of reasons, including brand loyalty from marketing and moral hazard); William H. Shrank et al., *The Consequences of Requesting 'Dispense as Written'*, Am. J. Med. 124; 4, 309-17, 315 (Apr. 2011) ("[p]hysicians with a strong preference for branded medications may not be aware of whether a generic is available").

product value.

As part of the regulatory movement that motivated Hatch-Waxman, all fifty states enacted generic substitution laws to correct these market failures. These laws give pharmacists the option (or in some states, require them) to fill prescriptions for a brand drug with an equivalent generic drug where one exists. JA 19. This substitution retains an FDA assurance of safety (generics must be therapeutically equivalent to FDA-approved drugs) while allowing generics the ability to compete at the only place they can cost-effectively access the market: the point of sale.

Substitution laws do not "stack the deck" against brand manufacturers who have already availed themselves of a patent term's worth of monopoly profits; they merely ensure access to "cheaper generic drugs in lieu of more expensive brand name drugs" if the patient does not specifically need the more expensive drug. *Pharmaceutical Soc. of State of New York, Inc. v. Lefkowitz*, 454 F. Supp. 1175, 1178 (S.D.N.Y. 1978), *aff'd* 586 F.2d 953 (2d Cir. 1978). The laws remove unnecessary transaction costs in marketing and physician-pharmacist communication that would occur each time a consumer wanted a cheaper generic drug, thereby reducing market friction and enhancing consumer choice and market competition. And they are part and parcel of the Hatch-Waxman compromise.[19]

[19] *See, e.g.*, *Drug Legislation: Hearing on H.R. 1554 and 3605 Before the Subcomm. on Health and the Environment of the H. Comm. on Energy and Commerce*, 98th

C. "Piggy-Back" Generic Entry Is Central to Hatch-Waxman's and Substitution Laws' Purposes and Mechanisms for Facilitating Competition and Is Not A Regulatory "Windfall" or "Bonus"

The district court wrongly characterized Mylan's reliance on the Hatch-Waxman and state substitution frameworks as a kind of undeserved "regulatory windfall" or "bonus for generics." JA 41, 44. In fact, however, these frameworks are precisely the balanced mechanism for facilitating generic competition that Hatch-Waxman and state drug substitution laws have carefully and deliberately created.[20]

The Supreme Court recognized the important role that Hatch-Waxman's abbreviated approval procedures play in allowing generics to "obtain approval while avoiding 'the costly and time-consuming studies'" needed for a pioneer drug and to "piggy-back on the pioneer's approval efforts, 'speed[ing] the introduction of low-cost generic drugs to market' . . . thereby furthering drug competition." *Actavis.*, 133 S. Ct. at 2228 (internal citations omitted). The same piggy-back principle applies to

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Cong. 6 (1983) (statement of Mark Novitch, M.D., Deputy Comm'r, Food and Drug Admin.) ("In 1980, [the FDA] began to publish a list of all approved drugs with therapeutic equivalence evaluations to aid States and purchasers of generic drugs to substitute such drugs with confidence."); H.R. Rep. No. 98-857(II), pt. 1, at 11 (1984) (noting that enacting Hatch-Waxman could produce savings if "generic copies of these drugs are substituted").

[20] Hatch-Waxman was intended to improve the system for approval of generic drugs that the House Report described as "too cumbersome and expensive." H.R. Rep. No. 98-857(II), pt. 1, at 5 (1984).

marketing efforts. *Namenda*, 787 F.3d at 755-57. The Hatch-Waxman framework thus positions generic drugs as low-cost alternatives that do not have to rely on expensive and time-consuming promotional efforts by their producers.[21] State drug substitution laws operate in a similar way, recognizing that, after patent expiration, speeding price competition into the marketplace has great value.

As the Second Circuit, the only appellate court that has considered product hopping, recognized in *Namenda*,

> Hatch-Waxman and state substitution laws were enacted, in part, because the pharmaceutical market is not a well-functioning market. In a well-functioning market, a consumer selects and pays for a product after evaluating the price and quality of the product. In the prescription drug market, however, the party who selects the drug (the doctor) does not fully bear its costs, which creates a price disconnect. Moreover, a patient can only obtain a prescription drug if the doctor writes a prescription for that particular drug. The doctor selects the drug, but the patient, or in most cases a third-party payor such as a public or private health insurer, pays for the drug. As a result, the doctor may not know or even care about the price and generally has no incentive to take the price into account.
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> * * * * *
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> State substitution laws are designed to correct for this price disconnect by shifting drug selection, between brand drugs and their corresponding generics from doctors, to

[21] *See* H.R. Rep. No. 98-857(II), pt. 1, at 4 (1984) (stating that Congress enacted Hatch-Waxman to allow generics to compete via "following on" branded drugs because other paths to get generics to market are not cost-effective).

> pharmacists and patients, who have greater financial incentives to make price comparisons.

Namenda, 787 F.3d at 645-46 (citations omitted).

This mechanism for facilitated generic entry and substitution solves the price disconnect between "prescribing doctors, who are not directly responsive to drug pricing, and paying insurers and consumers, who do not directly select the prescribed drug."[22] As a result, drugs are much cheaper and more widely available today than they were before Hatch-Waxman.[23] Without these laws and the procompetitive mechanisms they create, generics could not compete cost-effectively in this highly regulated marketplace. *See, e.g.*, *Namenda*, 787 F.3d at 657-58; *In re Suboxone Antitrust Litig.*, 64 F.Supp.3d 665, 683-84 (E.D. Pa.) ("[V]arious market forces unique to the pharmaceutical industry make generic substitution the cost-efficient means of competing for companies selling generic pharmaceuticals."). The ability of generics to succeed in the market by expedited approval and substitution on brand prescriptions is precisely the sort of procompetitive "piggy-backing" to reduce prices for consumers that these regulatory regimes are designed to enable.

D. Product Hopping by Brand-Drug Manufacturers Contravenes These Regulatory Frameworks and Harms Competition from

[22] Carrier, *supra* note 6, at 1017 (noting that drug substitution laws "carve out a role for pharmacists, who are much more sensitive to prices than doctors.").

[23] The first generic to enter the market is typically 20% to 30% cheaper than the branded drug. Subsequent generic entry creates greater price competition, with discounts of 85% off the branded price.

Generics

The kind of product hopping at issue in this case—essentially withdrawing existing drugs from the market and forcing patients to switch to newer versions—thwarts the procompetitive benefits intended by Hatch-Waxman and substitution laws and precludes effective generic entry and the competition and lower prices entry would bring.[24]

Product hopping delays generic competition in several ways. First, by making modifications to its brand product, the firm can require its generic rival to start the ANDA process over again, repeating FDA review for the new drug.[25] Second, where the branded drug's patent is still in force, the new ANDA can prompt a fresh litigation-triggered stay.[26] Third, product hopping prevents pharmacists from substituting generic versions for the new drug pursuant to state substitution laws until the generic's new ANDA is approved.[27] Where, as in this case, the brand-drug firm withdraws its previous drug from the market and thus forces most doctors to

[24] Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 Tex. L. Rev. 685, 709 (2009); *IP & Antitrust* § 15.3c, at 15-78.
[25] Dogan & Lemley, *supra* note 24, at 712; *IP & Antitrust* § 15.3c, at 15-78.
[26] Dogan & Lemley, *supra* note 24, at 711-12.
[27] Carrier, *supra* note 6, at 1017-18 (discussing how product reformulations further delay generics' attempts to achieve bioequivalence, sometimes by years); *IP & Antitrust* § 15.3c, at 15-78.4 ("[U]ntil the ANDA for that new product is approved . . . state laws limit the ability of pharmacists to substitute the 'old' generic for the 'new' branded drug.").

write prescriptions for the new version, the market for generics will collapse.[28] With doctors prescribing only the new branded drug, generics must await completion of the additional ANDA approval process to even be considered for substitution, since substitution laws typically allow only equivalent generics to be prescribed.[29]

Product hopping "therefore presents a paradigmatic case of a regulatory game. . . . [It] exploits the product-approval process precisely because of its exclusionary effects and converts it into a tool for suppressing competition."[30] Without the FDA's lengthy product-approval process, generic firms could quickly go to market with competing versions of brand drugs when brand-drug patents expire. But the regulatory framework prevents them from doing so, and the ability of brand-drug firms to exploit Hatch-Waxman and force generics into multiple ANDAs before they can reach the market powerfully excludes such competition.[31] As some of the amici describe this problem in their treatise, "product hopping seems clearly to be an effort to game the rather intricate FDA rules."[32]

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[28] Dogan & Lemley, *supra* note 24, at 712; Hemphill & Lemley, *supra* note 8, at 960 (while the generic firm waits for its new ANDA approval it may still sell its version of the old drug, "but that is often small comfort because pharmacists cannot substitute the old drug for the new brand-name drug.").

[29] Carrier, *supra* note 6, at 1018. *See also IP & Antitrust* § 15.3c, at 15-78.2 (citing *Abbott Labs*, 432 F. Supp. 2d at 422, to show how product hopping creates anticompetitive effects by delaying generic substitution); *Namenda*, 787 F.3d at 644-45, 656-57 & n.33.

[30] *IP & Antitrust* § 15.3c, at 15-78.4-79.

[31] *Id*.

[32] *Id*. at 15-78.

II. Product Hopping Can Constitute Exclusionary Conduct that Violates Section 2 of the Sherman Act

Standard antitrust monopolization analysis is well-suited to evaluate product design changes such as product hopping for effects on competition under Section 2 of the Sherman Act. *See, e.g.*, *United States v. Microsoft Corp.*, 253 F.3d 34 (D.C. Cir. 2001) (en banc) (change in versions of Windows). The Supreme Court has specifically approved antitrust scrutiny in the pharmaceutical industry for reverse-payment settlements, another form of Hatch-Waxman regulatory gaming. *Actavis*, 133 S. Ct. at 2225. Like reverse-payment settlements, product hopping can create a danger of exclusion of generic competition and is appropriately subject to antitrust scrutiny under Section 2.

A. Section 2 Is Well-Suited to Address Product Hopping Through Its Straightforward Analytical Approach to Monopolization

A firm with market power illegally monopolizes if it willfully acquires or maintains that power through exclusionary conduct rather than "growth or development as a consequence of a superior product, business acumen, or historical accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966); *see ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 269 n.9 (3d Cir. 2012), *cert. denied,* 133 S. Ct. 2025 (2013). Exclusionary conduct by a monopolist impairs opportunities for rivals to compete and "does not further competition on the merits or does so in an unnecessarily restrictive way." *Aspen Skiing Co. v. Aspen Highlands Corp.*, 472

U.S. 585, 605 n.32 (1985). It is conduct "without a legitimate business purpose that makes sense only because it eliminates competition." *In re Adderall XR Antitrust Litigation*, 754 F.3d 128, 133 (2d Cir. 2014). Essentially, exclusionary conduct enables the monopolist to "prevent[] actual or potential rivals from competing or impair[] their opportunities to do so effectively."[33]

Courts have developed and successfully applied a straightforward standard to determine whether a product change constitutes illegal monopolization. Once a plaintiff demonstrates that the change has anticompetitive effects and harms competition, the defendant must present a "procompetitive justification" for its conduct, "a nonpretextual claim that its conduct is indeed a form of competition on the merits." *Microsoft*, 253 F.3d at 59; *Namenda*, 787 F.3d at 652. The plaintiff must then rebut the procompetitive justification or demonstrate that, even if it is valid, it is outweighed by the anticompetitive harm of the conduct. *Microsoft,* 253 F.3d. at 58-59.[34]

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[33] 3 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 651 (4th ed. 2013).

[34] *See IP & Antitrust* § 15.3c, at 15-78.1 (suggesting that plaintiffs can establish antitrust liability by demonstrating that anticompetitive harm outweighs procompetitive benefit even when defendants establish a valid business reason for their conduct); Dogan & Lemley, *supra* note 24, at 716-17. This weighing of anticompetitive effects against procompetitive justifications is similar to the rule-of-reason analysis in Section 1 cases. *See Microsoft*, 253 F.3d at 59.

1. Antitrust Laws Apply Fully in the Hatch-Waxman Pharmaceutical Context

The mere fact that an industry is heavily regulated or features patent-protected products does not immunize behavior in that industry from antitrust scrutiny. Antitrust analysis "must always be attuned to the particular structure and circumstances of the industry at issue" and it may be considerably more important in industries where "nothing built into the regulatory scheme . . . performs the antitrust function." *Verizon Communications, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411-12 (2004) (internal citations omitted); *see also Meritor*, 696 F.3d at 283; *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 189 (3d Cir. 2005) (antitrust analysis must be guided by the economic realities of the industry at issue); *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056 (3d Cir. 1978) (in a pharmaceutical bundling case, holding that antitrust analysis must be specifically attuned to the special circumstances of the pharmaceutical industry).

The Supreme Court in *Actavis* upheld antitrust liability for pharmaceutical companies, even where the challenged conduct occurred squarely within the Hatch-Waxman "drug-regulatory framework." 133 S. Ct. at 2230 (reverse-payment settlements engineered to delay generic entry under Hatch-Waxman can violate the

Sherman Act).[35] Product hopping, like the reverse-payment settlements in *Actavis*, can manipulate the regulatory framework to exclude generic entry in a way not intended by that framework. *See id.* at 2234 (relying on the "general procompetitive thrust" and specific entry-promoting provisions of the Hatch-Waxman Act as reasons to recognize antitrust liability for reverse-payment settlements).

The FDA is not able to prevent this regulatory gaming because it explicitly avoids consideration of competition effects when approving pharmaceuticals. *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 241 (4th Cir. 2002) (describing the FDA's approach to Hatch-Waxman as "focus[ing] on its primary task of ensuring that drugs are safe and effective" while letting private parties sort out their respective rights).[36] The inability of regulation to curtail potentially

[35] Antitrust scrutiny of regulatory gaming of Hatch-Waxman is hardly novel. *See, e.g., In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340, 351 n.14 (D.N.J. 2009) ("Antitrust claims are, moreover, frequently based on allegations of manipulation of the Hatch-Waxman regulatory framework."); *Walgreen Co. v. Organon, Inc.* (*In re Remeron Antitrust Litigation*), 335 F. Supp. 2d 522, 532 (D.N.J. 2004) ("Within the maze of Hatch-Waxman, if a patent-holder's actions unlawfully maintain otherwise lawful monopoly power or use a lawful patent to manipulate the ANDA process, such actions could lead to anticompetitive effects in the relevant market.")

[36] *See also IP & Antitrust* § 15.3c, at 15-79 ("Making matters worse, the [FDA] regulators can do nothing to thwart this obvious abuse of their administrative function.").

anticompetitive behavior does not compel antitrust to "get out of the way to avoid interference in the regulatory scheme."[37]

2. Appropriate Antitrust Scrutiny of a Monopolist's Anticompetitive Product Changes Does Not Threaten Innovation

Although courts generally "are properly very skeptical" that product design changes harm competition, it is well established that in certain circumstances a monopolist's product changes can do precisely that. *Microsoft*, 253 F.3d at 65 (holding unanimously that Microsoft's software-design changes constituted exclusionary conduct because "through something other than competition on the merits" they restricted rivals' ability to compete).[38] Product changes are anticompetitive where they have no purpose "other than protecting [the] monopoly" and where they "unfairly tend[] to destroy competition itself." *Id.* at 58 (quoting *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993)).

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[37] Dogan & Lemley, *supra* note 24, at 717; *see* C. Scott Hemphill, *Paying for Delay, Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1557 (2006) ("A particular regulatory regime sets the boundaries of feasible anticompetitive conduct.").

[38] *See* Areeda & Hovenkamp, *supra* note 33 at ¶ 776a (Although "product improvement without more is protected and beyond antitrust challenge[,] . . . strategic creation of incompatibility can have serious anticompetitive consequences, particularly in 'network' industries where compatibility itself is often an essential ingredient to product success.") Given the regulatory framework for pharmaceuticals, incompatibility arises when branded drugs are modified to prevent bioequivalence with generics and slow their substitution for the branded drugs.

Thus, deference to product innovation "does not mean that a monopolist's product design decisions are per se lawful." *Id*. at 65; *see also C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1382 (Fed. Cir. 1988) (upholding jury verdict finding redesign of patented product violated Section 2). Nor should a general skepticism in cases of genuine innovation provide broad antitrust immunity for conduct that "impedes competition through means other than competition on the merits." *See Namenda*, 787 F.3d at 652. Rather, "established case law makes clear that product redesign is anticompetitive when it coerces consumers and impedes competition." *Id*. at 652-53.

The district court's concern in this case that subjecting product hopping to antitrust scrutiny could have "adverse, unintended consequences" and risk "slowing or even stopping pharmaceutical innovation," JA 43-44, is misplaced. As cases like *Microsoft* and *Namenda* demonstrate, courts are fully capable of distinguishing truly predatory conduct from procompetitive innovation. The Second Circuit rejected a similar argument in *Namenda*, and noted instead that "immunizing product hopping from antitrust scrutiny may deter significant innovation by encouraging manufacturers to focus on switching the market to trivial or minor product reformulations rather than investing in the research and development necessary to develop riskier, but medically significant innovations." 787 F.3d at 659.

As some of the amici conclude in their treatise:

> While monopolists have no general duty to help their competitors, they do have an obligation to refrain from acts that have no purpose or effect except to exclude competition. And while distinguishing between the two can be tricky, courts have proven themselves up to the task, even in cases involving product design. It makes no sense to immunize patently anticompetitive behavior because of the risk that some cases might prove tough to decide. The proper standard requires deference to innovation, but not complete abdication.[39]

Product changes in the pharmaceutical industry, such as the introduction of new drugs with significant benefits that increase patient choice, can represent genuine innovation that furthers competition on the merits. Other changes, however, such as withdrawing a successful drug from the market and forcing patients and doctors to switch to a new version, particularly when made with no legitimate business justification (and, as in this case, as part of an "anti-generic strategy" with the intent "primarily to defeat generic competition," JA 25), have no purpose but to exclude competition and are anticompetitive.[40] Such changes exploit the regulatory framework of Hatch-Waxman and subvert state substitution laws, with the result of maintaining the brand firm's monopoly position by keeping out generic competition that would otherwise occur via those substitution laws.

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[39] *IP & Antitrust* § 15.3c, at 15-79 (citations omitted).
[40] *See* Carrier, *supra* note 6, at 1020.

Excessive deference to pharmaceutical product changes is especially inappropriate because of the regulatory barriers and market factors that restrict consumer choice between products and eliminate market competition when a product switch occurs.[41] In pharmaceutical markets, "the success of a product switching scheme does not depend on whether consumers prefer the reformulated version of the product over the original, or whether the reformulated version provides any medical benefit."[42] Product reformulations accompanied by withdrawal of the previous versions prevent "consumers from weighing the relative merits of competing products."[43]

Genuine innovation increases consumer choice; hard product switches like those in this case eliminate both consumer choice and drug competition. Because the previous version of the drug is removed from the market, patients are denied choices (both about which branded drug to choose and about whether to choose the branded drug or a generic), not given greater choice. *See Namenda*, 787 F.3d at 653-54 (rejecting defendants' argument that launching a new product "'advances competition by adding a better product to the market and by paving the way for further innovation,'" because, while "*introducing* [a new version] may be procompetitive, that argument provides no procompetitive justification

[41] *IP & Antitrust* § 15.3c, at 15-79.
[42] FTC Amicus, JA 204-05.
[43] *Id.* at 205.

for *withdrawing*" the old version.); *Abbott Labs v. Teva Pharms. U.S.A., Inc.*, 432 F. Supp. 2d 408, 422-24 (D. Del. 2006).

3. Excluding Generic Competition by Manipulating the Hatch-Waxman and State Substitution Frameworks Is Anticompetitive Conduct

Anticompetitive conduct in product hopping cases does not require total foreclosure of competitors from the market; it only requires barring them "from their cost-efficient means of competing." *Abbott Labs,* 432 F. Supp. 2d at 423 (citing *Microsoft*, 253 F.3d at 64); *see Meritor,* 696 F.3d at 282-85; *Dentsply,* 399 F.3d at 191 ("[I]t is not necessary that all competition be removed from the market. The test is not total foreclosure but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit.").

Because the only cost-effective means of competition for generic drugs under the Hatch-Waxman framework is substitution laws,[44] foreclosing these channels means effective exclusion, even if generics could theoretically engage in expensive marketing and reach doctors directly. *See Abbott Labs*, 432 F. Supp. 2d at 423-24; *Microsoft*, 253 F.3d at 70.

The district court lost sight of these principles, and of the unique characteristics and economic realities of the pharmaceutical industry,[45] in

[44] *See* Section I.C., *supra.*
[45] *See, e.g., Dentsply,* 399 F.3d at 189.

concluding that Mylan's generic drug was not foreclosed because Mylan could have spent money to market, advertise and promote it rather than choosing to rely instead on the "'promotion' provided by state automatic substitution laws." JA 39. In fact, as the Second Circuit recognized, the essence of the Hatch-Waxman and state substitution framework is that "competition through state drug substitution laws is the only cost-efficient means of competing available to generic manufacturers" and that "additional expenditures by generics on marketing would be impractical and ineffective . . . ." 787 F.3d at 655-56.

The district court's erroneous view of the regulatory frameworks as some sort of regulatory "bonus," JA 41, or "regulatory windfall" that gives generics a "regulatory 'preferred place'" cannot be squared with the clear purposes of those frameworks. The Second Circuit readily disposed of similar arguments in *Namenda*, noting that "what Defendants call 'free riding'—generic substitution by pharmacists following the end of Namenda IR's exclusivity period—*is authorized by law; is the explicit goal of state substitution laws; and furthers the goals of the Hatch-Waxman Act by promoting drug competition* . . . and by preventing the 'practical extension of [brand drug manufacturers'] monopoly.'" 787 F.3d at 657-58 (citations omitted) (emphasis added).

B. Product Switches that Harm Competition Without Procompetitive Business Justification Violate Section 2

Forced product switches and other types of product hopping that harm competition and have no countervailing procompetitive business justification constitute exclusionary conduct that violates Section 2. All four cases that have addressed product hopping antitrust claims found that product hopping can be anticompetitive; the particular effects on competition and consumer choice in each case were determinative.

In *Namenda*, the defendants' hard switch—the combination of introducing a new product and effectively withdrawing the old product—forced patients to switch to a new drug and therefore "would likely impede generic competition by precluding generic substitution through state drug substitution laws." 787 F.3d at 654. The Second Circuit upheld the district court's finding that "careful consideration of the unique characteristics of the pharmaceutical market" demonstrated that price competition at the pharmacy level, "facilitated by state substitution laws, is the principal means by which generics are able to compete in the United States," *id*. at 655, and dismissed defendant's arguments that the generic could compete through marketing, third-party payor requirements, etc. *Id*. at 655-56.

The defendants' hard switch, not only introducing a new product but also withdrawing the previous drug, "crosses the line from persuasion to coercion and is anticompetitive." *Id.* at 654. When a monopolist "*combines* product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than

persuade them on the merits . . . and to impede competition, . . . its actions are anticompetitive under the Sherman Act." *Id*. The defendants' withdrawal of the previous version deprived consumers of the choice between the two products and allowed the defendants to avoid competing on the merits with lower cost generics through drug substitution laws. *Id*. at 655.

Finally, the Second Circuit rejected an argument that "antitrust law is not a vehicle for enforcing the 'spirit' of drug laws," *id.* at 658, similar to the district court's erroneous conclusion in this case that, because Hatch-Waxman is silent about product hopping, that conduct cannot be deemed anticompetitive. JA 44. The Supreme Court rejected a similar narrow, artificial application of the Sherman Act in the pharmaceutical context in *Actavis*, upholding antitrust liability for reverse-payment settlements even though Hatch-Waxman is silent as to such settlements, based on the "general procompetitive thrust" and entry-promoting features of the Act. 133 S. Ct. at 2234.

In *Abbott Labs*, a district court in this Circuit held that the plaintiffs properly alleged that product-hopping defendants illegally excluded generic competition by introducing new drug formulations, withdrawing prior versions, and changing prior versions' National Drug Data File codes to "obsolete." *Abbott Labs*, 432 F. Supp. 2d at 424. These actions prevented pharmacists from filling prescriptions with generic alternatives because the drug to which those alternatives were AB-certified

was no longer available to be prescribed. *Id.* at 415-16. Meanwhile, pharmacists were also unable to substitute prior-version generics on new branded-version prescriptions because the generics had not yet received AB-certification for the new branded formulation. Consumer choice and competition were eliminated; there was no "open market where the merits of any new product [could] be tested by unfettered choice." *Id.* at 422. In effect, the brand firm functionally excluded generics from the market since the generics could not compete cost-effectively on either version of the drug. Consumers had no access to the prior version—whether brand or generic—and were forced into the new brand version.

Abbott's "hard" or forced switch is distinguishable from a brand company merely introducing a new product version but leaving the old product on the market as an additional choice for consumers. In *Walgreen Co. v. AstraZeneca Pharmaceuticals L.P.*, 534 F. Supp. 2d 146, 151 (D.D.C. 2008), the manufacturer introduced and began vigorously marketing a newly patented drug, but kept the original drug on the market at the same level of availability (though it ceased marketing it). The court found that, unlike in *Abbott Labs*, the manufacturer did not "deliberately limit rather than expand consumers' choices by merely changing the formulation of the drug." *Id.* The new product introduction in that case, the court

found, did not saddle generics with a product withdrawal and forced switch that essentially prevented substitution. *Id.*[46]

A more recent product hopping case from a district court in this Circuit further illustrates the centrality of consumer choice and the anticompetitive effects of product withdrawals and forced switches. In *In re Suboxone Antitrust Litig.*, the brand manufacturer allegedly fabricated safety concerns about its existing version in order to remove it from the market in favor of a new patented version. The court found this conduct coercive because a patient preferring the existing version might be persuaded to switch "believing that their favored product would soon be removed from the market." 64 F.Supp.3d at 682. The switch would lock consumers into the new non-substitutable brand version once the old version was removed. Generic competitors would effectively be excluded even though they had nominal access to the market through selling outside of the substitution system, because the switch would bar their cost-efficient means of distribution (substitution). *Id.* at 683-84 (citing *Microsoft*, 253 F.3d at 64).

A nuanced analysis of pharmaceutical markets, the Hatch-Waxman Act, and drug substitution laws, as applied by the courts in the above cases, makes clear that

[46] *See Berkey Photo, Inc. v. Eastman Kodak Co*., 603 F.2d 263, 287 & n.39 (2d Cir. 1979) (finding no liability for introducing new product but stating that "the situation might be completely different" if the defendant stopped producing old products or removed them from the market).

product hopping can constitute anticompetitive conduct under Section 2 where it excludes cost-effective generic competition and reduces consumer choice. When, as here, brand-drug manufacturers introduce product changes and effectively withdraw their prior versions, including by destroying and buying back portions of the remaining inventory of those versions, JA 21, they prevent generics from being automatically substituted for the prior version, while their new version is protected from competition by FDA approval timelines (or, in other cases, by patents). Consumers, insurers, and the government all pay higher prices for drugs for a longer time. This exclusionary conduct deprives consumers of competitive choices and, in the absence of a procompetitive business justification, violates Section 2.

The anticompetitive effects of product hopping can be particularly pronounced when the conduct includes, as in this case, changes timed to occur before impending generic entry, proffered justifications for the changes that are pretextual or lacking in evidentiary support, evidence of an "anti-generic strategy" involving product hops undertaken "primarily to defeat generic competition," JA 25, or similar evidence that demonstrates the actual intent and effect of the product switch are to protect monopoly revenue from generic competition, rather than to achieve a legitimate business purpose.

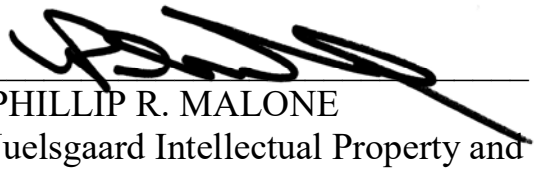
CONCLUSION

Forced switches and other forms of product hopping can thwart Hatch-Waxman's and state substitution laws' goals of promoting efficient generic pharmaceutical competition. The product changes in this case, including a series of product reformulations combined with the withdrawal of previous versions and a related course of exclusionary conduct (including buying back and destroying old inventory), prevent generics from using the carefully crafted mechanism of Hatch-Waxman and state substitution laws to efficiently and cost-effectively introduce critical competition to branded drugs. Product switches such as these that impede generic competition are precisely the sort of exclusionary conduct that Section 2 condemns. *See Namenda*, 787 F.3d at 653-58.[47]

[47] *See also IP & Antitrust* § 15.3c, at 15-79.

Dated: September 30, 2015

Respectfully submitted,



PHILLIP R. MALONE
Juelsgaard Intellectual Property and Innovation Clinic
559 Nathan Abbott Way
Stanford, CA 94305
Telephone: 650-725-6369
Facsimile: 650-723-4426
pmalone@law.stanford.edu

Attorney for Amici Curiae

CERTIFICATE OF COUNSEL

I, Phillip R. Malone, hereby certify that:

1. Pursuant to Third Circuit Local Appellate Rule 46.1, I am a member of the bar of this court;

2. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B), as modified for amici by Fed. R. App. P. 29(d), because this brief contains 6981 words, excluding the parts of this brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii);

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Dated: September 30, 2015
Stanford, CA

PHILLIP R. MALONE
Juelsgaard Intellectual Property and
Innovation Clinic
559 Nathan Abbott Way
Stanford, CA 94305
Telephone: 650-725-6369
Facsimile: 650-723-4426
pmalone@law.stanford.edu

Attorney for Amici Curiae

CERTIFICATE OF SERVICE

I hereby certify that, on this 30th day of September, 2015 the foregoing Brief for Intellectual Property and Antitrust Professors as Amici Curiae in Support of Appellants was filed electronically with the Clerk of the United States Court of Appeals for the Third Circuit via the CM/ECF system. To the best of my knowledge, all parties to this appeal are represented by counsel who are registered CM/ECF users and will be served electronically by the CM/ECF system.

PHILLIP R. MALONE
Juelsgaard Intellectual Property and Innovation Clinic
559 Nathan Abbott Way
Stanford, CA 94305
Telephone: 650-725-6369
Facsimile: 650-723-4426
pmalone@law.stanford.edu

Attorney for Amici Curiae

APPENDIX

Michael A. Carrier is Distinguished Professor and Co-Director of the Rutgers Institute for Information Policy & Law at Rutgers University School of Law. He has written extensively on the intersection of intellectual property and antitrust law, including more than 20 articles in the context of the pharmaceutical industry.[i] He is a co-author of the seminal treatise on intellectual property and antitrust law, and has testified before the Senate Judiciary Committee on these issues. His scholarship on pharmaceutical patents and their effects on competition has been cited twice by the Supreme Court, including a 2013 amicus brief in *FTC v. Actavis*, co-authored with other amici here.[ii]

Stacey L. Dogan is Professor and Law Alumni Scholar at Boston University School of Law. She is a leading scholar of intellectual property and competition law and coauthored the authoritative article on regulatory gaming in the pharmaceutical

[i] *E.g.*, Michael A. Carrier, *How Not To Apply Actavis*, 109 Nw. U. L. Rev. Online 113 (2015); Michael A. Carrier, *Payment After Actavis*, 100 Iowa L. Rev. 7 (2014); Michael A. Carrier, *A Real World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 Fla. L. Rev. 1010 (2010); Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich. L. Rev. 37 (2009); Michael A. Carrier, *Of Trinko, Tea Leaves, and Intellectual Property*, 31 J. Corp. L. 357 (2005).

[ii] Br. Amici Curiae of 118 L., Econ., & Bus. Professors & the Am. Antitrust Inst., No. 12-416, *FTC v. Actavis*, 133 S. Ct. 2223 (2013).

industry.[iii] She is the former Chair of the Intellectual Property Section of the Association of American Law Schools.

Harry First is the Charles L. Denisn Professor of Law at New York University School of Law and Co-Director of the law school's Competition, Innovation, and Information Law Program. He has written on numerous issues involving antitrust law and competition policy, including articles[iv] and books[v] relating to various aspects of intellectual property and innovation. He is most recently the co-author, with Andrew Gavil, of "The Microsoft Antitrust Cases: Competition Policy for the Twenty-first Century" (2014). He serves as a contributing editor of the *Antitrust Law Journal* and Foreign Antitrust Editor of the *Antitrust Bulletin*. From 1999-2001 he served as Chief of the Antitrust Bureau of the Office of the Attorney General of the State of New York.

[iii] Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 Tex. L. Rev. 685 (2009)

[iv] Harry First, *Antitrust and Trade Secrets*, in *The Law and Theory of Trade Secrecy: A Handbook of Contemporary Research* (Rochelle Dreyfuss & Katherine Strandburg eds.) (2011); Harry First, *Controlling the Intellectual Property Grab: Protect Innovation, Not Innovators*, 38 Rutgers L. J. 365 (2007); Harry First, Microsoft *and the Evolution of the Intellectual Property Concept*, 2006 Wis. L. Rev. 1369, reprinted, 39 Intellectual Prop. L. Rev. 711 (2007).

[v] Harry First, *Working Within the Boundaries of Intellectual Property* (with Rochelle Dreyfuss and Diane Zimmerman, eds.) (2010); Harry First, *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (with Rochelle Dreyfuss and Diane Zimmerman, eds.) (2001).

C. Scott Hemphill is Professor of Law at NYU School of Law. His scholarship focuses on the balance between innovation and competition created by intellectual property and antitrust law. He has written extensively about regulation in the pharmaceutical industry and competition between generic and branded-drug manufacturers.[vi] He previously served as Chief of the Antitrust Bureau in the Office of the New York State Attorney General.

Herbert Hovenkamp is the Ben and Dorothy Willie Chair at the University of Iowa College of Law. He is co-author of the seminal treatises on antitrust law and on the intersection of IP and antitrust law,[vii] and has written numerous books and articles on the topic of antitrust law and its interaction with innovation.[viii] In 2008,

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[vi] Aaron Edlin, Scott Hemphill, Herbert Hovenkamp, and Carl Shapiro, *The Actavis Inference: Theory and Practice*, 67 Rutgers U. L. Rev. 585 (2015); C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. Health Econ. 327 (2012); C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 Antitrust L.J. 947 (2011); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553 (2006); Aaron S. Edlin, C. Scott Hemphill, Herbert J. Hovenkamp, & Carl Shapiro, *Activating Actavis*, Antitrust Magazine, Aug. 2013, at 16.

[vii] 3 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* (4th ed. 2013); Herbert Hovenkamp, Mark D. Janis, Mark A. Lemley, & Christopher R. Leslie, *IP & Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* (2d ed. Supp. 2013).

[viii] See, e.g., Herbert Hovenkamp*, Innovation and Competition Policy: Cases and Materials* (2d ed. 2013); Christina Bohannon & Herbert Hovenkamp, *Creation Without Restraint: Promoting Liberty and Rivalry in Innovation* (2012); Herbert Hovenkamp, *The Antitrust Enterprise: Principle and Execution* (2006); Herbert Hovenkamp, *Consumer Welfare in Competition and Intellectual Property Law*, 9

he received the John Sherman Award from the Antitrust Division of the Department of Justice, an award presented only once every three years to an individual for their outstanding achievements in antitrust law.

Mark A. Lemley is the William H. Neukom Professor of Law at Stanford Law School. He is the author of seven books and is among the world's most-cited law review authors.[ix] His scholarship focuses on intellectual property law, antitrust law and technology and the law. He is a co-author of the seminal IP and antitrust law treatise and has written extensively on the topic of regulatory gaming in the pharmaceutical context, including specifically on the issue of product hopping.[x] His works have been cited over 140 times by courts, including seven United States Supreme Court opinions, and over 9,500 times in books and law review articles.

Competition Policy Int'l J. 53 (2014); Herbert Hovenkamp, *Markets in IP and Antitrust*, 100 Geo. L.J. 2133 (2012); Herbert Hovenkamp, *Antitrust and the Regulatory Enterprise*, 2004 Colum. Bus. L. Rev. 335 (2004).

[ix] Fred R. Shapiro & Michelle Pearse, *The Most-Cited Law Review Articles of All Time*, 110 Mich. L. Rev. 1483 (2012) (finding that Lemley has authored or co-authored 9 of the 100 most-cited law review articles).

[x] Herbert Hovenkamp, Mark D. Janis, Mark A. Lemley, & Christopher R. Leslie, *IP & Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* (2d ed. Supp. 2013); Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 Tex. L. Rev. 685 (2009); C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 Antitrust L.J. 947 (2011); Mark. A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 Tex. L. Rev. 1031 (2005).

Christopher Leslie is the Chancellor's Professor of Law at the University of California, Irvine School of Law. He is a co-author (with other amici here) of the seminal treatise on the intersection of IP and antitrust law[xi] as well as the author of a leading casebook on the intersection of antitrust law and intellectual property rights.[xii] He is a senior editor of the *Antitrust Law Journal* and has served as the Chair of the Antitrust Law Section of the Association of American Law School.

[xi] Herbert Hovenkamp, Mark D. Janis, Mark A. Lemley, & Christopher R. Leslie, *IP & Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* (2d ed. Supp. 2013).

[xii] Christopher R. Leslie, *Antitrust Law & Intellectual Property Rights: Cases and Materials* (2011).